DISEASES ANIMAL HEALTH Part 1

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 2.5.2005
[SANCO/10090/2005 Final]
EC (2005) 554 FINAL

COMMISSION STAFF WORKING DOCUMENT

Draft position of the Community on the report of the meeting of the OIE Terrestrial Animal Health Standards Commission [Paris January 2005] to be submitted for consideration and possible adoption in the 73rd General Session to be held in May 2005 in Paris

UNION EUROPEENNE

Bruxelles, le
D(2005) 520441 HLB

Subject : **General session of the OIE**

Dear Director General,

Please find attached as Annex I the position of the Community concerning the report of the Terrestrial Animal Health Standards Commission in view of the preparation of the General Session to be held in May 2005 in Paris. In addition the Community positions on revisions to the OIE diagnostic manual are included as Annex II and the Community has also attached a list of BSE tests which it would like included in the OIE Diagnostic Manual at Annex III.

Relating to the proposed amendments to the BSE chapter and the Appendix on surveillance the Member States expressed unanimously the position that any amendment of the three key topics i.e. list of tradeable products, number of categories and surveillance is seen as a package. Therefore the endorsement of the list of tradeable products will only be possible if the proposed amendments on the BSE chapter and the Appendix on surveillance can be supported by the Member States

Furthermore the Community supports the new designations of (1) Switzerland as a country free from CBPP without vaccination, (2)a zone in Peru free from FMD without vaccination, (3) a zone and certain municipalities in Brazil free from FMD with vaccination, (4) certain zones of Colombia free from FMD with vaccination, (5)Lebanon, Nigeria and Tanzania as free from rinderpest disease, (6) Benin, Bhutan, Eritrea, Mongolia, Senegal, Togo and Turkey free from rinderpest infection, (7) a described zone in Ethiopia and one in Sudan free from rinderpest disease.

I trust you will take the Community points on board prior to or during the meeting

Thank you for your continued cooperation

Kind regards

Dr. Arthur Besch
Directeur
Administration des Services Vétérinaires
Luxembourg

Jaana Husu-Kallio
Deputy Director General

Enclosures: 2

Copy: CVOs all Member States

CVOs Andorra, Bulgaria, Iceland, Norway, Romania and Switzerland

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

ANNEX 1

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

Original: English
January 2005

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

Paris, 17-28 January 2005

The OIE Terrestrial Animal Health Standards Commission (hereafter referred to as the Terrestrial Code Commission) met at the OIE Headquarters in Paris from 17-28 January 2005, and discussed some common issues with the Scientific Commission for Animal Diseases (hereafter referred to as the Scientific Commission) on 18 January 2005. The President of the Terrestrial Code Commission also met with the Aquatic Animal Health Standards Commission (hereafter referred to as the Aquatic Animals Commission).

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

The Director General of the OIE, Dr B. Vallat, welcomed the members and thanked them all for their willingness to participate in this important OIE work. He emphasised his strong commitment towards progress on some important texts, especially those concerning bovine spongiform encephalopathy (BSE) and avian influenza, as a result of the discussions at the 72nd General Session:

– regarding BSE, Dr Vallat was confident that the Member Countries would support a three category approach but the level of surveillance required remained an issue for many Member Countries; he supported the Terrestrial Code Commission's emphasis on safe commodities and considered that 'boneless skeletal muscle meat' was an important commodity which needed to be discussed in this regard;

– Dr Vallat considered that it was important for the Terrestrial Code Commission to harmonise the work done by experts and the Scientific Commission in revising the chapters and in drafting surveillance appendices for foot and mouth disease (FMD), BSE and avian influenza;

– Dr Vallat noted that the Terrestrial Code Commission's proposals on avian influenza would be discussed at an upcoming conference on 7-8 April 2005 at the OIE Headquarters;

– Dr Vallat commended the work of the animal welfare experts in drafting recommendations on land and sea transport, slaughter for human consumption and killing for disease control purposes, and the Animal Welfare Working Group in coordinating this work;

– on bluetongue, Dr Vallat was of the view that it was important that the revised chapter being submitted for adoption reflected the outcomes of the 2003 OIE Bluetongue Conference in Sicily; subject to adoption of the chapter at the 73rd General Session, work on a surveillance appendix could commence;

– on food safety, Member Countries' comments on the draft papers needed to be examined by the Working Group at its meeting in March 2005, and then reviewed by the Terrestrial Code Commission;

– on bovine tuberculosis, Dr Vallat was of the opinion that the experts' recommendations regarding a revised chapter should be examined, and the chapter proposed for adoption; work could then commence on a review of the bovine brucellosis chapter;

– Dr Vallat noted that the Terrestrial Code Commission would be discussing new proposals for the OIE disease lists with the Aquatic Animals Commission and with the OIE Animal Health Information Department.

Dr Vallat encouraged the Terrestrial Code Commission and the Aquatic Animals Commission to continue their collaborative work on harmonisation of the two *Codes*.

The Terrestrial Code Commission was strongly supportive of the new transparency procedures for publication of Commission reports. Several members proposed that there be a discussion at the 73rd General Session on the addition of Member Countries' comments to the material published on the OIE Web page; they considered that such publication would assist in improving participation of Member Countries in the development of OIE standards.

The Terrestrial Code Commission received comments from Australia regarding the inclusion of statements on the 'national treatment' obligations of Member Countries in individual chapters. The Terrestrial Code Commission felt that these obligations are adequately covered in Article 1.2.1.2. and therefore need not be duplicated in all *Terrestrial Code* chapters.

The Terrestrial Code Commission examined draft revised *Terrestrial Code* texts circulated for Member Countries' comment by the Bureau of the Terrestrial Code Commission after its July 2004 meeting, and comments received on those texts. The outcome of the Terrestrial Code Commission's work is presented as appendices to this report. Amendments made to existing chapters and previously circulated drafts are shown as double underlined text, with deleted text in strikeout. A grey background is used to distinguish amendments and deletions made at this meeting from amendments and deletions proposed in the same chapters or appendices at the meeting of the Bureau in July 2004.

The following Member Countries: Canada, Taipei China, the Southern Cone countries of South America, the United States of America (USA), Australia, New Zealand, Chile, the European Union (EU), Norway, Japan, Switzerland, Peru and El Salvador commented on the report of the Bureau of the Terrestrial Code Commission. The Terrestrial Code Commission strongly encourages Member Countries to participate in the development of the OIE's international standards by sending comments in sufficient time for them to be considered by the Commission. It would assist the Terrestrial Code Commission if comments were submitted as specific proposed text changes, supported by a scientific rationale.

Member Countries are invited to comment on all aspects of this report. Comments need to reach the OIE Headquarters by **7 May 2005** in order to be reviewed prior to the 73rd General Session. Comments requiring minor changes to the *Terrestrial Code* will be considered at a meeting of the Bureau of the Terrestrial Code Commission just before the General Session, and a revised text presented for adoption by Member Countries. Comments requiring major changes will be deferred to the meeting of the Bureau of the Terrestrial Code Commission in July 2005.

A. TEXTS WHICH ARE SUBMITTED FOR ADOPTION BY THE INTERNATIONAL COMMITTEE AT THE 73rd GENERAL SESSION IN MAY 2005

Community position:

The Community strongly suggests to the OIE to ensure a better planning of the Code Commission meetings in order to ensure that all countries have sufficient time to submit their comment. The volume of work grows each year and is becoming more and more difficult to handle. More time is needed to ensure a well informed and justified response is given to the very important work carried out by the OIE.

Secondly the use of the words 'should', 'shall' and 'must' which are used apparently interchangeably throughout the Code must be reviewed. The Community would refer the OIE to document from the CODEX on the use of these words.

1. General definitions (Chapter 1.1.1.)

Community position:

The Community can support the amendments proposed in Appendix III but would like the points mentioned in the appendix to be taken on board and see below concerning the buffer area. In addition the Community considers it is very important that as far as is practical the definitions in the terrestrial code and the aquatic code should be the same. In addition the same remark applies to Surveillance Chapters.

After further discussion with an expert, the Terrestrial Code Commission decided not to modify the term 'artificial insemination centre' (as proposed by Australia) as that term was the one accepted worldwide by the industry.

After consideration of Member Countries' comments on 'buffer zone' and 'surveillance zone', the Terrestrial Code Commission agreed that there was potential for confusion between the two definitions; as a result, the definition of 'buffer zone' was modified and the term 'surveillance zone' deleted. In the case of a free country or zone being contiguous with an infected country or zone, as the current definition had required that the 'buffer zone' be located in the infected country or zone, the free country or zone had not been in a position to establish or enforce any appropriate controls within such a zone. Under the modified definition, the free country or zone may implement certain necessary controls in the 'buffer zone' to protect its status, without those measures affecting its status. The Terrestrial Code Commission did not adopt the EU proposal on 'buffer zone' as it considered it too prescriptive.

Community position:

The Community can support this appendix and strongly supports the new OIE position vis-à-vis the buffer zone, as this concept is partly already implemented in certain Community animal health legislation.

The Community however regrets that the OIE was not in a position to support the EU-proposal for a buffer zone definition.

The definition of ‘case’ was modified by the Terrestrial Code Commission in order to encourage reporting of diseases not listed by the OIE, including new emerging diseases and pathogens. The additional text in the definition of ‘emerging disease’ was designed to limit reporting to those pathogens or diseases showing a significant impact on animal or public health. A definition for ‘Competent Authority’ was proposed to address those situations where ‘Veterinary Services’ may be situated within a larger authority.

A definition of 'notifiable disease' (to be applied nationally) has been proposed. Another definition on notifiable diseases with reference to the OIE will be proposed in May 2005.

Several other modifications to the list of definitions were made in accordance with comments received from Member Countries, and after discussions with the Scientific Commission, the Aquatic Animals Commission and the Head of the Animal Health Information Department.

Suggested changes, shown in Appendix III, are presented for adoption.

2. Evaluation of Veterinary Services (Chapter 1.3.3.)

Community position:
The Community fully supports this.

In response to the recommendation on the quality of *Veterinary Services* arising from the OIE/AU-IBAR seminar held in Cairo in October 2004, requesting that the OIE develop more detailed guidelines for the establishment and functioning of the ‘Veterinary Statutory Body’ and some guidelines for community animal health workers, the Terrestrial Code Commission requested the Director General to convene an *ad hoc* Group of experts to develop such guidelines.

The Terrestrial Code Commission noted the Cairo seminar recommendations on strengthening ‘Veterinary Services’ and urged Member Countries to implement fully the guidelines in the *Terrestrial Code*.

3. Zoning and compartmentalisation (Chapter 1.3.5.)

Community position:
The Community can only support proposal at Appendix IV if the points mentioned in the appendix are taken on board. Furthermore it is very important that clear requirements and transparency is given to compartmentalisation for individual diseases. The requirements for compartmentalisation will vary from disease to disease and it may not be appropriate to include compartmentalisation in all disease chapters. In addition it may be necessary to include some elements of zoning (area of freedom around compartments) in order to ensure adequate safety for trade purposes.

The Terrestrial Code Commission drafted a revised Chapter 1.3.5. following discussions with the Aquatic Animals Commission and the Scientific Commission. The aim of the revision is to provide more guidance to Member Countries on the procedures of zoning and compartmentalisation.

Explanatory examples of compartmentalisation for diseases of birds, mammals, crustaceans and fish have been drafted in conjunction with the Aquatic Animals Commission. Avian influenza and classical swine fever are presented as examples below but the full text may be found in the report of the Bureau of that Commission for the meeting of October 2004 (http://www.oie.int/aac/eng/commission/en_reports.htm).

Compartmentalisation for terrestrial animals

Compartmentalisation could be an appropriate approach to separate and protect a commercial poultry industry when dealing with avian influenza. In most countries or zones, one can recognize at least three types of poultry sub-populations: the commercial poultry industry, the traditional back yard poultry and wild birds (including migratory waterfowl). In most countries, differentiating domestic poultry from migratory birds is nearly impossible using the concept of zoning/regionalization. While the separation of back yard birds and wild birds from individual commercial poultry operations can be achieved, it would be very difficult to demonstrate a different health status over widely separated parts of vertically integrated conventional poultry enterprises using these concepts. Therefore, compartmentalisation of the industrial poultry sector, based on strict and auditable biosecurity management protocols operated by individual enterprises, may be able to provide for safe trade in poultry and poultry products from this compartment even if other sectors cannot be declared free of avian influenza.

Compartmentalisation can also be applied to the differentiation of industrial swine production from traditional free-range pigs and wild pig populations, for example in cases where there is a risk from classical swine fever from feral and/or wild pigs. Industrial swine production in most countries is vertically integrated, including all steps in the chain, from feed production, breeding, fattening and slaughter to primary processing. Appropriate steps may be taken to isolate this industry from various disease threats. A systematic approach to managing the biosecurity at all steps of the production chain, with an identification of the critical control points and the accompanying auditing procedures may be able to provide for safe trade of pigs and pig products through compartmentalisation, even if the other pig sub-populations are affected by classical swine fever.

The revised Chapter 1.3.5. is submitted for adoption (Appendix IV).

4. General Guidelines for Animal Health Surveillance (Appendix 3.8.1.)

Community position:
The Community can support the amendments proposed in Appendix V but would like the points mentioned in the appendix to be taken on board.

The Terrestrial Code Commission received from the Scientific Commission a revised appendix on general guidelines for animal health surveillance. In revising the appendix, the Scientific Commission indicated that it had taken into account comments received from Member Countries (Australia, New Zealand, the EU, the USA and Switzerland). Text shown as double underlined or strikeout indicates changes which have been made to the text which was circulated for Member Countries' comment in July 2004.

It is proposed that this text be placed in Section 3.8. of the *Terrestrial Code* to serve as an introduction to the appendices dealing with surveillance of specific diseases. This new appendix would replace the content of the existing Chapter 1.3.6. (Surveillance and monitoring of animal health) and Appendix 3.8.1. (General principles for recognising a country or zone free from a given disease/infection). Definitions of 'early detection system' and 'surveillance', adopted via this Appendix, would replace those currently in Chapter 1.1.1.

The Terrestrial Code Commission presents this revised text (Appendix V) for adoption.

5. Criteria for listing diseases (Chapter 2.1.1.)

Community position:
The Community can support the amendments proposed in Appendix VI but would like the points mentioned in the appendix to be taken on board.

The Terrestrial Code Commission met with Drs Karim Ben Jebara and Julio Pinto, Head and Deputy-Head respectively of the OIE Animal Health Information Department, to discuss animal disease notification. The latest version of the OIE list of terrestrial diseases has been developed by an *ad hoc* Group on disease/pathogen notification by judging the diseases against the agreed criteria.

The Terrestrial Code Commission presents this revised list (Appendix VI) for adoption.

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

Community position:

The Community can support the amendments proposed for FMD appendix VII and in Appendix VIII but would like the points mentioned in the appendices to be taken on board. In addition it would ask the OIE to continue to develop the draft surveillance Chapter further with experts in particular including examples of surveillance designs.

In response to the comment received from the EU, the Terrestrial Code Commission's view was that, in a vaccinated population where it can be demonstrated that vaccination had been carried out in accordance with the *Terrestrial Manual*, the maturation and deboning of meat should not be required for countries or zones free from foot and mouth disease with vaccination. The Scientific Commission endorsed this view.

In Article 5, the Terrestrial Code Commission removed the reference to 'outbreak' as, if an outbreak occurs, the country or zone would need to follow the recommendations in Article 7 for recovery of status.

The revised chapter is presented for adoption at Appendix VII.

The Terrestrial Code Commission is appreciative of the work of the Scientific Commission in revising the draft surveillance appendix for FMD (Appendix 3.8.7.). The Terrestrial Code Commission made some minor editorial changes in harmonising the draft with similar drafts for avian influenza and classical swine fever (CSF), and is presenting the appendix (Appendix VIII) for adoption.

7. Bluetongue (Chapter 2.2.13.)

Community position:

The Community can support the amendments proposed in Appendix IX but would like the points mentioned in the appendix to be taken on board.

The Terrestrial Code Commission discussed with the Scientific Commission Member Countries' comments on the revised chapter on bluetongue. The Terrestrial Code Commission examined comments received from Member Countries but made changes only when scientific justification accompanied those comments; this approach was endorsed by the Scientific Commission.

The two Commissions were not aware of any new information to contradict the conclusions of the 2003 OIE Bluetongue Conference in Sicily regarding the infective period for bluetongue, and the Terrestrial Code Commission did not make any changes in this regard.

The comment from Australia that the terminology relating to the *Culicoides* vector be modified to 'likely to support BTV transmission' was not adopted as the Terrestrial Code Commission considered that its proposed wording 'likely to be competent' adequately addressed the biology of the vector population and used accepted terminology.

In response to comments from Australia and the EU, the period for which animals need to be vaccinated before movement was increased to 60 days to make it consistent with the accepted viraemic period.

The comment from Peru regarding the point of departure in Article 2.2.13.6. was not adopted as the definition 'place of shipment' was considered to adequately cover the intent of the Article.

After consulting with an expert, the Terrestrial Code Commission accepted changes recommended by the USA regarding the timing of serological testing in various articles relating to semen and embryo collection.

The revised chapter is presented for adoption (Appendix IX).

The Scientific Commission indicated that it was developing an appendix on surveillance for bluetongue.

8. Bovine tuberculosis (Chapter 2.3.3.)

Community position:
The Community can support the amendments proposed in Appendix X provided the points mentioned in the appendix are taken on board.

The Terrestrial Code Commission received from the Scientific Commission a revised chapter on bovine tuberculosis based on the current *Terrestrial Code* chapter. The revision had been developed by an OIE *ad hoc* Group taking into account Member Countries' comments, including on the zoonotic aspects of the disease.

In line with a recommendation from the Scientific Commission, references to hides and skins were deleted.

The revised chapter, with proposed modifications from the current chapter marked, is presented for adoption (Appendix X).

9. Bovine spongiform encephalopathy (Chapter 2.3.13. and Appendix 3.8.4.)

Community position:

The Community welcomes the action taken by the OIE Terrestrial Animal Health Standards Commission to draft a new text reflecting a simplified categorisation system for BSE but would like the detailed comments made in the Appendices taken on board.

a) Chapter 2.3.13.

The report of the April 2004 meeting of the *ad hoc* Group on the BSE chapter (which was included in the report of the July 2004 meeting of the Bureau) is attached for completeness (Appendix XXIV).

The Terrestrial Code Commission was very appreciative of the detailed submissions received in support of its work on the proposed three category system, from the USA, the EU, Australia, New Zealand, Japan and Chile. The OIE Regional Commissions for Europe and the Americas also supported this approach. In addition, other Member Countries made comment on specific articles in this version (Peru, the Southern Cone countries of South America, Norway and Switzerland). An invited submission was also received from the gelatin manufacturing industries in Europe, South America, and Asia and the Pacific. Invited OIE experts also provided comments.

As a result of the outcome of the discussion on BSE at the 72nd General Session, the universal support in comments received and the endorsement from the Scientific Commission, the Terrestrial Code Commission decided to prepare for adoption a revised BSE chapter based on the three category system. Because of the significant time spent on BSE during its meeting (on the chapter and surveillance appendix), the Terrestrial Code Commission did no further work on the five category chapter which was an alternative proposal in the July report.

Within this support for a three category system, while Japan preferred a prevalence-based approach, most countries explicitly or implicitly supported a risk-based approach. The latter approach formed the basis for the changes proposed below by the Terrestrial Code Commission.

The Terrestrial Code Commission was of the view that the concern over hides and skins from the head has arisen from a potential for surface contamination of the hide by brain material following penetrative stunning methods. However, it believed that there were many conditions which would have to be met before the hypothetical likelihood of contamination translated into an actual risk to human health. Surface contamination of the hide would be eliminated through the routine industry processes of soaking of the hides for hair removal and subsequent washing. In addition, further processing steps, e.g. for extraction and conversion into gelatin, would help ensure the safety of the final product. The Terrestrial Code Commission has proposed that the exception for hides and skins from the head be removed.

With regard to blood and blood products, the Terrestrial Code Commission recalled the views of the BSE *ad hoc* Group which met in April 2004, that the information available indicated that bovine blood and blood by-products would be safe, subject to stunning having been carried out in accordance with Article 2.3.13.15. Accordingly, it has recommended that blood and blood products be placed in the first list of commodities (those which require no BSE-specific risk mitigation measures). (See Article 1, paragraph 1.)

The Terrestrial Code Commission was of the view that there was no scientific basis for considering that boneless skeletal muscle meat (excluding mechanically derived meat) was likely to contain BSE infectivity. Mouse and calf bioassays conducted on muscle tissue collected from clinical cases had not detected BSE infectivity. The Terrestrial Code Commission recommended that boneless skeletal muscle meat also be placed in the first list of commodities.

The Terrestrial Code Commission did not make changes to the factors to be considered in a risk assessment. The Terrestrial Code Commission followed the views of the BSE *ad hoc* Group in considering that the changes proposed by Australia and New Zealand (replacing TSEs with BSE) would have unnecessarily narrowed the scope of the risk assessment.

The Terrestrial Code Commission discussed the criteria listed in Article 2 for the determination of the BSE risk status of a country, zone or compartment. After considering submissions from several Member Countries that the surveillance burdens be commensurate with the BSE risk determined through a structured, formal science-based risk assessment, the Terrestrial Code Commission proposed that the formal surveillance requirements specified in Appendix 3.8.4. should not apply to those Member Countries where the BSE risk has been assessed as negligible. However, criteria 2, 3 and 4 of Article 2 would still apply, in particular the compulsory notification and investigation of all cattle showing clinical signs consistent with BSE. This is consistent with requirements for many other OIE listed diseases. The paragraphs in Article 2 on release and exposure assessments were modified at the recommendation of an OIE expert.

Several Member Countries requested that the text on the feed ban be strengthened and this was done in Articles 3 and 4. In addition, in Articles 3 and 4, the Terrestrial Code Commission has placed more emphasis on the risk assessment and less on prevalence. In Article 4, it could not identify any significant difference in final risk presented regarding whether indigenous BSE had occurred more or less than 7 years ago; accordingly, it has deleted paragraph 3) of Article 4 and reworded paragraph 2) to cover all circumstances in which there had been an indigenous case. The

Terrestrial Code Commission considered that the significant difference between the requirements of Articles 3 and 4 was whether a Member Country could demonstrate that the appropriate generic measures had been in place for the relevant period of time.

The Terrestrial Code Commission recalled that the reason for the inclusion of a requirement for post mortem inspection was to ensure a minimum standard of professional involvement, particularly in countries where the removal of specified risk materials (SRMs) was required.

Comments from Member Countries which were essential to the revision of the three category approach were addressed by the Terrestrial Code Commission and have been included in the revised chapter; matters requiring consideration by BSE experts will be addressed after the 73rd General Session.

The articles in the proposed three category chapter have been temporarily numbered from 1 to 16 for ease of reference. The chapter (Appendix XI) is proposed for adoption.

b) Appendix 3.8.4.

The report of the *ad hoc* Group on surveillance for BSE is at Appendix XXIV for the information of Member Countries.

The Terrestrial Code Commission examined the appendix proposed by the experts and made some changes in line with the explanations below. The Appendix on surveillance for BSE (Appendix XII) is proposed for adoption.

A commonality among submissions received was that the current surveillance requirements should be modified. However, there were also significant differences among submissions. Some Member Countries recommended that high levels of surveillance and risk mitigation measures be applied in all countries while others recommended a more balanced approach between the level of risk identified through the process described in Article 2 of the proposed chapter, and the severity of mitigating measures and the intensity of surveillance. In this latter category were Member Countries (New Zealand, Chile and the Southern Cone countries of South America) recommending a significant reduction in surveillance burdens in countries which had already demonstrated negligible risk.

The Terrestrial Code Commission thanked Japan for its detailed submission. The calculations provided showed that, to prove a prevalence of less than one case in one million adult cattle, a greatly increased test load would need to be implemented. The EU also provided a detailed submission in which it reiterated its support for the *BSurvE* computer model. The Terrestrial Code Commission noted that the *ad hoc* Group had been reluctant to recommend the use, without adaptation, of this model by Member Countries. The Terrestrial Code Commission also noted that the EU had requested that the OIE assist the EU to undertake a peer-review of the model.

The Terrestrial Code Commission noted that the 'point values' used in the approach recommended by the *ad hoc* Group had not been selected arbitrarily but were derived from an in-depth statistical analysis of all EU (other than the United Kingdom [UK]) data on BSE cases detected by all methods of surveillance. The detailed submission received from the USA and comments from Norway supported this approach.

The Terrestrial Code Commission noted that the *ad hoc* Group on BSE surveillance would need to meet again after the 73rd General Session to further consider 'maintenance surveillance'.

10. Transmissible spongiform encephalopathy agents inactivation procedures (Appendix 3.6.3.)

Community position:
The Community can support the amendments proposed in Appendix XIII.

The revised text circulated for Member Countries' comment in July 2004 (Appendix XIII) is proposed for adoption.

11. Classical swine fever (Chapter 2.6.7.)

Community position:

As the Community has on a number of occasions previously stated it can only support the amendments proposed in Appendix XIV if the points mentioned in the appendix are taken on board. The Community believes that the control of waste food feeding etc are key elements in the granting of free status. In addition it would ask the OIE to continue to develop the draft further with experts in particular examples of surveillance designs

The Terrestrial Code Commission considered the EU comment on Article 2.6.7.4. and reiterated its view that points b), c), d) and f) of paragraph 2 should be deleted and point g) of paragraph 2 modified as those measures were not required in order for a free country or zone to maintain its status.

In its meeting with the Terrestrial Code Commission, the Scientific Commission encouraged the Terrestrial Code Commission to include the concept of compartmentalisation in the revised chapter; this work will be done over the next year. Guidance will also be provided to Member Countries regarding the risk factors referred to in point 1) of Article 2.6.7.2.

The revised chapter is proposed for adoption (Appendix XIV).

The Terrestrial Code Commission is appreciative of the work of the Scientific Commission in developing a surveillance appendix for CSF. The Terrestrial Code Commission made some minor editorial changes in harmonising the draft with similar drafts for avian influenza and FMD, and is presenting the Appendix as clean text (Appendix XV) for adoption.

12. Highly pathogenic avian influenza (Chapter 2.7.12. and surveillance appendix)

Community position:
The Community can support the amendments proposed in Appendices XVI and XVII but would like the points mentioned in the appendix to be taken on board. In addition it would ask the OIE to continue to develop the surveillance draft further with experts including examples of surveillance designs

Chapter 2.7.12.

During the 72nd General Session, a revised *Terrestrial Code* chapter on highly pathogenic avian influenza was adopted by the OIE International Committee, incorporating (under study) the Terrestrial Code Commission's proposals. This revised chapter and the comments received until that time from Member Countries formed the basis for expert discussion at an *ad hoc* Group meeting in November 2004. The report of the *ad hoc* Group meeting is at Appendix XXV for the information of Member Countries. The views of the experts, comments received since November from Member Countries and two risk assessments from the UK Department of Environment, Farming and Rural Affairs (DEFRA) were considered by the Terrestrial Code Commission in its deliberations on the chapter.

Two DEFRA risk assessments:

(http://www.defra.gov.uk/animalh/diseases/monitoring/pdf/lpai-table-eggs.pdf

http://www.defra.gov.uk/animalh/diseases/monitoring/pdf/lpai-poultrymeat.pdf)

confirmed that there was a negligible likelihood of introduction to a country of low pathogenic notifiable avian influenza (LPNAI) virus via fresh poultry meat or eggs for human consumption, originating from a country not known to be free from LPNAI virus.

The Terrestrial Code Commission appreciated the detailed comments provided by Taipei China, the EU, Japan and Chile. The concerns expressed by Chile and Japan regarding the safety of trading from an 'NAI free establishment' located within a compartment not known to be free from LPNAI, were considered. However, the Terrestrial Code Commission considered that deleting the term 'NAI free establishment' and allowing trade only from a NAI free compartment would unnecessarily restrict trade in genetic material.

The Terrestrial Code Commission addressed the concerns regarding commodities for human consumption (fresh meat and eggs), on basis of the above risk assessments and recently published information. The Terrestrial Code Commission has recommended (see Articles 2.7.12.13. and 2.7.12.21.) that these commodities should originate from establishments free from evidence of NAI for the previous 21 days. In making these recommendations, the Terrestrial Code Commission weighed the evidence for the low likelihood of LPNAI transmission against the possible negative effects onerous trade measures may have on Member Countries reluctance to report LPNAI. Failure to report LPNAI accurately will increase the likelihood of spread of the virus.

The comments of Member Countries regarding vaccination had been considered by the experts who did not recommend any changes to the current wording.

The revised chapter (Appendix XVI) is presented for adoption.

b) Surveillance Appendix

The Terrestrial Code Commission is appreciative of the work of the experts under the Scientific Commission in developing a surveillance appendix for avian influenza. The Terrestrial Code Commission made some minor editorial changes in harmonising the draft with similar drafts for CSF and FMD, and is presenting the Appendix (Appendix XVII) for adoption as clean text.

13. Semen and embryo related matters

Community position:

The Community can support the amendments proposed in Appendices XVIII and XIX. However the Community wishes to caution about non-peer reviewed findings and emphasises the risks of manipulating FMD infected animals, irrespective of the status of the embryo. It is furthermore important to differentiate between in-vivo derived and in-vitro produced embryos.

The Terrestrial Code Commission consulted with an expert who briefed the Commission on the continuing work of the International Embryo Transfer Society (IETS) in categorising diseases and pathogens regarding the likelihood of their transmission via embryos. He noted for example that a non-peer reviewed paper had shown that embryos collected from FMD positive animals had not transmitted the disease into recipients.

Appendix 3.3.5. was modified in accordance with the IETS' work and is submitted as clean text for adoption (Appendix XVIII).

The expert expected that new data on contagious bovine pleuropneumonia and lumpy skin disease would soon allow those chapters to be updated. The expert also examined the comments from the USA on the timing of testing for bluetongue, and his recommendations have been included in the text.

The Terrestrial Code Commission also discussed with the expert his work in combining Appendices 3.2.1. and 3.2.2. into a single appendix on bovine and small ruminant semen, which had been done at the request of the Terrestrial Code Commission. The Terrestrial Code Commission thanked the expert for his work and is submitting the new appendix as clean text (Appendix XIX) for adoption; if adopted, this new appendix would replace Appendices 3.2.1 and 3.2.2.

The expert also provided the following text on the *Evaluation of risks that bovine embryos arising from fertilization with virus-infected semen will transmit infection to recipients* which had been developed by the Research Subcommittee of the IETS Health and Safety Advisory Committee. The text will be used as a basis for future modifications to the relevant chapters and is included here for the information of Member Countries.

> *The proposed new EU legislation prompted a scientific literature review. From studies in laboratory animals, humans and horses, it is apparent that viruses may sometimes attach to, or be integrated into, spermatozoa. Although in domestic livestock, including cattle, this seems to be a rare phenomenon, and carriage of virus through the zona pellucida into the oocyte by fertilizing sperm has never been described in these species.*
>
> *Four specific viruses: enzootic bovine leucosis virus (EBLV), bovine herpesvirus-1 (BHV-1), bovine viral diarrhoea virus (BVDV) and bluetongue virus (BTV), all of which tend to cause subclinical infections in cattle, but which can occur in bovine semen, might lead to production of infected embryos.*
>
> *With regards to* in vivo*-derived embryos, when internationally-approved embryo processing protocols are used, the risks from EBLV- and BTV-infected semen appear to be negligible, and the same is almost certainly true for BHV-1 if the embryos are also treated with trypsin. This would apply especially to bulls that are not proven to be BHV-1 negative. For BVDV, there is insufficient data on how the virus is carried in semen and how different BVDV strains can interact with sperm, oocytes and embryos. There is a potential, at least, that in vivo-derived embryos resulting from virus-infected semen might carry BVDV, although field studies so far suggest this very unlikely.*
>
> *With regard to* in vitro*-produced embryos, the use of semen infected with any of the four viruses, with probable exception of EBLV, will often lead to contaminated embryos, and virus removal from IVF embryos is difficult even when the internationally-approved embryos processing protocols are used. However, it has never been demonstrated that such embryos have resulted in transmission of infection to recipients or offspring.*

14. Rift Valley fever

Community position:
The Community can support the amendments proposed in Appendix XX but would like the points mentioned in the appendix to be taken on board.

The expert proposed the addition of an article on embryos to the chapter on Rift Valley fever.

The revised chapter (Appendix XX) is presented for adoption.

15. Antimicrobial resistance (Section 3.9.)

Community position:
The Community can support the amendments proposed in Appendix XXI but would like the points mentioned in the appendix to be taken on board.

The Terrestrial Code Commission received from the Biological Standards Commission revised appendices on the prudent use of antimicrobials and risk assessment for antimicrobial resistance. The Terrestrial Code Commission is presenting this text for adoption (Appendix XXI) as received from the Biological Standards Commission. It also received a definition for ´antimicrobial agent´ (at Appendix III).

16. Animal welfare

Community position:
The Community can support the amendments proposed in Appendix XXII but would like the points mentioned in the appendix to be taken on board.

The Terrestrial Code Commission commended the Working Group on Animal Welfare on coordinating the four *ad hoc* Groups which produced draft animal welfare guidelines on land and sea transport, killing for disease control purposes and slaughter for human consumption. The report of the most recent Working Group meeting (December 2004) is attached (Appendix XXVI).

The four texts are presented for adoption (Appendix XXII).

B. OTHER ISSUES CONSIDERED

17. Carcass disposal

Community position:
The Community can support the amendments proposed in Appendix XXIII but would like the points mentioned in the appendix to be taken on board.

The Terrestrial Code Commission received from the Scientific Commission a new text on carcass disposal. The Terrestrial Code Commission is presenting this text unchanged for consideration and comment by Member Countries (Appendix XXIII).

18. Animal identification and traceability

Community position:
The Community supports the work being done in this area and Community experts would be pleased to help.

The Terrestrial Code Commission was briefed on the preparatory work underway in OIE Headquarters on animal identification and traceability, under the auspices of the Working Group on Animal Production Food Safety.

The aim of this work is to provide the Working Group with information on the current state of animal identification in the different OIE regions. The data were collected from the responses to an OIE questionnaire on 'Animal Identification and Traceability' circulated to OIE Member Countries in January 2004 and from additional information currently being collected. From this preliminary work, the lack of homogeneity of approach among OIE Member Countries on this issue is evident.

The Terrestrial Code Commission welcomed this work while noting that future guidelines on animal identification and traceability in the Terrestrial Animals Health Code would need to focus on both animal and public health issues. Such guidelines would have to propose various options for animal identification in order to take into account the identified differences existing among OIE Member Countries. Among those options, identification by herd or lot, and when relevant individual animal identification, would need to be examined.

The Terrestrial Code Commission also recognised that the OIE's work in this field was a key point towards the application of zoning and compartmentalisation. The Terrestrial Code Commission concluded by inviting the Working Group on Animal Production Food Safety to produce terms of reference for an *ad hoc* Group on Animal Identification and Traceability to be convened by the Director General in 2005.

19. Animal production food safety

The Terrestrial Code Commission examined the report of the April 2004 meeting of the Working Group on Animal Production Food Safety and decided to circulate it for Member Countries' comment (Appendix XXVII). The Terrestrial Code Commission will provide its comments on the report for the upcoming meeting of the Working Group in March 2005.

20. Future work programme

The Terrestrial Code Commission noted that the Bureau of the Terrestrial Code Commission will review the Commission's work programme in July 2005, taking into account the outcomes of the 73rd General Session, submissions received from Member Countries, and input from the Scientific Commission and the Biological Standards Commission.

Items already scheduled for consideration include the development of a revised chapter on paratuberculosis, and the updating of chapters on dourine and surra. It also noted the need to address some points raised in the report of the OIE delegation to China for the Beijing Olympics.

Community position:

The Community proposes that work on Newcastle disease be given a priority following the good progress made on the AI chapter. In addition work on inactivation of disease agents for diseases where this has not been done should be completed urgently. The Community strongly supports the revision of the chapters on surra and dourine.

The Community furthermore urges the OIE to address to the authorities in China the needs for rapid actions in preparation of the Olympic Games, notably sufficient information on the equine health situation, including regionalisation and the certifiable freedom from certain equine disease over the required period, and their conditions fpr participation in the games.

21. Small hive beetle of honey bees (*Aethina tumida*) (Section 2.9.)

As a result of the recommendation of the *ad hoc* Group on bee diseases in 2003, the Terrestrial Code Commission decided that it would request a New Zealand expert to draft a supporting document and chapter on the small hive beetle of honey bees. The Terrestrial Code Commission also noted that the EU was producing a proposed new chapter (with a supporting document).

Community position:
The Community has already sent to the OIE a draft chapter on the small hive beetle and hopes that the OIE will be able to progress this quickly.

22. Rinderpest / Peste des petits ruminants

Community position:
The Community supports this work.

The Terrestrial Code Commission is awaiting information from the Scientific Commission on the use of vaccines for these diseases.

C. REPORTS OF *AD HOC* GROUPS

The following reports are for the information of Member Countries:

- ***Ad hoc* Groups on the BSE chapter and on surveillance for BSE** (Appendix XXIV)
- ***Ad hoc* Group on avian influenza** (Appendix XXV)
- **Animal Welfare Working Group** (Appendix XXVI)
- **Animal Production Food Safety Working Group** (Appendix XXVII).

The list of chapters and appendices proposed for adoption is in Section A of this report.

.../Appendices

Appendix I

MEETING OF THE OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 17-28 January 2005

List of Participants

MEMBERS OF THE TERRESTRIAL CODE COMMISSION

Dr A. Thiermann

President

US Mission to the OECD

19, rue de Franqueville

75016 Paris
FRANCE
Tel: 33-(0)1 44 15 18 69

E-mail: a.thiermann@oie.int

Dr W-A. Valder

Vice President

National Expert, SANCO

European Commission

Rue Froisart 101/ 3-72

Brussels
BELGIUM

Tel: (32-2)-2958916

E-mail: wolf-arno.valder@cec.eu.in

Prof S.C. MacDiarmid

Secretary General

Principal Adviser,

Zoonoses and Animal Health,

New Zealand Food Safety Authority

P.O. Box 2835

Wellington
NEW ZEALAND
Tel: (64-4) 463 2648
E-mail: stuart.macdiarmid@nzfsa.g

Dr S.K. Hargreaves

Principal Director of Livestock

and Veterinary Services

Ministry of Agriculture and

Rural Development

PO Box CY66 Causeway
Harare
ZIMBABWE

Tel: (263-4) 791 355/722 358

E-mail: skhargreaves@zol.co.zw

veeu@africaonline.co.zw

Prof. A.N. Panin

Director

The All-Russian State Centre for Qu
and Standardisation of Veterinary
Drugs and Feedstuff (VGNKI)

Ministry of Agriculture

5, Zvenigorodskoye shosse

123022 Moscow
RUSSIA

Tel/fax: (7-095) 253 14 91

E-mail: vgnki-vet@mtu-net.ru

Prof. A.M. Hassan

Undersecretary

Ministry of Animal Resources

PO Box 293

Khartoum
SUDAN

Tel: (249)183 465218 / 464 984 / 476 958
Fax: (249) 183 475996

E-mail: pacesud@yahoo.com

ahmedhassan32@hotmail.com

OTHER PARTICIPANTS

Prof. M. Thibier

(semen and embryo matters only)

Directeur général

Direction générale de l'enseignement
et de la recherche

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

75700 Paris
FRANCE

Tel: 01-49-55-42-40

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

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

Tel.: 33 (0)1 44.15.18.80

E-mail: d.wilson@oie.int

Dr F. Berlingieri

Project Officer

Dr Tomoko Ishibashi

Chargée de mission

International Trade Department

Tel.: 33 (0)1 44.15.18.92

E-mail: t.ishibashi@oie.int

Dr K. Ben Jebara

Head
Animal Health Information Departm

Dr A. Petrini

Chargé de mission

International Trade Department

Tel: 33 (0)1 44 15 18 89

E-mail: a.petrini@oie.int

International Trade Department

Tel: 33 (0)1 44 15 18 90

E-mail: f.berlingieri@oie.int

Tel: 33 (0)1 44 15 18 52

E-mail: k.benjebara@oie.int

Dr J. Pinto
Deputy-Head
Animal Health Information Departm
Tel: 33 (0)1 44 15 18 72

E-mail: j.pinto@oie.int

Appendix II

MEETING OF THE OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 17-28 January 2005

———

Agenda

PART ONE: Matters concerning the OIE Terrestrial Animal Health Standards Commission

Item 1 General definitions (Chapter 1.1.1.)

Item 2 Evaluation of Veterinary Services (Chapter 1.3.3.)

Item 3 Zoning and compartmentalisation (Chapter 1.3.5.)

Item 4 General guidelines for animal health surveillance (Appendix 3.8.1.)

Item 5 Animal disease notification (Chapter 1.1.2.) and Criteria for listing diseases (Chapter 2.1.1.)

Item 6 Foot and mouth disease (Chapter 2.2.10. and Appendix 3.8.7.)

Item 7 Bluetongue (2.2.13.)

Item 8 Bovine tuberculosis (Chapter 2.3.3.)

Item 9 Bovine spongiform encephalopathy (Chapter 2.3.13. and Appendix 3.8.4.)

Item 10 Transmissible spongiform encephalopathy agents inactivation procedures (Appendix 3.6.3.)

Item 11 Classical swine fever (Chapter 2.6.7.)

Item 12 Highly pathogenic avian influenza (Chapter 2.7.12.)

Item 13 Semen and embryo matters (Sections 3.2. and 3.3.)

Item 14 Rift Valley fever (Chapter 2.2.14.)

Item 15 Antimicrobial resistance (Section 3.9.)

Item 16 Carcass disposal

Item 17 Animal welfare

Item 18 Animal identification and traceability

Item 19 Animal production food safety

Item 20 Future work programme

Item 21 Small hive beetle of honey bees

Item 22 Rinderpest / Peste des petits ruminants

Item 23 Others

PART TWO: Matters discussed with the Scientific Commission for Animal Diseases

General definitions

Zoning and compartmentalisation

General guidelines for animal health surveillance

Foot and mouth disease

Bluetongue

Bovine tuberculosis

Classical swine fever

Highly pathogenic avian influenza

Antimicrobial resistance

Carcass disposal

Rinderpest / Peste des petits ruminants

Appendix III

CHAPTER 1.1.1.

GENERAL DEFINITIONS

Community position:

The Community can support the amendments proposed but would like the points mentioned below to be taken on board. The Community would like to thank the OIE for taking most of its previous comments into account. In addition the Community considers it is very important that as far as is practical the definitions in the terrestrial code and the aquatic code should be the same. Furthermore the Community believes that it would be better to keep to a proper definition without including requirements as these would be better placed in the relevant Chapters.

Buffer zone

A zone established ~~within, and along the border of,~~ to protect the health status of animals in a free country or *free zone*, from those in a country or *zone* of a different animal health status, using measures based on the epidemiology of the disease under consideration to prevent spread of the causative pathogenic agent into a free country or *free zone*. These measures may include, but are not limited to, vaccination, movement control and an intensified degree of disease surveillance.

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

Community position:
The Community would prefer to leave the reference to vaccination and would propose the following wording as an amendment "Where vaccination is carried out then the animals should be recognizable by a specific permanent mark". In addition the previous wording suggested by the Community is again proposed to be added (taking into account Article 2.1.1.8 for FMD but which is applicable in general to other diseases) "Movement of animals through other parts of the infected zone into the buffer zone should be carried out by mechanized transport under official control and only for immediate slaughter."

However it would be more preferable to leave the definition as proposed and to include buffer zone in chapter 1,3,5 (Zoning, regionalisation and compartmentalisation).

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

~~Surveillance zone~~

~~means a zone established within, and along the border of, a *free zone* separating the *free zone* from an *infected zone.*~~

~~The *surveillance zone* should have an intensified degree of surveillance.~~

Competent Authority

The *Veterinary Services*, or other Authority of a Member Country, having the responsibility and competence for ensuring or supervising the implementation of the animal health measures or other standards in the *Terrestrial Code.*

Notification

The procedure by which:

a) the *Veterinary Administration* informs the *Central Bureau*,

b) the *Central Bureau* informs *Veterinary Administrations*,

of the ~~suspicion or confirmation~~ occurrence of an *outbreak* of disease or infection, according to the provisions of Chapter 1.1.3. of the *Terrestrial Code*.

Official control programme

A programme which is approved, and managed or supervised by the *Veterinary Administration* of a country for the purpose of controlling a vector, pathogen or *disease* by specific measures applied throughout that country, or within a *zone* or *compartment* ~~or *zones*~~ of that country.

Case

An individual *animal* infected by a pathogenic agent ~~listed by the OIE~~, with or without clinical signs.

Emerging disease

A new *infection* resulting from the evolution or change of an existing pathogenic agent, a known *infection* spreading to a new geographic area or *population*, or a previously unrecognized pathogenic agent or *disease* diagnosed for the first time and which has a significant impact on animal or public health.

Community position:
The Community is concerned that if it's a previously unrecognised pathogenic agent or disease diagnosed for the first time its significant impact may not be known in which case the precautionary principle should apply. The Community proposes the following wording "A new *infection* resulting from the evolution or change of an existing pathogenic agent, a known *infection* spreading to a new geographic area or *population*, or a previously unrecognized pathogenic agent or *disease* diagnosed for the first time and which may have a significant impact on animal or public health."

Epidemiological unit

A group of animals with a defined epidemiological relationship that share approximately the same likelihood of exposure to a pathogen. This may be because they share a common environment (e.g. animals in a pen), or because of common management practices. Usually, this is a herd or a flock. However, an epidemiological unit may also refer to groups such as animals belonging to residents of a village, or animals sharing a communal dipping tank system. The epidemiological relationship may differ from disease to disease, or even strain to strain of the pathogen.

Notifiable disease

A *disease* listed by the *Veterinary Administration*, and that, as soon as detected or suspected, must be brought to the attention of the *Veterinary Authority*, in accordance with national regulations.

Outbreak of disease or infection

~~an~~ The occurrence of one or more cases of ~~the *diseases*~~ a *disease* or an *infection* ~~listed by the OIE~~ in an *epidemiological unit* ~~*establishment*~~, ~~breeding establishment or premises, including all buildings and all adjoining premises, where *animals* are present~~.

~~Where it cannot be defined in this way, the *outbreak* shall be considered as occurring in the part of the territory in which, taking local conditions into account, it cannot be guaranteed that both susceptible and non-susceptible animals have had no direct contact with affected or suspected *cases* in that area.~~

~~For example, in the case of certain parts of Africa, an *outbreak* means the occurrence of the *disease* within a sixteenth square degree; the occurrence is still referred to as an *outbreak* even though the *disease* may occur in several places within the same sixteenth square degree.~~

Community position:

The Community welcomes the clarification that infection is part of the outbreak definition. Because the outbreak definition is linked to the Epidemiological Unit, the role of means of transport, border posts and slaughterhouses becomes unclear. In addition the Community proposes that each outbreak is serially numbered according to the year and the sequential numbering that year this is very important epidemiologically and would be much more transparent. The Community proposes the following wording is added at the end of the sentence "and each outbreak is serially numbered by year and sequence e.g. first outbreak of a specific disease in 2005 would be 2005/1 and so on for that disease".

Antimicrobial agent

A naturally occurring, semi-synthetic or synthetic substance that exhibits antimicrobial activity (kill or inhibit the growth of micro-organisms). Anthelmintics and substances classed as disinfectants or antiseptics are excluded from this definition.

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

~~—~~ text deleted

Appendix IV

CHAPTER 1.3.5.

ZONING~~, REGIONALISATION~~ AND COMPARTMENTALISATION

Community position:

The Community can only support the amendments proposed if the points mentioned below are taken on board. It is very important that clear requirements and transparency is given to compartmentalisation for individual diseases. The requirements for compartmentalisation will vary from disease to disease and it may not be appropriate to include compartmentalisation in all disease chapters. In addition it will be necessary to include some elements of zoning (area of freedom around compartments) in order to ensure adequate safety for trade purposes.

Article 1.3.5.1.

Introduction

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

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

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

This chapter is to assist OIE Member Countries to establish and maintain different *subpopulations* within their national boundaries using the procedures of compartmentalisation and zoning. It also outlines a process for trading partners to follow in achieving recognition of such *subpopulation*. These procedures are best implemented by trading partners through establishing parameters and gaining agreement on the necessary measures prior to *disease outbreaks.*

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

Article 1.3.5.2.

General considerations

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

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

An *exporting country* which is establishing a *zone* or *compartment* within its territory for *international trade* purposes should clearly define the *subpopulation* in accordance with the measures stipulated in the relevant Chapters in the *Terrestrial Code* and should be able to explain to an *importing country* the basis for its claim of a distinct animal health status for the *zone* or *compartment* in such terms. ~~Animals and herds belonging to a *sub-population* need to be clearly recognisable as such. The *Veterinary Administration* should document in detail the measures taken to ensure the identification of the animals and herds belonging to a *sub-population* and the recognition and maintenance of its health status.~~

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

Community position:

The Community believes that is critical that any compartment proposed is capable of being maintained so it must both be under the supervision and control of the Veterinary services.

~~The extent of a *zone* and its limits should be established by the *Veterinary Administration* on the basis of natural, artificial or legal boundaries, and made public through official channels. The requirements regarding a *compartment* should be established by the *Veterinary Administration* on the basis of relevant criteria such as management and husbandry practices, and made public through official channels.~~

~~Thus defined, the *zones* and *compartments* constitute the relevant *sub-populations* for the application of the recommendations in Part 2 of the *Terrestrial Code*.~~

~~Article 1.3.5.3.~~

~~When an *exporting country* has defined a *zone* or *compartment* within its territory in respect of one or more of the diseases covered by the *Terrestrial Code*, it needs to implement the measures stipulated in the *Terrestrial Code* for establishing and maintaining such a *zone* or *compartment*.~~

An *importing country* should recognise the existence of this *zone* or *compartment* and accept the application of the appropriate measures recommended in the *Terrestrial Code* corresponding to the *animal health status* of the *zone* or *compartment* with regard to the importation, or transit through its territory, of *commodities* from the *zone* or *compartment*.

Article 1.3.5.3.

Prerequisite considerations in defining a zone or compartment

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

Article 1.3.5.4.

Principles for defining a zone or compartment

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

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

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

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

4) The requirements necessary to preserve the distinct health status of a *zone* or *compartment* must be appropriate to the particular *disease* and will depend on the epidemiology of the *disease*, environmental factors, control measures and surveillance.

Community position:

The Community proposes that biosecurity management measures and husbandry practices must be included here as well (see 2 above) therefore Community proposes the following wording "The requirements necessary to preserve the distinct health status of a *zone* or *compartment* must be appropriate to the particular *disease* and will depend on the epidemiology of the *disease*, environmental factors, biosecurity management, animal husbandry practices, control measures and surveillance**".**

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

Article 1.3.5.5.

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

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

1. For zoning:

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

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

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

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

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

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

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

iv) other relevant OIE standards;

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

i) recognition of the *zone*;

ii) request for further information; or

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

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

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

2) For compartmentalisation:

a) based on discussions with the relevant enterprise/industry, the *exporting country* identifies within its territory one or more *establishments* or other premises owned by an enterprise(s) which operates under a common biosecurity management system, and which it considers contains an animal *subpopulation* with a distinct health status with respect to a specific disease/specific diseases;

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

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

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

Community position:

The Community highlights again that the crucial part of supervision by the veterinary services is missing and must be included. The Community proposes the following wording "the surveillance and monitoring programme in place is appropriate to verify and maintain the free status of such *establishment*(s) with respect to such disease(s) under the supervision and control of the veterinary services"**.**

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

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

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

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

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

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

   iv) other relevant OIE standards;

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

   i) recognition of the *compartment*;

   ii) request for further information; or

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

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

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

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

Appendix V

APPENDIX 3.8.1. ~~CHAPTER 1.3.6~~

GENERAL GUIDELINES FOR ANIMAL HEALTH SURVEILLANCE

Community position:
The Community can support the proposed amendments but would like the points mentioned below taken on board.

Article 3.8.1.1.

Introduction and objectives

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

2) Animal health surveillance is an essential component necessary to detect diseases, to monitor disease trends, to control endemic and exotic diseases, to support claims for freedom from *disease* or *infection*, to provide data to support the risk analysis process, for both animal health and/or public health purposes, and to substantiate the rationale for sanitary measures. Surveillance data underpin the quality of disease status reports and should satisfy information requirements for accurate risk analysis both for *international trade* as well as for ~~internal~~ national decision-making.

3) Essential prerequisites to enable a Member Country to provide information for the evaluation of its animal health status are:

   a) that the particular Member Country complies with the provisions of Chapter 1.3.3. of the *Terrestrial Code* on the quality and evaluation of the *Veterinary Services*;

   b) that, where possible, surveillance data be complemented by other sources of information (e.g. scientific publications, research data, documented field observations and other non-survey data);

   c) that transparency in the planning and execution of surveillance activities and the analysis and availability of data and information, be maintained at all times, in accordance with Chapter 1.1.2. of the *Terrestrial Code*.

4) The objectives of this Appendix are to:

   a) provide guidance to the type of outputs that a surveillance system should generate;

   b) provide guidelines to assess the quality of disease surveillance systems.

Article 3.8.1.2.

Definitions

Community position:
The Community proposes that if a definition appears in more that one chapter it should be included in Chapter 1.1.1.

The following definitions apply for the purposes of this Appendix:

Bias: A tendency of an estimate to deviate in one direction from a true value. ~~(as by reason of nonrandom sampling)~~

Case definition: A case definition is a set of criteria used to classify an animal or epidemiological unit as a case ~~or non-case~~.

Confidence: In the context of demonstrating freedom from *infection*, confidence is the probability that the type of surveillance applied would detect the presence of *infection* if the population were infected. The confidence depends on, among ~~others the design prevalence, or~~ other parameters, the assumed level of *infection* in an infected population. ~~Confidence therefore~~ The term refers to our confidence in the ability of the surveillance applied to detect *disease*, and is equivalent to the sensitivity of the surveillance system.

Early detection system: A system for the timely detection and identification of an incursion or emergence of *disease/infection* in a country, *zone* or *compartment*. An early detection system should be under the control of the *Veterinary Services* and should include the following characteristics:

a) representative coverage of target animal populations by field services;

b) ability to undertake effective disease investigation and reporting;

c) access to laboratories capable of diagnosing and differentiating relevant diseases;

d) a training programme for veterinarians, *veterinary para-professionals* and others involved in handling animals for detecting and reporting unusual animal health incidents;

e) the legal obligation of private veterinarians in relation to the *Veterinary Administration*;

f) timely reporting system of the event to the *Veterinary Services*;

g) a national chain of command.

Community position:
The Community proposes that either the definition of early detection systems (Chapter 1.1.1) is changed according to the above or deleted.

Epidemiological unit: A group of animals with a defined epidemiological relationship that share approximately the same likelihood of exposure to a pathogen. This may be because they share a common environment (e.g. animals in a pen), or because of common management practices. Usually, this is a herd or flock; however, an epidemiological unit may also refer to groups such as the animals belonging to residents of a village, or animals sharing a communal dipping tank system.

Community position:
The Community proposes that monitoring be included here as " Monitoring means the systematic collection , collation and analysis of data with a view to determine a disease agent's prevalence or incidence".

Outbreak definition: An outbreak definition is a set of criteria used to classify the occurrence of one or more cases in a group of animals or units as an outbreak.

Probability sampling: A sampling strategy in which every unit has a known non-zero probability of inclusion in the sample.

Sample: The group of elements (sampling units) drawn from a population, on which tests are performed or parameters measured to provide surveillance information.

Sampling units: The unit that is sampled, either in a random survey or in non-random surveillance. This may be an individual animal or a group of animals (e.g. an epidemiological unit). Together, they comprise the sampling frame.

Sensitivity: The proportion of truly positive units that are correctly identified as positive by a test.

Specificity: The proportion of truly negative units that are correctly identified as negative by a test.

Study population: The population from which surveillance data are derived. This may be the same as the target population or a subset of it.

Surveillance: The systematic ongoing collection, collation, and analysis of data, and the timely dissemination of information to those who need to know so that action can be taken.

Surveillance system: A method of surveillance that may involve one or more component activities that generates information on the ~~animal~~ health, disease or zoonosis status of animal populations.

Survey: An investigation in which information is systematically collected, usually carried out on a sample of a defined population group, within a defined time period.

Target population: The population about which conclusions are to be inferred ~~drawn from a study~~.

Test: A procedure used to classify a unit as either positive, negative or suspect with respect to an *infection* or *disease*.

Community position:
The Community proposes to use the word ”inconclusive” rather than ‘suspect’.

Test system: A combination of multiple tests and rules of interpretation which are used for the same purpose as a test.

~~**Unit:** An individually identifiable element. This is a generic concept used to describe, for example, the members of a population, or the elements selected when sampling. In these contexts, examples of units include individual animals, pens, farms, holdings, villages, districts etc.~~

Article 3.8.1.3.

Principles of surveillance

1) Types of surveillance

   a) Surveillance may be based on many different data sources and can be classified in a number of ways, including:

      i) the means by which data are collected (active versus passive surveillance);

      ii) the disease focus (pathogen-specific versus general surveillance); and

      iii) the way in which units for observation are selected (structured surveys versus non-random data sources).

   b) In this Appendix, surveillance activities are classified as being based either on:

i) structured population-based surveys, such as:

– systematic <u>random</u> sampling at slaughter;

– random surveys; or

ii) structured non-random surveillance activities, such as:

– disease reporting or notifications;

– control programmes/health schemes;

– targeted testing/screening;

– ante-mortem and post-mortem inspections;

– laboratory investigation records;

– biological specimen banks;

– sentinel units;

– field observations;

– farm production records.

c) In addition, surveillance data should be supported by related information, such as:

i) data on the epidemiology of the infection, including environmental, host population distribution, and climatic information;

ii) data on animal movements and trading patterns for animals and animal products;

<u>iii) national animal health regulations, including information on compliance with them and their effectiveness</u>;

iv) history of imports of potentially infected material; and

v) biosecurity measures in place.

d) The sources of evidence should be fully described. In the case of a structured survey, this should include a description of the sampling strategy used for the selection of units for testing. For structured non-random data sources, a full description of the system is required including the source(s) of the data, when the data were collected, and a consideration of any biases that may be inherent in the system.

2) <u>Critical elements</u>

In assessing the quality of a surveillance system, the following critical elements need to be addressed over and above quality of *Veterinary Services* (Chapter 1.3.3.).

a) Populations

<u>Ideally</u>, surveillance should be carried out in such a way as to take into account all animal species susceptible to the infection in a country, *<u>zone</u>* or *compartment*. The surveillance activity may cover all individuals in the population or part of them. <u>When surveillance is conducted only on a *subpopulation*</u> ~~In the latter case,~~ care should be taken regarding the inferences made from the results.

Definitions of appropriate populations should be based on the specific recommendations of the disease chapters of the *Terrestrial Code*.

~~TO PROPOSE FOR INSERTION IN CHAPTER 1.1.1~~

- **Carriers** – animals that harbour the agent and may spread it directly or indirectly while not

~~demonstrating clinical signs of the disease. Depending on the disease, an animal may serve as a carrier animal for shorter or longer periods of time. The length of time that an infection can be spread by inapparent carriers is important in designing a surveillance scheme.~~

- ~~**Reservoirs** – some pathogens require either a living organism or inanimate environment for multiplication. Recognition of the location and role of a reservoir in the persistence of an infectious agent should be considered.~~
- ~~**Vectors** - a pathogen can be vector borne. Where this is the case, the biology and ecology (including seasonal effects) of vector populations should be considered.~~
- ~~**Immune status** – age of an animal, previous exposure to a specific pathogens, and use of vaccination are factors that need to be considered in determining appropriate diagnostic tests or clinical measures for evidence of infection.~~
- ~~**Genetic resistance** – some animals may not be susceptible to specific disease agents because of genetic resistance. If this is true for an infectious agent under surveillance, a method for identifying those animals that are susceptible or resistant may need to be factored into the design for surveillance.~~
- ~~**Age, sex, and other host criteria** – some pathogens can only affect animals that possess certain host related criteria. These type of criteria should be accounted for in the definition of the target population, surveillance design and interpretation of the results~~

Community position:
The Community believes that the above should be inserted in the definition Chapter 1.1.1.

b) Epidemiological unit

The relevant epidemiological unit for the surveillance system should be defined and documented to ensure that it is representative of the population. Therefore, it should be chosen taking into account factors such as carriers, reservoirs, vectors, immune status, genetic resistance and age, sex, and other host criteria.

c) Clustering

Infection in a country, *zone* or *compartment* usually clusters rather than being uniformly or randomly distributed through a population. Clustering may occur at a number of different levels (e.g. a cluster of infected animals within a herd, a cluster of pens in a building, or a cluster of farms in a *compartment*). Clustering should be taken into account in the design of surveillance activities and the statistical analysis of surveillance data, at least at what is judged to be the most significant level of clustering for the particular animal population and infection.

d) Case and outbreak definitions

Clear and unambiguous case and outbreak definitions should be developed and documented for each pathogen under surveillance, using, where they exist, the standards in the *Terrestrial Code*.

e) Analytical methodologies

Surveillance data should be analysed using appropriate methodologies, and at the appropriate organisational levels to facilitate effective decision making, whether it be planning interventions or demonstrating status.

Methodologies for the analysis of surveillance data should be flexible to deal with the complexity of real life situations. No single method is applicable in all cases. Different methodologies may be needed to accommodate the relevant pathogens, varying production and surveillance systems, and types and amounts of data and information available.

The methodology used should be based on the best available information that is in accord with current scientific thinking. The methodology should be in accordance with this Appendix and fully documented, and supported by reference ~~to the OIE Standards,~~ to the scientific literature and other sources, including expert opinion. Sophisticated mathematical or statistical analyses should only be carried out when justified by the proper amount and quality of field data.

Consistency in the application of different methodologies should be encouraged and transparency is essential in order to ensure fairness and rationality, consistency in decision making and ease of understanding. The uncertainties, assumptions made, and the effect of these on the final conclusions should be documented.

f) Testing

Surveillance involves the detection of *disease* or *infection* by the use of appropriate case definitions based on the results of one or more tests for evidence of infection or immune status. In this context, a test may range from detailed laboratory examinations to field observations and the analysis of production records. The performance of a test at the population level (including field observations) may be described in terms of its sensitivity and specificity. Imperfect sensitivity and/or specificity will have an impact on the conclusions from surveillance. Therefore, predictive values of the test should, whenever possible, be taken into account in the design of surveillance systems and analysis of surveillance data.

The values of sensitivity and specificity for the tests used should be specified, and the method used to determine or estimate these values should be documented. Alternatively, where values for sensitivity and/or specificity for a particular test are specified in the *Terrestrial Manual*, these values may be used as a guide ~~without justification~~.

Samples from a number of animals or units may be pooled ~~together~~ and subjected to a single test. The results should be interpreted using sensitivity and specificity values that have been determined or estimated for that particular pool size and testing procedure.

g) Quality assurance

Surveillance systems should incorporate the principles of quality assurance and be subjected to periodic auditing to ensure that all components of the system function and provide verifiable documentation of procedures and basic checks to detect significant deviations of procedures from those documented in the design.

h) Validation

Results from animal health surveillance systems are subject to one or more potential biases. When assessing the results, care should be taken to identify potential biases that can inadvertently lead to an over-estimate or an under-estimate of the parameters of interest.

i) Data collection and management

The success of a surveillance system is dependent on a reliable process for data collection and management. The process may be based on paper records or computerised. Even where data are collected for non-survey purposes (e.g. during disease control interventions, inspections for movement control or during disease eradication schemes), the consistency and quality of data collection and event reporting in a format that facilitates analysis, is critical. Factors influencing the quality of collected data include:

- the distribution of, and communication between, those involved in generating and transferring data from the field to a centralised location;
- the ability of the data processing system to detect missing, inconsistent or inaccurate data, and to address these problems;
- maintenance of disaggregated data rather than the compilation of summary data;
- minimisation of transcription errors during data processing and communication.

Article 3.8.1.4.

Structured population-based surveys

In addition to the principles for surveillance discussed above, the following guidelines should be used when planning, implementing and analysing surveys.

1) Types of surveys

Surveys may be conducted on the entire target population (i.e. a census) or on a sample. A sample may be selected in either of the two following ways ~~manners~~:

a) non-probability based sampling methods, such as:

i) convenience;

ii) expert choice;

iii) quota;

b) probability based sampling methods, such as:

i) simple random selection;

ii) cluster sampling;

iii) stratified sampling.

Non-probability based sampling methods will not be discussed further.

2) Systematic selection

Periodic or repeated surveys conducted in order to document disease freedom should be done using probability based sampling methods so that data from the study population can be extrapolated to the target population in a statistically valid manner.

The sources of information should be fully described and should include a detailed description of the sampling strategy used for the selection of units for testing. Also, consideration should be made of any biases that may be inherent in the survey design.

3) Survey design

The population of epidemiological units should first be clearly defined; hereafter sampling units appropriate for each stage, depending on the design of the survey, should be defined.

The design of the survey will depend on the size and structure of the population being studied, the epidemiology of the infection and the resources available.

4) Sampling

The objective of sampling from a population is to select a subset of units from the population that is representative of the population with respect to the object of the study such as the presence or

absence of infection. Sampling should be carried out in such a way as to provide the best likelihood that the sample will be representative of the population, within the practical constraints imposed by different environments and production systems. In order to detect the presence of an infection in a population of unknown disease status targeted sampling methods that optimise the detection of infection can be used. In such cases, care should be taken regarding the inferences made from the results.

5) Sampling methods

When selecting epidemiological units from within a population, ~~a formal~~ probability sampling ~~method~~ (e.g. simple random sampling) should be used. When this is not possible, sampling should provide the best practical chance of generating a sample that is representative of the target population.

In any case, the sampling method used at all stages should be fully documented and justified.

6) Sample size

In general, surveys are conducted either to demonstrate the presence or absence of a factor (e.g. infection) or to estimate a parameter (e.g. the prevalence of infection). The method used to calculate sample size for surveys depends on the purpose of the survey, the expected prevalence, the level of confidence desired of the survey results and the performance of the tests used.

Article 3.8.1.5.

Structured non-random surveillance

• Surveillance systems routinely use structured non-random data, either alone or in combination with surveys. ~~There is a wide variety of non-random data sources that can be used.~~

1) Common non-random surveillance sources

A wide variety of non-random surveillance sources may be available. These vary in their primary purpose and the type of surveillance information they are able to provide. Some surveillance systems are primarily established as early detection systems, but may also provide valuable information to demonstrate freedom from infection. Other systems provide cross-sectional information suitable for prevalence estimation, either once or repeatedly, while yet others provide continuous information, suitable for the estimate of incidence data (e.g. disease reporting systems, sentinel sites, testing schemes). Surveillance systems routinely use structured non-random data, either alone or in combination with surveys.

a) Disease reporting or notification systems

Data derived from disease reporting systems can be used in combination with other data sources to substantiate claims of animal health status, to generate data for risk analysis, or for early detection. Effective laboratory support is an important component of any reporting system. Reporting systems relying on laboratory confirmation of suspect clinical cases should use tests that have a ~~good~~ high specificity. Reports should be released by the laboratory in a timely manner, with the amount of time from disease detection to report generation minimized (to hours in the case of introduction of a foreign animal disease).

b) Control programmes / health schemes

Animal disease control programmes or health schemes, while focusing on the control or eradication of specific diseases, should be planned and structured in such a manner as to generate data that are scientifically verifiable and contribute to structured surveillance.

c) Targeted testing / screening

This may involve testing targeted to selected sections of the population (subpopulations), in

which disease is more likely to be introduced or found. Examples include testing culled and dead animals, swill fed animals, those exhibiting clinical signs, animals located in a defined geographic area and specific age or commodity group.

d) Ante-mortem and post-mortem inspections

Inspections of animals at abattoirs may provide valuable surveillance data. The sensitivity and specificity of the particular slaughterhouse inspection system for detecting the presence of infectious agents of surveillance interest under the particular inspection arrangements applying in a country should be pre-determined by the *Competent Authority* if the data is to be fully utilised. The accuracy of the inspection system will be influenced by:

i) the level of training and experience of the staff doing the inspections, and the ratio of staff of different levels of training;

ii) the involvement of the *Competent Authorities* in the supervision of ante-mortem and post-mortem inspections;

iii) the quality of construction of the abattoir, speed of the slaughter chain, lighting quality, etc; and

iv) staff morale/motivation for accurate and efficient performance.

Abattoir inspections are likely to provide good coverage only for particular age groups and geographical areas. ~~Statistical biases are likely to be more frequent for infected animals originating from larger, better managed farms rather than for animals originating from smallholder or backyard production farms, as well as for healthy rather than diseased animals.~~ Abattoir surveillance data are subject to obvious biases in relation to target and study populations (e.g. only animals of a particular class and age may be slaughtered for human consumption in significant numbers). Such biases need to be recognized when analysing surveillance data.

Both for traceback in the event of detection of disease and for analysis of spatial and herd-level coverage, there should be, if possible, an effective identification system that relates each animal in the abattoir to its ~~property/~~locality of origin.

e) Laboratory investigation records

Analysis of laboratory investigation records may provide useful surveillance information. The coverage of the system will be increased if analysis is able to incorporate records from national, accredited, university and private sector laboratories. Valid analysis of data from different laboratories depends on the existence of standardised diagnostic procedures and standardised methods for interpretation and data recording. As with abattoir inspections, there needs to be a mechanism to relate specimens to the farm of origin.

f) Biological specimen banks

Specimen banks consist of stored specimens, gathered either through representative sampling or opportunistic collection or both. Specimen banks may contribute to retrospective studies, including providing support for claims of historical freedom from infection, and may allow certain studies to be conducted more quickly and at lower cost than alternative approaches.

g) Sentinel units

Sentinel units/sites involve the identification and regular testing of one or more of animals of known health/immune status in a specified geographical location to detect the occurrence of disease (usually serologically). They are particularly useful for surveillance of diseases with a strong spatial component, such as vector-borne diseases. Sentinel units provide the opportunity to target surveillance depending on the likelihood of infection (related to vector habitats and

host population distribution), cost and other practical constraints. Sentinel units may provide evidence of freedom from infection, or provide data on prevalence and incidence as well as the distribution of disease.

h) Field observations

Clinical observations of animals in the field are an important source of surveillance data. The sensitivity and specificity of field observations may be relatively low, but these can be more easily determined and controlled if a clear, unambiguous and easy to apply standardised case definition is applied. Education of potential field observers in application of the case definition and reporting is an important component. Ideally, both the number of positive observations and the total number of observations should be recorded.

i) Farm production records

Systematic analysis of farm production records may be used as an indicator of the presence or absence of disease at the herd or flock level. In general, the sensitivity of this approach may be quite high (depending on the disease), but the specificity is often quite low.

2) Critical elements for structured non-random surveillance

There is a number of critical factors which should be taken into account when using structured non random surveillance data such as coverage of the population, duplication of data, and sensitivity and specificity of tests that may give rise to difficulties in the interpretation of data. Surveillance data from non-random data sources may increase the level of confidence or be able to detect a lower level of prevalence with the same level of confidence compared to structured surveys.

3) Analytical methodologies

Different methodologies may be used for the analysis of non-random surveillance data.

Different scientifically valid methodologies may be used for the analysis of non-random surveillance data. Where no data are available, estimates based on expert opinions, gathered and combined using a formal, documented and scientifically valid methodology may be used.

~~Analytical methodologies based on the use of step-wise probability estimates to describe the surveillance system may determine the probability of each step either by:~~

~~a) the analysis of available data, using a scientifically valid methodology; or where no data are available,~~

~~b) the use of estimates based on expert opinion, gathered and combined using a formal, documented and scientifically valid methodology~~.

4) Combination of multiple sources of data

The methodology used to combine the evidence from multiple data sources should be scientifically valid, and fully documented including references to published material.

Surveillance information gathered from the same country, *zone* or *compartment* at different times may provide cumulative evidence of animal health status. Such evidence gathered over time may be combined to provide an overall level of confidence. For instance, repeated annual surveys may be analysed to provide a cumulative level of confidence. However, a single larger survey, or the combination of data collected during the same time period from multiple random or non-random sources, may be able to achieve the same level of confidence in just one year.

Analysis of surveillance information gathered intermittently or continuously over time should, where possible, incorporate the time of collection of the information to take the decreased value of older information into account. The sensitivity, specificity and completeness of data from each source

should also be taken into account for the final overall confidence level estimation.

Article 3.8.1.6.

~~SURVEILLANCE TO DEMONSTRATE FREEDOM FROM INFECTION~~

Surveillance to demonstrate freedom from disease/infection ~~International recognition of freedom from infection~~

1) ~~Introduction~~ Requirements to declare a country, zone or compartment free from disease/infection without pathogen specific surveillance

- This Article provides general principles for declaring a country, *zone* or *compartment* free from *disease/infection* in relation to the time of last occurrence and in particular for the recognition of historical freedom.

- The provisions of this Article are based on the principles described in Article 3 of this Appendix and the following premises:

– in the absence of disease and vaccination, the animal population would become susceptible over a period of time;

– the disease agents to which these provisions apply are likely to produce identifiable clinical signs in susceptible animals;

– competent and effective *Veterinary Services* will be able to investigate, diagnose and report disease, if present;

– the absence of *disease/infection* over a long period of time in a susceptible population can be substantiated by effective disease investigation and reporting by ~~the *Veterinary Services* of~~ a Member Country.

~~4.2. Additional requirements to declare a country or compartment free from infection without pathogen specific surveillance~~

a) Historically free

Unless otherwise specified in the relevant disease chapter, a country, *zone* or *compartment* may be recognised free from infection without formally applying a pathogen-specific surveillance programme when:

i) there has never been occurrence of disease, or

ii) eradication has been achieved or the *disease/infection* has ceased to occur for at least 25 years,

provided that for at least the past 10 years:

iii) it has been a notifiable disease;

iv) an early detection system has been in place;

v) measures to prevent *disease/infection* introduction have been in place; no vaccination against the disease has been carried out unless otherwise provided in the *Terrestrial Code*;

vi) infection is not known to be established in wildlife within the country or *zone* intended to be declared free. (A country or *zone* cannot apply for historical freedom if there is any evidence of infection in wildlife. However, specific surveillance in wildlife is not necessary.)

b) Last occurrence within the previous 25 years

Countries, *zones* or *compartment*s that have achieved eradication (or in which the *disease/infection* has ceased to occur) within the previous 25 years, should follow the pathogen-specific surveillance requirements in the *Terrestrial Code* if they exist. In the absence of specific

requirements for surveillance in the *Terrestrial Code*, countries should follow the general guidelines for surveillance to demonstrate animal health status outlined in this Appendix provided that for at least the past 10 years:

i) it has been a notifiable disease;

ii) an early detection system has been in place;

iii) measures to prevent *disease/infection* introduction have been in place;

iv) no vaccination against the disease has been carried out unless otherwise provided in the *Terrestrial Code*;

v) infection is not known to be established in wildlife within the country or *zone* intended to be declared free. (A country or *zone* cannot apply for freedom if there is any evidence of infection in wildlife. However, specific surveillance in wildlife is not necessary.)

2) Guidelines for the discontinuation of pathogen-specific screening after recognition of freedom from infection

• A country, *zone* or *compartment* that has been recognised as free from infection following the provisions of the *Terrestrial Code* may discontinue pathogen-specific screening while maintaining the infection-free status provided that:

a) it is a notifiable disease;

b) an early detection system is in place;

c) measures to prevent *disease/infection* introduction are in place;

d) vaccination against the disease is not applied;

e) infection is known not to be established in wildlife. (Specific surveillance in wildlife has demonstrated the absence of infection.)

3) International recognition of disease/infection free status

• For diseases for which procedures exist whereby the OIE can officially recognise the existence of a *disease/infection* free country, *zone* or *compartment*, a Member Country wishing to apply for recognition of this status shall, via its Permanent Delegate, send to the OIE all the relevant documentation relating to the country, *zone* or *compartment* concerned. Such documentation should be presented according to guidelines prescribed by the OIE for the appropriate animal diseases.

4) Demonstration of freedom from infection

• A surveillance system to demonstrate freedom from infection should meet the following requirements in addition to the general requirements for surveillance outlined in Article 3 of this Appendix.

• Freedom from infection implies the absence of the pathogenic agent in the country, *zone* or *compartment*. Scientific methods cannot provide absolute certainty of the absence of infection. Demonstrating freedom from infection involves providing sufficient evidence to demonstrate (to a level of confidence acceptable to Member Countries) that infection with a specified pathogen is not present in a population. In practice, it is not possible to prove (i.e., be 100% confident) that a population is free from infection (unless every member of the population is examined simultaneously with a perfect test with both sensitivity and specificity equal to 100%). Instead, the aim is to provide adequate evidence (to an acceptable level of confidence), that infection, if present, is present in less than a specified proportion of the population

- However, finding evidence of infection at any level in the target population automatically invalidates any freedom from infection claim.

Community position:
The Community would like to point out that the above paragraph is in contradiction to the Chapters on country/zone freedom from bovine brucellosis, tuberculosis leucosis and IBR. The Community proposed last time that an addition to the sentence is made as follows: "unless otherwise stated in the relevant disease chapters". Or the appropriate Chapters need to be amended.

- Evidence from targeted, random or non-random data sources, as stated before, may increase the level of confidence or be able to detect a lower level of prevalence with the same level of confidence compared to structured surveys.

Article 3.8.1.7.

Surveillance for distribution and occurrence of infection

- Surveillance to determine distribution and occurrence of infection or of other relevant health related events is widely used to assess progress in the control or eradication of selected diseases and pathogens and as an aid to decision making. It has, however, relevance for the international movement of animals and products when movement occurs among infected countries.

- In contrast to surveillance to demonstrate freedom from infection, surveillance used to assess progress in control or eradication of selected diseases and pathogens is usually designed to collect data about a number of variables of animal health relevance, for example:

1) prevalence or incidence of infection;

2) morbidity and mortality rates;

3) frequency of *disease/infection* risk factors and their quantification ~~when the risk factors are expressed by continuous [real numbers] or discrete [integers] variables~~;

4) frequency distribution of herd sizes or the sizes of other epidemiological units;

5) frequency distribution of antibody titres;

6) proportion of immunised animals after a vaccination campaign;

7) frequency distribution of the number of days elapsing between suspicion of infection and laboratory confirmation of the diagnosis and/or to the adoption of control measures;

8) farm production records, etc.

- ~~All~~ of ~~the listed data may also have relevance for the risk analysis~~.

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

CHAPTER 2.1.1.

CRITERIA FOR LISTING DISEASES

Community position:

The Community can support the amendments proposed in Appendix VI. In addition the Community requests an explanation concerning the consequences of reporting one of the following diseases TB, Brucellosis and EBL in particular, where the freedom of disease requirements are laid down both in the Chapter and the appendices. There would appear to be contradictions which could result in different interpretations and therefore give rise to unfounded trade problems.

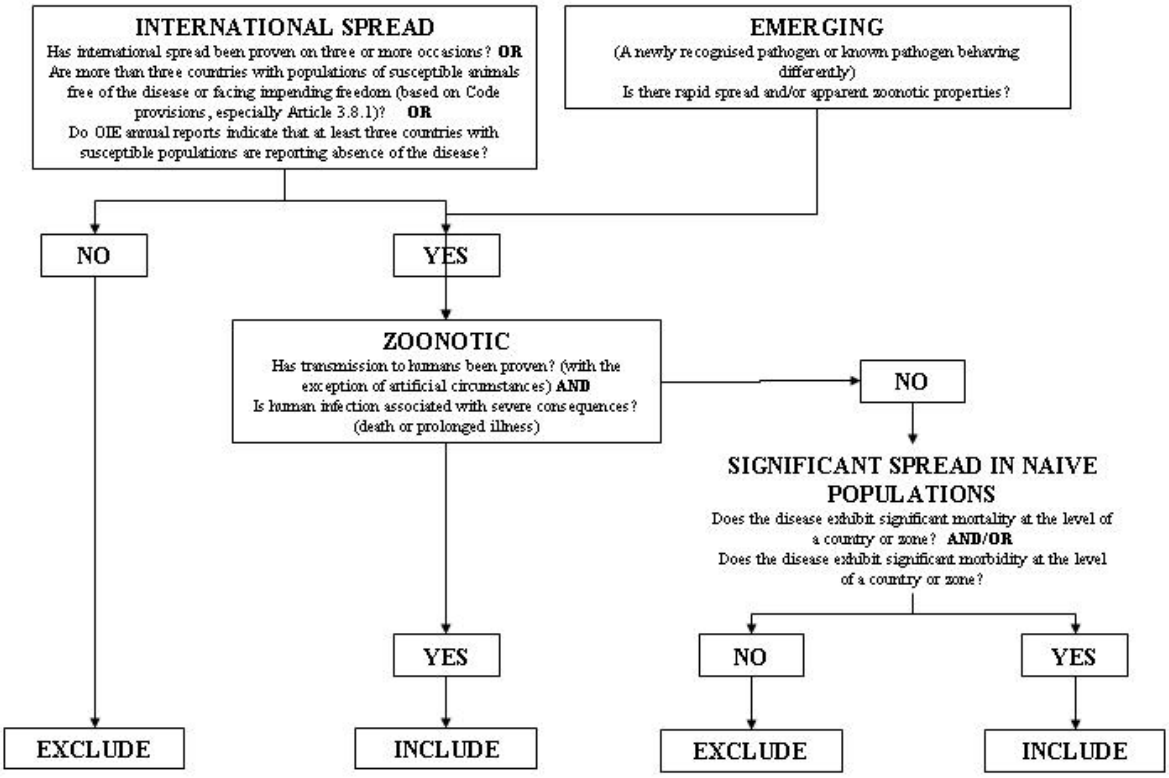
Article 2.1.1.1.

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

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

Article 2.1.1.2.

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



Article 2.1.1.3.

The following diseases are included in the OIE *List*.

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

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

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

Community position:
The Community proposes that "other TSEs" (Mink encephalopathy and CWD) are included.

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

- Bovine anaplasmosis
- Bovine babesiosis
- ~~Bovine brucellosis~~ **
- ~~Bovine cysticercosis~~
- Bovine genital campylobacteriosis
- Bovine spongiform encephalopathy
- Bovine viral diarrhoea *
- Bovine tuberculosis
- Contagious bovine pleuropneumonia
- ~~Dermatophilosis~~
- Enzootic bovine leukosis
- Haemorrhagic septicaemia
- Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis
- Lumpy skin disease ***
- Malignant catarrhal fever
- ~~Rinderpest~~ ***
- Theileriosis
- Trichomonosis
- Trypanosomosis (tsetse–transmitted).

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

- ~~Caprine and ovine brucellosis (excluding *B. ovis*)~~ **
- Caprine arthritis/encephalitis
- Contagious agalactia
- Contagious caprine pleuropneumonia
- Enzootic abortion of ewes (ovine chlamydiosis)
- ~~Ovine pulmonary adenomatosis~~
- Nairobi sheep disease
- Maedi–visna
- Ovine epididymitis (*Brucella ovis*)
- Peste des petits ruminants

- Salmonellosis (*S.* abortusovis)
- Scrapie
- Sheep pox and goat pox.

4) The following diseases are included within the category of equine diseases:

- African horse sickness
- Contagious equine metritis
- Dourine
- ~~Epizootic lymphangitis~~
- ~~Equine encephalomyelitis (Eastern and Western)~~ **
- Equine encephalomyelitis (Eastern) **
- Equine encephalomyelitis (Western) **
- Equine infectious anaemia
- Equine influenza
- Equine piroplasmosis
- Equine rhinopneumonitis
- Equine viral arteritis
- Glanders
- ~~Horse mange~~
- ~~Horse pox~~
- ~~Japanese encephalitis~~ ***
- Surra (*Trypanosoma evansi*)
- Venezuelan equine encephalomyelitis.

5) The following diseases are included within the category of swine diseases:

- African swine fever
- ~~Atrophic rhinitis of swine~~
- Classical swine fever
- Nipah virus encephalitis *
- Porcine cysticercosis
- ~~Porcine brucellosis~~ **
- Porcine reproductive and respiratory syndrome
- ~~Enterovirus encephalomyelitis~~
- Swine vesicular disease
- Transmissible gastroenteritis.

6) The following diseases are included within the category of avian diseases:

- Avian chlamydiosis
- Avian infectious bronchitis
- Avian infectious laryngotracheitis
- Avian mycoplasmosis (*M. gallisepticum*)
- Avian mycoplasmosis (*M. Synoviae*) *
- ~~Avian tuberculosis~~
- Duck virus hepatitis
- ~~Duck virus enteritis~~
- ~~Fowl cholera~~
- ~~Fowl pox~~
- Fowl typhoid
- Highly pathogenic avian influenza
- Infectious bursal disease (Gumboro disease)
- Marek's disease
- Newcastle disease
- Pullorum disease
- Turkey rhinotracheitis *.

Community position:

The Community proposes that Low pathogenic avian influenza is included and that it is clarified that Turkey Swollen head syndrome is included under Turkey Rhinotracheitis above as it caused by the same virus..

7) The following diseases are included within the category of lagomorph diseases:

- Myxomatosis
- Rabbit haemorrhagic disease
- Tularemia ***.

Community position:

The Community proposes that Tularemia is deleted here as it already appears in Section 1.

8) The following diseases are included within the category of bee diseases:

- Acarapisosis of honey bees
- American foulbrood of honey bees
- European foulbrood of honey bees
- Small hive beetle infestation (*Aethina tumida*) *
- *Tropilaelaps* infestation of honey bees
- Varroosis of honey bees.

9) The following disease is included within the category of other diseases:

- Camelpox *
- Leishmaniosis.

* Added disease
** Changed name
*** Change of species category

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

CHAPTER 2.2.10

FOOT AND MOUTH DISEASE

Community position:

The Community can in general support the amendments proposed but would like the points mentioned below to be taken on board. However before the Community can support the addition of compartmentalisation in this Chapter the requirements for compartmentalisation must be clearly laid down. In addition the Community repeats its previous concerns to maintain de-boning and maturation for meat from vaccinated animals from countries or zones free with vaccination. In addition it is important that a satisfactory vaccine is used under proper guidelines.

Article 2.2.10.1.

For the purposes of the *Terrestrial Code*, the *incubation period* for foot and mouth disease (FMD) shall be 14 days.

For the purposes of this Chapter, ruminants include animals of the family of Camelidae.

For the purposes of this Chapter, a *case* includes an animal infected with FMD virus (FMDV).

For the purposes of *international trade*, this Chapter deals not only with the occurrence of clinical signs caused by FMDV, but also with the presence of infection with FMDV in the absence of clinical signs.

The following defines the occurrence of FMDV infection:

1) FMDV has been isolated and identified as such from an animal or a product derived from that animal, or

2) viral antigen or viral RNA specific to one or more of the serotypes of FMDV has been identified in samples from one or more animals showing clinical signs consistent with FMD, or epidemiologically linked to a confirmed or suspected *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV, or

3) antibodies to structural or nonstructural proteins of FMDV that are not a consequence of vaccination, have been identified in one or more animals showing clinical signs consistent with FMD, or epidemiologically linked to a confirmed or suspected *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV.

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

Article 2.2.10.2.

FMD free country where vaccination is not practised

To qualify for inclusion in the existing list of FMD free countries where vaccination is not practised, a country should:

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

2) send a declaration to the OIE stating that:

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

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

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

and supply documented evidence that surveillance for both FMD and FMDV infection in accordance with Appendix 3.8.7. is in operation and that regulatory measures for the prevention and control of FMD have been implemented;

3) not have imported since the cessation of vaccination any animals vaccinated against FMD.

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

Article 2.2.10.3.

FMD free country where vaccination is practised

To qualify for inclusion in the list of FMD free countries where vaccination is practised, a country should:

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

2) send a declaration to the OIE that there has been no *outbreak* of FMD for the past 2 years and no evidence of FMDV circulation for the past 12 months, with documented evidence that:

a) surveillance for FMD and FMDV circulation in accordance with Appendix 3.8.7. is in operation, and that regulatory measures for the prevention and control of FMD have been implemented;

b) routine vaccination is carried out for the purpose of the prevention of FMD;

c) the vaccine used complies with the standards described in the *Terrestrial Manual*.

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

If an FMD free country where vaccination is practised wishes to change its status to FMD free country where vaccination is not practised, the country should wait for 12 months after vaccination has ceased and provide evidence showing that FMDV circulation has not occurred during that period.

Article 2.2.10.4.

FMD free zone where vaccination is not practised

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

Community Position.

The Community supports the amended text.

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 Articles 2.2.10.8.;

3) supply documented evidence that surveillance for both FMD and FMDV infection in accordance with Appendix 3.8.7. is in operation in the FMD free zone where vaccination is not practised;

4) describe in detail:

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

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

   c) the system for preventing the entry of the virus (including the movement of susceptible animals) into the FMDV free zone (in particular if the procedure described in Article 2.2.10.8. is implemented),

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

The 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 position:
The Community can support the proposed amendments.

Article 2.2.10.5.

FMD free zone where vaccination is practised

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

Community position:

The last part of the above sentence reading "and animal health measures that effectively prevent the entry of the virus ~~must~~ should be implemented" should be deleted to be in line with previous Article and to avoid duplication with point 4 (c).

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

Community position:

The concept of compartmentalisation is not established for FMD, therefore a zoo should be a zone, as it has a fence, but not a compartment, because it depends on visitors and is therefore limited in applying biosecurity measures. .

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

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

2) send a declaration to the OIE that it wishes to establish an FMD free zone where vaccination is practised, where there has been no *outbreak* of FMD for the past 2 years and no evidence of FMDV circulation for the past 12 months, with documented evidence that surveillance for FMD and FMDV circulation in accordance with Appendix 3.8.7. is in operation;

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

4) describe in detail:

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

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

   c) the system for preventing the entry of the virus into the FMD free zone (in particular if the procedure described in Article 2.2.10.8. is implemented),

   and supply evidence that these are properly implemented and supervised;

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

Community position:
The above text would be clearer if it would read as follows:

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

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

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

Community position:

The Community supports the proposed amendment, as the interval to the last outbreak is already defined.

Article 2.2.10.6.

FMD infected country or zone

An FMD infected country is a country that does not fulfil the requirements to qualify as either an FMD free country where vaccination is not practised or an FMD free country where vaccination is practised.

An FMD infected zone is a zone that does not fulfil the requirements to qualify as either an FMD free zone where vaccination is not practised or an FMD free zone where vaccination is practised.

Article 2.2.10.7.

Recovery of free status

1) When an FMD *outbreak* or FMDV infection occurs in an FMD free country or zone where vaccination is not practised, one of the following waiting periods is required to regain the status of FMD free country or zone where vaccination is not practised:

   a) 3 months after the last *case* where a *stamping out policy* and serological surveillance are applied in accordance with Appendix 3.8.7., or

   b) 3 months after the slaughter of all vaccinated animals where a *stamping out policy*, emergency vaccination and serological surveillance are applied in accordance with Appendix 3.8.7., or

   c) 6 months after the last *case* or the last vaccination (according to the event that occurs the latest), where a *stamping out policy*, emergency vaccination not followed by the slaughtering of all vaccinated animals, and serological surveillance are applied in accordance with Appendix 3.8.7., provided that a serological survey based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of infection in the remaining vaccinated population.

   Where a *stamping out policy* is not applied, Article 2.2.10.4. applies.

Community position:

In principle the Community supports the inclusion of a recovery procedure whereby a country, following an outbreak, continues vaccination for a certain period of time. , However, a simple reference to Article 2.2.10.4 is misleading, as this Article refers to a zone, rather than a country, and the inserted paragraph should therefore read as follows:

d) Where a *stamping out policy* is not applied, the provisions of paragraphs 1 to 4 of Article 2.2.10.4 apply.

2) When an FMD *outbreak* or FMDV infection occurs in an FMD free country or zone where vaccination is practised, one of the following waiting periods is required to regain the status of FMD free country or zone where vaccination is practised:

   a) 6 months after the last *case* where a *stamping-out policy*, emergency vaccination and serological surveillance in accordance with Appendix 3.8.7. are applied, provided that the serological surveillance based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of virus circulation, or

   b) 18 months after the last *case* where a *stamping-out policy* is not applied, but emergency vaccination and serological surveillance in accordance with Appendix 3.8.7. are applied, provided that the serological surveillance based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of virus circulation.

Article 2.2.10.8.

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

~~Live animals from FMD susceptible species can~~ FMD susceptible animals should only leave the infected zone if moved by mechanised transport to the nearest designated abattoir located in the *buffer zone* ~~or the *surveillance zone* for immediate~~ directly to 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 directly to ~~for immediate~~ slaughter only under the following conditions:

Community position:

The Community supports the proposed amendments.

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

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

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

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

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

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

6~~7~~) *vehicles* and the abattoir must be subjected to thorough cleansing and *disinfection* immediately after use.

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

Community position:

The Community supports the changes.

Animals moved into a free zone for other purposes must be moved under the supervision of the *Veterinary Authority* and comply with the conditions in Article 2.2.10.11.

Article 2.2.10.9.

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

for FMD susceptible animals

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

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

2) were kept in an FMD free country or zone where vaccination is not practised since birth or for at least the past 3 months.

Community position:
In order to be consistent with the provisions in Article 2.2.10.10, the vaccination status of the animal in question should be clarified by inserting:
"3) have not been vaccinated."
As it would be possible for vaccinated animals to be present which were vaccinated before the free country or zone was established.

Article 2.2.10.10.

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

for domestic ruminants and pigs

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

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

2) were kept in an FMD free country since birth or for at least the past 3 months; and

3) have not been vaccinated and were subjected, with negative results, to tests for antibodies against FMD virus, when destined to an FMD free country or zone where vaccination is not practised.

Article 2.2.10.11.

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

for domestic ruminants and pigs

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

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

2) were kept in the *establishment* of origin since birth or

   a) for the past 30 days, if a *stamping out policy* is in force in the *exporting country*, or

   b) for the past 3 months, if a *stamping out policy* is not in force in the *exporting country*,

   and that FMD has not occurred within a 10-kilometre radius of the *establishment* of origin for the relevant period as defined in points a) and b) above; and

3) were isolated in an *establishment* for the 30 days prior to shipment, and all animals in isolation were subjected to diagnostic tests (probang and serology) for evidence of FMDV infection with negative results at the end of that period, and that FMD did not occur within a 10-kilometre radius of the *establishment* during that period; or

4) were kept in a *quarantine station* for the 30 days prior to shipment, all animals in quarantine were subjected to diagnostic tests (probang and serology) for evidence of FMDV infection with negative results at the end of that period, and that FMD did not occur within a 10-kilometre radius of the *quarantine station* during that period;

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

Article 2.2.10.12.

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

for fresh semen of domestic ruminants and pigs

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

1) the donor animals:

   a) showed no clinical sign of FMD on the day of collection of the semen;

   b) were kept in an FMD free country or zone where vaccination is not practised for at least 3 months prior to collection;

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

Article 2.2.10.13.

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

for frozen semen of domestic ruminants and pigs

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

1) the donor animals:

   a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;

   b) were kept in an FMD free country or zone where vaccination is not practised for at least 3 months prior to collection;

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

Article 2.2.10.14.

When importing from FMD free countries or zones where vaccination is practised, *Veterinary*

Administrations should require:

for semen of domestic ruminants and pigs

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

1) the donor animals:

   a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;

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

   c) if destined to an FMD free country or zone where vaccination is not practised:

      i) have not been vaccinated and were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMD virus, with negative results; or

      ii) had been vaccinated at least twice, with the last vaccination not more than 12 and not less than one month prior to collection;

2) no other animal present in the *artificial insemination centre* has been vaccinated within the month prior to collection;

3) the semen:

   a) was collected, processed and stored in conformity with the provisions of Appendix 3.2.1., Appendix 3.2.2. or Appendix 3.2.3., as relevant;

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

Article 2.2.10.15.

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

for semen of domestic ruminants and pigs

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

1) the donor animals:

   a) showed no clinical sign of FMD on the day of collection of the semen;

   b) were kept in an *establishment* where no animal had been added in the 30 days before collection, and that FMD has not occurred within 10 kilometres for the 30 days before and after collection;

   c) have not been vaccinated and were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMD virus, with negative results; or

   d) had been vaccinated at least twice, with the last vaccination not more than 12 and not less than one month prior to collection;

2) no other animal present in the *artificial insemination centre* has been vaccinated within the month prior to collection;

3) the semen:

   a) was collected, processed and stored in conformity with the provisions of Appendix 3.2.1., Appendix 3.2.2. or Appendix 3.2.3., as relevant;

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

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

Article 2.2.10.16.

Irrespective of the FMD status of the *exporting country* or zone, *Veterinary Administrations* should authorise without restriction on account of FMD the import or transit through their territory of *in vivo* derived embryos of cattle subject to the presentation of an *international veterinary certificate* attesting that the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.1. or Appendix 3.3.3., as relevant.

Community position:

The Community believes that this does not offer sufficient health guarantees in all situations. The Community wishes to caution about non-peer reviewed findings and emphasises the risks of manipulating FMD infected animals, irrespective of the status of the embryo. It is furthermore important to differentiate between in-vivo derived and in-vitro produced embryos.

Article 2.2.10.17.

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

for *in vitro* produced embryos of cattle

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

1) the donor females:

   a) showed no clinical sign of FMD at the time of collection of the oocytes;

   b) were kept in a country or zone free from FMD at the time of collection;

2) fertilisation was achieved with semen meeting the conditions referred to in Articles 2.2.10.12., 2.2.10.13., 2.2.10.14. or 2.2.10.15., as relevant;

3) the oocytes were collected, and the embryos were processed and stored in conformity with the provisions of Appendix 3.3.2. or Appendix 3.3.3., as relevant.

Article 2.2.10.18.

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

for *in vitro* produced embryos of cattle

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

1) the donor females:

   a) showed no clinical sign of FMD at the time of collection of the oocytes;

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

c) if destined for an FMD free country or zone where vaccination is not practised:

i) have not been vaccinated and were subjected, with negative results, to tests for antibodies against FMD virus, or

ii) had been vaccinated at least twice, with the last vaccination not less than one month and not more than 12 months prior to collection;

2) no other animal present in the *establishment* has been vaccinated within the month prior to collection;

3) fertilization was achieved with semen meeting the conditions referred to in Articles 2.2.10.12., 2.2.10.13., 2.2.10.14. or 2.2.10.15., as relevant;

4) the oocytes were collected, and the embryos were processed and stored in conformity with the provisions of Appendix 3.3.2. or Appendix 3.3.3., as relevant.

Article 2.2.10.19.

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

for *fresh meat* of FMD susceptible animals

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

1) have been kept in the FMD free country or zone where vaccination is not practised since birth, or which have been imported in accordance with Article 2.2.10.9., Article 2.2.10.10. or Article 2.2.10.11.;

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

Article 2.2.10.20.

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

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

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

1) have been kept in the FMD free country or zone where vaccination is practised since birth, or which have been imported in accordance with Article 2.2.10.9., Article 2.2.10.10. or Article 2.2.10.11.;

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

Article 2.2.10.21.

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

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

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

1) have been kept in the FMD free country or zone where vaccination is practiced since birth, or which have been imported in accordance with Article 2.2.10.9., Article 2.2.10.10. or Article 2.2.10.11.;

2) ~~have not been vaccinated~~;

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

Community position
The Community supports the amendments.

Article 2.2.10.22.

When importing from FMD infected countries or zones, where an official control programme exists, involving compulsory systematic vaccination of cattle, *Veterinary Administrations* should require:

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

Community position

The heading should be in line with other Articles and the content of this Article, it is proposed to replace the heading by:

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

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

1) comes from animals which:

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

   b) have remained, during this period, in a part of the country where cattle are regularly vaccinated against FMD and where official controls are in operation;

   c) have been vaccinated at least twice with the last vaccination not more than 12 months and not less than one month prior to slaughter;

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

   e) have been transported, in a *vehicle* which was cleansed and disinfected before the cattle were loaded, directly from the *establishment* of origin to the *approved abattoir* without coming into contact with other animals which do not fulfil the required conditions for export;

   f) have been slaughtered in an *approved abattoir*:

      i) which is officially designated for export;

      ii) in which no FMD has been detected during the period between the last *disinfection* carried out before slaughter and the shipment for export has been dispatched;

g) have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results within 24 hours before and after slaughter;

2) comes from deboned carcasses:

a) from which the major lymph nodes have been removed;

b) which, prior to deboning, have been submitted to maturation at a temperature above + 2°C for a minimum period of 24 hours following slaughter and in which the pH value was below 6.0 when tested in the middle of both the longissimus dorsi.

Article 2.2.10.23.

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

for *meat products* of domestic ruminants and pigs

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

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

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

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

Article 2.2.10.24.

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

for *milk* and *milk products* intended for human consumption and for products of animal origin (from FMD susceptible animals) intended for use in animal feeding or for agricultural or industrial use

the presentation of an *international veterinary certificate* attesting that these products come from animals which have been kept in the country or zone since birth, or which have been imported in accordance with Article 2.2.10.9., Article 2.2.10.10. or Article 2.2.10.11.

Community position:

The Community cannot agree to imports for use in animal feeding of milk or milk products not treated in accordance with 3.6.2.6 , in particular where milk is produced in a country with vaccination.

Article 2.2.10.25.

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

for *milk*, cream, milk powder and *milk products*

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

1) these products:

   a) originate from herds or flocks which were not infected or suspected of being infected with FMD at the time of *milk* collection;

   b) have been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Article 3.6.2.5. and in Article 3.6.2.6.;

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

Article 2.2.10.26.

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

for blood and meat-meals (from domestic or wild ruminants and pigs)

the presentation of an *international veterinary certificate* attesting that the manufacturing method for these products included heating to a minimum internal temperature of 70°C for at least 30 minutes.

Article 2.2.10.27.

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

for wool, hair, bristles, raw hides and skins (from domestic or wild ruminants and pigs)

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

1) these products have been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Articles 3.6.2.2., 3.6.2.3. and 3.6.2.4.;

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

Veterinary Administrations can authorise, without restriction, the import or transit through their territory of semi-processed hides and skins (limed hides, pickled pelts, and semi-processed leather - e.g. wet blue and crust leather), provided that these products have been submitted to the usual chemical and mechanical processes in use in the tanning industry.

Article 2.2.10.28.

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

for straw and forage

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

1) are free of grossly identifiable contamination with material of animal origin;

2) have been subjected to one of the following treatments, which, in the case of material sent in bales, has been shown to penetrate to the centre of the bale:

a) either to the action of steam in a closed chamber such that the centre of the bales has reached a minimum temperature of 80°C for at least 10 minutes,

b) or to the action of formalin fumes (formaldehyde gas) produced by its commercial solution at 35-40% in a chamber kept closed for at least 8 hours and at a minimum temperature of 19°C;

OR

3) have been kept in bond for at least 3 months (under study) before being released for export.

Article 2.2.10.29.

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

for skins and trophies derived from 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).

Community position:

Skins and trophies from wild susceptible animals from countries practicing vaccination should only be allowed untreated if the wildlife was part of the surveillance with satisfactory results and if it is ensured that the population is confined to that country, otherwise such skins and trophies should be subject to a treatment in accordance with Article 3.6.2.7.

Article 2.2.10.30.

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

for skins and trophies derived from wild animals susceptible to FMD

the presentation of an *international veterinary certificate* attesting that these products have been processed to ensure the destruction of the FMD virus in conformity with the procedures referred to in Article 3.6.2.7.

[Note: International veterinary certificates *for animal products coming from infected countries or zones may not be required if the products are transported in an approved manner to premises controlled and approved by the* Veterinary Administration *of the* importing country *for processing to ensure the destruction of the FMD virus in conformity with the procedures referred to in Articles 3.6.2.2., 3.6.2.3. and 3.6.2.4.]*

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

— text deleted

Appendix VIII

APPENDIX 3.8.~~6~~7

~~GUIDELINES FOR THE SURVEILLANCE REQUIRED TO SUPPORT THE ESTABLISHMENT OR REGAINING OF RECOGNITION FOR A FOOT AND MOUTH DISEASE FREE COUNTRY OR ZONE~~

GUIDELINES FOR THE SURVEILLANCE OF FOOT AND MOUTH DISEASE

Community position:
The Community can support this proposal but would like the points given in the text below taken on board.

Article 3.8.~~6~~7.1.

Introduction

This document defines the principles and provides a guide for the surveillance of foot and mouth disease (FMD) in accordance with Appendix 3.8.1. applicable to countries seeking recognition from the OIE for freedom from FMD, either with or without the use of vaccination. This may be for the entire country or a *zone* or *compartment* within the country. Guidance for countries seeking reestablishment of freedom from FMD for the whole country or a *zone* or a *compartment*, either with or without vaccination, following an *outbreak*, as well as guidelines for the maintenance of FMD status are ~~is~~ provided. These guidelines are intended to expand on and explain the requirements of Chapter 2.2.10. Applications to the OIE for ~~such~~ recognition of freedom should follow the format and answer all the questions posed by the "Questionnaire on FMD" available from the OIE Central Bureau.

~~Reference to vaccination in this guide implies vaccination as part of an official disease control programme under the supervision of the *Veterinary Administration* aimed at interrupting the transmission of FMD virus (FMDV) in the zone or country concerned. The level of herd immunity required to achieve interruption of transmission will depend on the size, composition (e.g. species) and density of the susceptible population. It is therefore impossible to be prescriptive in this matter but, in general, unless there are good reasons to employ a different target, the aim should be to vaccinate at least 80% of the susceptible population in the manner and at the frequency prescribed by the manufacturer of the vaccine concerned. The vaccine must also comply with the provisions stipulated for FMD vaccines in the *Terrestrial Manual*. It may be that a decision is reached to vaccinate only certain species or other subset of the total susceptible population. In that case the rationale should be contained within the dossier accompanying the application to the OIE for recognition of a free country or zone or recovery of such status.~~

The impact and epidemiology of FMD differ widely in different regions of the world and therefore it is impossible to provide specific guidelines for all situations. It is axiomatic that the surveillance strategies employed for demonstrating freedom from FMD at an acceptable level of confidence will need to be adapted to the local situation. For example, the approach to proving freedom from FMD following an outbreak caused by a pig-adapted strain of FMD virus (FMDV) should differ significantly from an application designed to prove freedom from FMD for a country or zone where African buffaloes (*Syncerus caffer*) provide a potential reservoir of infection. It is incumbent upon the applicant country to submit a dossier to the OIE in support of its application that not only explains the epidemiology of FMD in the region concerned but also demonstrates how all the risk factors are managed. This should include

provision of–scientifically based supporting data. There is therefore considerable latitude available to Member Countries to provide a well-reasoned argument to prove that the absence of FMDV infection (in non-vaccinated populations) or circulation (in vaccinated populations) is assured at an acceptable level of confidence.

Surveillance for FMD ~~may~~ should be in the form of a continuing ~~disease surveillance~~ programme ~~or it may be a specific programme~~ designed to establish that the whole territory or part of it is free from FMDV infection/circulation.

For the purpose of this Appendix, virus circulation means transmission of FMDV as demonstrated by clinical signs, serological evidence or virus isolation.

Article 3.8.~~6~~7.2.

General conditions and methods

1) A surveillance system in accordance with Appendix 3.8.1 should be under the responsibility of the *Veterinary Administration*. A procedure should be in place for the rapid collection and transport of samples from suspect cases of FMD to a laboratory for FMD diagnoses as described in the *Terrestrial Manual.*

2) The FMD surveillance programme should:

   a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers who have day-to-day contact with livestock, as well as diagnosticians, should ~~be encouraged to~~ report promptly any suspicion of FMD ~~clinical disease resembling FMD~~. They should be supported directly or indirectly (e.g. through private veterinarians or veterinary para-professionals) by government information programmes and the *Veterinary Administration*. All suspect cases of FMD should be investigated immediately. Where suspicion cannot be resolved by epidemiological and clinical investigation, samples should be taken and submitted to an approved laboratory ~~and, if still considered suspect, samples should be taken and submitted to an approved laboratory~~. This requires that sampling kits and other equipment are available for those responsible for surveillance. Personnel responsible for surveillance should be able to call for assistance from a team with expertise in FMD diagnosis and control;

   b) implement, when relevant, regular and frequent clinical inspection and serological testing of high-risk groups of animals, such as those adjacent to an FMD infected country or zone (for example, bordering a game park in which infected wildlife are present).

   An effective surveillance system will periodically identify suspicious cases that require follow up and investigation to confirm or exclude that the cause of the condition is FMDV. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from FMDV infection/circulation should, in consequence, provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of laboratory testing and the control measures to which the animals concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

   ~~During investigation into suspected *outbreaks* of FMD, it is necessary to apply measures that will contain the infection to its original locality until such time as the diagnosis is confirmed or refuted, e.g. through application of quarantine measures. The details of actions that need to be applied in such situations are not covered by this guide.~~

~~3) These general requirements apply in all Member Countries submitting their annual request for re-confirmation of FMD free status although active surveillance for FMD is not a requirement for countries that are recognised by the OIE as being free from FMD without vaccination. An active surveillance programme is required from Member Countries applying for the first time for recognition of freedom from FMD for the whole country or zone either with or without vaccination.~~

~~It is also a requirement for countries seeking recognition for the recovery of their former status following an *outbreak*.~~

Article 3.8.~~6~~7.2.bis

Surveillance strategies

The target population for surveillance aimed at identification of *disease* and *infection* should cover all the susceptible species within the country or zone to be recognised as free from FMDV infection/circulation.

The strategy employed may be based on randomised sampling requiring surveillance consistent with demonstrating the absence of FMDV *infection*/circulation at an acceptable level of statistical confidence. The frequency of sampling should be dependent on the epidemiological situation. Targeted surveillance (e.g. based on the increased likelihood of *infection* in particular localities or species) may be an appropriate strategy. The applicant country should justify the surveillance strategy chosen as adequate to detect the presence of FMDV infection/circulation in accordance with Appendix 3.8.1. and the epidemiological situation. It may, for example, be appropriate to target clinical surveillance at particular species likely to exhibit clear clinical signs (e.g. cattle and pigs). If a Member Country wishes to apply for recognition of a specific *zone* or *compartment* within the country as being free from FMDV infection/circulation, the design of the survey and the basis for the sampling process would need to be aimed at the population within the *zone* or *compartment*.

For random surveys, the design of the sampling strategy will need to incorporate an epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect infection/circulation if it were to occur at a predetermined minimum rate. The sample size and expected disease prevalence determine the level of confidence in the results of the survey. The applicant country must justify the choice of design prevalence and confidence level based on the objectives of surveillance and the epidemiological situation, in accordance with Appendix 3.8.1. Selection of the design prevalence in particular clearly needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the survey design selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the vaccination/infection history and production class of animals in the target population.

Irrespective of the testing system employed, surveillance design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether they are indicative of infection/circulation or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as herds which may be epidemiologically linked to it.

The principles involved in surveillance for *disease/infection* are technically well defined. The design of surveillance programmes to prove the absence of FMDV infection/circulation needs to be carefully followed to avoid producing results that are either insufficiently reliable to be accepted by the OIE or international trading partners, or excessively costly and logistically complicated. The design of any surveillance programme, therefore, requires inputs from professionals competent and experienced in this field.

1) Clinical surveillance

Clinical surveillance aims at the detection of clinical signs of FMD by close physical examination of susceptible animals. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, surveillance based on clinical inspection should not be underrated. It may be able to provide a high level of confidence of detection of disease if a sufficiently large number of clinically susceptible animals is examined.

Clinical surveillance and laboratory testing should always be applied in series to clarify the status of FMD suspects detected by either of these complementary diagnostic approaches. Laboratory testing may confirm clinical suspicion, while clinical surveillance may contribute to confirmation of positive serology. Any sampling unit within which suspicious animals are detected should be classified as infected until contrary evidence is produced.

A number of issues must be considered in clinical surveillance for FMD. The often underestimated labour intensity and the logistical difficulties involved in conducting clinical examinations should not be underestimated and should be taken into account.

Identification of clinical cases is fundamental to FMD surveillance. Establishment of the molecular, antigenic and other biological characteristics of the causative virus, as well as its source, is dependent upon disclosure of such animals. It is essential that FMDV isolates are sent regularly to the regional reference laboratory for genetic and antigenic characterization.

2) Virological surveillance

Virological surveillance using tests described in the *Terrestrial Manual* should be conducted:

a) to monitor at risk populations;

b) to confirm clinically suspect cases;

c) to follow up positive serological results;

d) to test "normal" daily mortality, to ensure early detection of infection in the face of vaccination or in establishments epidemiologically linked to an outbreak.

3) Serological surveillance

Serological surveillance aims at the detection of antibodies against FMDV. Positive FMDV antibody test results can have four possible causes:

a) natural infection with FMDV;

b) vaccination against FMD;

c) maternal antibodies derived from an immune dam (maternal antibodies in cattle are usually found only up to 6 months of age but in some individuals and in some species, maternal antibodies can be detected for considerably longer periods);

d) heterophile (cross) reactions.

It is important that serological tests, where applicable, contain antigens appropriate for detecting antibodies against viral variants (types, subtypes, lineages, topotypes, etc.) that have recently occurred in the region concerned. Where the probable identity of FMDVs is unknown or where exotic viruses are suspected to be present, tests able to detect representatives of all serotypes should be employed (e.g. tests based on nonstructural viral proteins – see below).

It may be possible to use serum collected for other survey purposes for FMD surveillance. However, the principles of survey design described in this Appendix and the requirement for a statistically valid survey for the presence of FMDV should not be compromised.

The discovery of clustering of seropositive reactions should be foreseen. It may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or the presence of field strain infection. As clustering may signal field strain infection, the investigation of all instances must be incorporated in the survey design. If vaccination cannot be

excluded as the cause of positive serological reactions, diagnostic methods should be employed that detect the presence of antibodies to nonstructural proteins (NSPs) of FMDVs as described in the *Terrestrial Manual.*

The results of random or targeted serological surveys are important in providing reliable evidence that FMDV infection is not present in a country or zone. It is therefore essential that the survey be thoroughly documented.

Article 3.8.~~6~~7.3.

Documentation of FMD free status

Countries applying for freedom from FMD for the whole country or a zone/compartment where vaccination is not practised

Community position:

The code has NO PROVISIONS for FMD-free compartments. The Guidelines must be in line with the Code.

~~1) Introduction~~

~~A Member Country applying for recognition of freedom for the country or a zone from FMD where vaccination is not practised should provide evidence for the existence of an effective surveillance programme. The strategy and design of the surveillance programme will depend on the prevailing epidemiological circumstances. Conventionally, a statistically significant proportion of the whole population should be subjected to clinical and serological surveillance to demonstrate absence of FMDV, i.e. circulation of virus, during the preceding 12 months. This requires the support of a national or other laboratory able to undertake identification of FMDV infection through virus/antigen/genome detection and antibody tests described in the *Terrestrial Manual*.~~

~~2) Survey design~~

~~The target population for surveillance aimed at identification of *disease* and *infection* should cover all the susceptible species within the country or zone to be recognised as free from infection. This would usually require stratification of different species.~~

~~Countries wishing to show freedom from FMDV infection in which a pig-adapted strain of virus had been prevalent should concentrate on sampling the national pig population. However, it would also be necessary to show that no spill-over into other susceptible species has occurred. In countries or zones in which an African buffalo population is present, the buffaloes should also be sampled if included in the proposed FMDV infection-free zone.~~

~~The strategy employed may be based either on randomised sampling requiring surveillance consistent with demonstrating the absence of *infection* at an acceptable level of statistical confidence. The frequency of sampling would be dependent on the epidemiological situation, but should occur at least once during the year preceding the application. Alternatively, targeted surveillance (e.g. based on the likelihood of infection in particular localities or species) may provide a more appropriate and cost-effective strategy. If the latter approach is used, it would be incumbent upon the applicant country to show that the surveillance conducted was at least as effective as randomised surveillance with stratification of different susceptible species. It may, for example, be appropriate to target clinical surveillance at particular species likely to exhibit clear clinical signs (e.g. cattle and pigs) while directing serological surveillance at species that tend to develop less obvious signs of infection such as sheep and, in some locations, goats and wildlife species.~~

If a Member Country wishes to apply for recognition of a specific zone/region within the country as being free from FMDV infection, the design of the survey and the basis for the sampling process would need to be aimed at the population within the zone/region.

For randomised surveillance, the design of the sampling strategy will need to incorporate an epidemiologically appropriate design prevalence because, obviously, the sample selected for testing will need to be large enough to detect infection if it were to occur at a predetermined minimum rate. The sample size and expected disease prevalence determine the level of confidence in the result of the survey. A typical random sampling strategy would be one that provides 95% probability of detecting evidence of FMD or FMDV infection if it were present in 1% of the primary sampling units. A minimum expected level of infection within sampling units also has to be set to ensure that a sufficient number of animals within each sampling unit is tested to detect the infection if it were present in the sampling unit. Typically this value is set somewhere between 5-20% with a confidence level of 95%. In many instances it could be safely assumed that within-sampling unit prevalence would be greater than 5% bearing in mind the contagiousness of FMDV. Selection of the prevalence estimate clearly needs to be based on the prevailing or historical epidemiological situation. The reasoning used in the selection of prevalence parameters needs to be clearly spelt out in the dossier supplied to the OIE when applications are made for recognition of freedom from FMD.

The sensitivities and specificities of the testing methods employed also affect the design of sampling strategies. Clinical inspection, for example, typically has low sensitivity, especially in species that tend to suffer mild or indistinct signs of FMD (e.g. sheep). In other words, the probability of detecting FMD infection through identification of clinical cases is not particularly dependable and this therefore needs to be allowed for in the sampling design. For proving absence of infection through serology, it is usually desirable to have either a test with both high sensitivity (likely to detect a high proportion of seropositive individuals) and specificity (few false positive animals likely to be identified) or to use a combination of tests that together provide high net sensitivity and specificity. However, even if the net specificity is high, in cases where the design prevalence is low (e.g. in situations where proving absence of FMD is the objective), the positive predictive value (PV) of a test or testing system may be considerably lower than 100% (because PV is mainly a function of specificity and prevalence). This means that in such circumstances it needs to be anticipated that false positive results will occur. If the characteristics of the testing system are known, the rate at which these false positive are likely to occur can be calculated. In such circumstances detected prevalence rates significantly greater than the calculated rate would be suspicious of infection. More typically, the parameters of the testing system are imprecisely known and therefore an element of judgement in the interpretation of serological results will be necessary. Whatever the case, there needs to be an effective procedure for following up serological positives to determine ultimately, to a high level of probability, whether they are indicative of infection or not. This should involve both supplementary laboratory tests (see below) and further field follow up to collect diagnostic material from the original sampling unit if possible as well as animals in the vicinity which may be epidemiologically linked to the suspect focus.

It is evident from the above that although the principles involved in surveillance for disease/infection are reasonably straight forward, design of large surveillance programmes to prove absence of FMD needs to be carefully done to avoid producing results that are either insufficiently reliable to be accepted by the OIE or international trading partners or excessively costly and logistically complicated. The design of any large surveillance programme therefore requires inputs from competent and experienced professionals in this field.

3) Clinical surveillance

Clinical surveillance aims at the detection of clinical signs of FMD by close inspection of susceptible animals. It is essential that all animals within the selected primary sampling unit are examined for signs of FMD. Any unit where suspicious animals are detected should be classified as infected until contrary evidence is produced.

There are a number of issues that need to be considered in clinical surveillance for FMD. Some of these (e.g. the general insensitivity of clinical surveillance and species differences) have been

~~mentioned above. The practical difficulty, hard work and boredom involved in conducting repetitive clinical examinations are almost invariably underestimated (hence the low sensitivity). This therefore needs to be borne in mind in the surveillance design.~~

~~Furthermore, now that the emphasis of the chapter of this *Terrestrial Code* on FMD is on detection of infection rather than disease, it needs to be remembered that in practice detection of disease is only one of the ways in which infection can be identified. Other techniques, such as serology, may be more sensitive especially in situations where vaccination is not practised but, on the other hand, identification of clinical cases is still fundamental to FMD surveillance. Identification of such cases is also vital in providing sources of the causative virus that enable the molecular, antigenic and other biological characteristics of the virus to be established. It is essential that FMDV isolates are sent regularly to the regional reference laboratory for genetic and antigenic characterization.~~

~~4)~~ ~~Serological surveillance~~

~~Serological surveillance aims at the detection of antibodies against FMDV. Positive tests for FMDV antibody tests can have four possible causes:~~

~~a) natural infection with FMDV;~~

~~b) vaccination against FMD;~~

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

~~d) heterophile (cross) reactions.~~

~~It is important that serological tests, where appropriate, contain antigens appropriate for detecting viral variants (types, subtypes, lineages, topotypes, etc.) that have recently occurred in the region concerned. Where the probable identity of FMDVs is unknown or where exotic viruses are suspected to be present, tests able to detect representatives of all serotypes should be employed (e.g. tests based on nonstructural viral proteins – see below).~~

~~It may be possible to use serum collected for other survey purposes for FMD surveillance but the requirement for a statistically valid survey for the presence of FMDV should not be compromised.~~

~~General considerations in the design and conduct of sero-surveys have been addressed above (see Survey design). An important issue requiring planning is the procedure to be followed in the event that seropositives are detected. As already indicated, it is likely that where the design prevalence is low false positive results should be anticipated. When these occur, both laboratory and field follow-up are necessary to differentiate between true and false positives.~~

~~Infected animals are unlikely to be evenly dispersed within the population and a cross sectional analysis will usually detect clusters of infection. FMD is no exception to this general rule. Therefore, it is important to identify clusters of seropositive animals through simple mapping or more sophisticated cluster analysis.~~

~~If vaccination cannot be excluded as the cause of positive serological reactions, testing for the presence of antibodies to the nonstructural proteins (NSPs) of FMDVs (as described in the *Terrestrial Manual*) should be used.~~

~~The results of random sample or targeted surveys based on serology are important in providing reliable evidence that no FMDV infection is present in a country or zone. It is therefore essential that the survey be thoroughly documented.~~

In addition to the general conditions described in Chapter 2.2.10., a Member Country applying for

recognition of FMD freedom for the country or a *zone/compartment* where vaccination is not practised should provide evidence for the existence of an effective surveillance programme. The strategy and design of the surveillance programme will depend on the prevailing epidemiological circumstances and will be planned and implemented according to general conditions and methods in this Appendix, to demonstrate absence of FMDV infection, during the preceding 12 months in susceptible populations. This requires the support of a national or other laboratory able to undertake identification of FMDV infection through virus/antigen/genome detection and antibody tests described in the *Terrestrial Manual.*

Article 3.8.~~6~~7.4.

Countries, zones or compartments applying for freedom from FMD where vaccination is practised

Community position:

The Code has NO PROVISIONS for freedom from FMD of compartments. The Community therefore strongly opposes such references in the Guidelines until the issue of compartmentalisation in case of FMD is regulated in the Chapter.

~~In addition to the general conditions, a country or zone applying for recognition of freedom from FMD with vaccination should show evidence of an effective surveillance programme for clinical disease and demonstrate that FMD has not occurred in the country or zone for the past 2 years. Furthermore, surveillance for FMDV infection should show that FMDV has not been circulating in the vaccinated population within the past 12 months. This will require serological surveillance incorporating tests able to detect antibodies to NSPs as described in Article 3.8.6.6.~~

In addition to the general conditions described in Chapter 2.2.10., a Member Country applying for recognition of country or *zone/compartment* freedom from FMD with vaccination should show evidence of an effective surveillance programme planned and implemented according to general conditions and methods in this Appendix. Absence of clinical disease in the country, *zone* or *compartment* for the past 2 years should be demonstrated. Furthermore, surveillance should demonstrate that FMDV has not been circulating in any susceptible population during the past 12 months. This will require serological surveillance incorporating tests able to detect antibodies to NSPs as described in the *Terrestrial Manual.* Vaccination to prevent the transmission of FMDV may be part of a disease control programme. The level of herd immunity required to prevent transmission will depend on the size, composition (e.g. species) and density of the susceptible population. It is therefore impossible to be prescriptive. However, in general the aim should be to vaccinate at least 80% of the susceptible population. The vaccine must comply with the *Terrestrial Manual*. Based on the epidemiology of FMD in the country, *zone* or *compartment*, it may be that a decision is reached to vaccinate only certain species or other subsets of the total susceptible population. In that case, the rationale should be contained within the dossier accompanying the application to the OIE for recognition of status.

Evidence to show the effectiveness of the vaccination programme ~~is recommended~~ should be provided.

Article 3.8.~~6~~7.5.

Countries, *zones* or *compartments* re-applying for freedom from FMD where vaccination is either practised or not practised, following an outbreak

In addition to the general conditions described in Chapter 2.2.10., a country re-applying for country, *zone* or *compartment* freedom from FMD where vaccination is practised or not practised should show evidence of an active surveillance programme for FMD as well as absence of FMDV infection/circulation.

Community position:

For the sake of clarity the sentence should read:

In addition to the general conditions described in Chapter 2.2.10., a country re-applying for country, or *zone* [or *compartment*] freedom from FMD where vaccination is not practised or is practised should show evidence of an active surveillance programme for FMD as well as absence of FMDV infection / circulation.

This will require serological surveillance incorporating, in the case of a country, *zone* or *compartment* practising vaccination, tests able to detect antibodies to NSPs as described in the *Terrestrial Manual*. ~~This is particularly important if a country intends for the whole of its territory or a zone to avail itself of the possibility of a reduced waiting period, i.e. less than 2 years after the last *outbreak*.~~

Four strategies are recognised by the OIE in a programme to eradicate FMDV infection following an *outbreak*:

1) slaughter of all clinically affected and in-contact susceptible animals;

2) slaughter of all clinically affected and in-contact susceptible animals and vaccination of at-risk animals, with subsequent slaughter of vaccinated animals;

3) slaughter of all clinically affected and in-contact susceptible animals and vaccination of at-risk animals, without subsequent slaughter of vaccinated animals;

4) vaccination used without slaughter of affected animals or subsequent slaughter of vaccinated animals.

Community position
The Community regrets that the imprecise phrasing of the above paragraphs is maintained.
It is suggested to use the wording agreed in the Code, where a distinction is made between a stamping out policy and slaughter of vaccinated animals.

The time periods before which an application can be made for re-instatement of freedom from FMD depends on which of these alternatives is followed. The time periods are prescribed in Article 2.~~1~~2.1~~0~~.7.

In all circumstances, a Member Country re-applying for country, *zone* or *compartment* freedom from FMD with vaccination or without vaccination ~~in a country or zone~~ should report the results of an active surveillance programme implemented according to general conditions and methods in this Appendix ~~in which the FMD susceptible population undergoes regular clinical examination or where active surveillance has targeted a statistically significant sample of the susceptible population. In addition, a statistically significant sample, based on the susceptible population at risk during the *outbreak*, would need to be tested for absence of FMDV infection. In particular circumstances, targeted surveillance could be used to accomplish the task. The procedures are outlined above.~~

Article 3.8.~~6~~7.6.

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

The recommended serological tests for FMD surveillance are described in the *Terrestrial Manual*.

~~ELISAs based on structural proteins are useful for screening sera for evidence of infection in animals that have not been vaccinated. However, although their sensitivity is generally high, their specificity, particularly in the case of the liquid-phase blocking ELISA (LPBE), is relatively low. This presents difficulties when it comes to proving freedom from infection. These tests are also effective for monitoring serological responses to vaccination where it is certain that the animals concerned have not been infected. The net specificity of serological screening with ELISAs can be improved by retesting positive sera using the virus neutralisation test (VNT). Precise values for sensitivity and specificity of these tests are not~~

~~available and, in any case, are likely to vary slightly between laboratories.~~

~~Any animal whose serum is positive by the VNT should be tested additionally for evidence of infection using either serological tests for antibodies to NSPs and/or by collection of oesophageal-pharyngeal material (probang testing) for virus detection on cell cultures or by PCR. Ideally, fresh serum should be collected from the animal(s) concerned because repeated freezing and thawing of stored sera tends to damage immunoglobulins.~~

~~Animals that have been vaccinated will have antibodies to the structural proteins of FMD virus, and some may have antibodies to the NSPs, depending on the number of times they have been vaccinated, and the amount of the NSPs present in the vaccine used. However, animals that have recovered from infection with FMD virus will have high levels of antibody to the NSPs. There are eight NSPs associated with the replication of FMD virus, namely L, 2A, 2B, 2C, 3A, 3B, 3C and 3D, and antibodies can be found to all of these in most recovered animals. Some do not persist for more than a few months, and some animals may fail to produce detectable levels to all NSPs. ELISAs have been developed to detect 2C, 3B or 3ABC antibodies, the former being detectable for up to one year after infection, and the latter for up to 2 years. A western blot technique (EITB) may also be used to detect the NSP antibodies to 2C, 3ABC, 3A, 3B and 3D; it is particularly specific and sensitive in identifying previously infected animals. All these tests have been extensively used in cattle. Similar testing in other species is on-going.~~

~~There is the option to use the NSP antibody test together with tests for detection of antibody to structural viral proteins, particularly in areas where vaccination has been used and virus activity is suspected. Titres higher than would be expected from vaccination alone may suggest FMDV infection and this can be confirmed by testing for the presence of antibodies to the NSPs.~~

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

~~Figure 1 provides a flowchart of the test protocol that could be used to test the samples collected in a serological survey. If the population being tested has not been previously vaccinated against FMD, the serum samples can be tested using ELISAs based on structural proteins. Sera positive on the test used should be retested using the VNT, which increases the net specificity. In addition, or in place of the VNT if the laboratory is not able to manipulate live FMDV, the positive sera may be retested using an NSP antibody test, such as the 3B, 3ABC or EITB. A positive VNT or NSP test would suggest that live virus had been circulating, and would require further investigation of the herd or flock to confirm or refute the possibility. Further investigation should include serum testing of the whole herd or flock from which the positive samples were obtained. NSP tests should be used for testing sera from vaccinated herds or flocks, as such sera will be positive by VNT. 3ABC or 3B positive samples may be repeat tested using the EITB for confirmation. All animals from the unit from which positive samples are obtained should be re tested for antibodies to NSPs.~~

~~The sensitivity and specificity of the NSP tests currently available are not fully documented, in particular for species other than cattle. Member Countries submitting to the OIE data derived from commercial or other NSP tests should provide information on the characteristics of the test being used.~~

Animals infected with FMDV produce antibodies to both the structural proteins (SP) and the nonstructural proteins (NSP) of the virus.

Community position:

It is recommended to include the following:

Animals infected with FMDV produce antibodies to both the structural proteins (SP) and, usually with a certain additional delay , to the non-structural proteins (NSP) of the virus.

Tests for SP antibodies to include SP-ELISAs and the virus neutralisation test (VNT). The SP tests are serotype specific and for optimal sensitivity should utilise an antigen or virus closely related to the field strain against which antibodies are being sought. Tests for NSP antibodies include NSP I-ELISA 3ABC and the electro-immunotransfer blotting technique (EITB) as recommended in the *Terrestrial Manual* or equivalent validated tests. In contrast to SP tests, NSP tests can detect antibodies to all serotypes of FMD virus. Animals vaccinated and subsequently infected with FMD virus develop antibodies to NSPs, but in some, the titre may be lower than that found in infected animals that have not been vaccinated. Both the NSP I-ELISA 3ABC and EITB tests have been extensively used in cattle. Validation in other species is ongoing. Vaccines used should comply with the standards of the *Terrestrial Manual* insofar as purity is concerned to avoid interference with NSP antibody testing.

Serological testing is a suitable tool for FMD surveillance. The choice of a serosurveillance system will depend on, amongst other things, the vaccination status of the country. A country, which is free from FMD without vaccination, may choose serosurveillance of high-risk subpopulations (e.g. based on geographical risk for exposure to FMDV). SP tests may be used in such situations for screening sera for evidence of FMDV infection/circulation if a particular virus of serious threat has been identified and is well characterised. In other cases, NSP testing is recommended in order to cover a broader range of strains and even serotypes. In both cases, serological testing can provide additional support to clinical surveillance. Regardless of whether SP or NSP tests are used in countries that do not vaccinate, a diagnostic follow-up protocol should be in place to resolve any presumptive positive serological test results.

In areas where animals have been vaccinated, SP antibody tests may be used to monitor the serological response to the vaccination. However, NSP antibody tests should be used to monitor for FMDV infection/circulation. NSP-ELISAs may be used for screening sera for evidence of infection/circulation irrespective of the vaccination status of the animal. All herds with seropositive reactors should be investigated. Epidemiological and supplementary laboratory investigation results should document the status of FMDV infection/circulation for each positive herd. Tests used for confirmation should be of high diagnostic specificity to eliminate as many false positive screening test reactors as possible. The diagnostic sensitivity of the confirmatory test should aproach that of the screening test. The EITB or another OIE-accepted test should be used for confirmation.

Information should be provided on the protocols, reagents, performance characteristics and validation of all tests used.

1) The follow up procedure in case of positive test results if no vaccination is used in order to establish or re-establish FMD free status without vaccination

Any positive test result (regardless of whether SP or NSP tests were used) should be followed up immediately using appropriate clinical, epidemiological, serological and where possible virological investigations of the reactor animal at hand, of susceptible animals of the same epidemiological unit and of susceptible animals that have been in contact or otherwise epidemiologically associated with the reactor animal. If the follow up investigations provide no evidence for FMDV infection, the reactor animal shall be classified as FMD negative. In all other cases, including the absence of such follow up investigations, the reactor animal should be classified as FMD positive.

2) The follow up procedure in case of positive test results if vaccination is used in order to establish or re-establish FMD free status with vaccination

In case of vaccinated populations one has to exclude that positive test results are indicative of virus circulation. To this end the following procedure should be followed in the investigation of positive serological test results derived from surveillance conducted on FMD vaccinated populations.

The investigation should examine all evidence that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were not due to virus circulation.

All the epidemiological information should be substantiated and the results should be collated in the final report.

It is suggested that in the primary sampling units where at least one animal reacts positive to the NSP test, the following strategy(ies) should be applied:

a) Following clinical examination, a second serum sample should be taken from the animals tested in the initial survey after an adequate interval of time has lapsed, on the condition that they are individually identified, accessible and have not been vaccinated during this period. Antibody titres against NSP at the time of retest should be statistically either equal to or lower than those observed in the initial test if virus is not circulating.

   The animals sampled should remain in the holding pending test results and should be clearly identifiable. If the three conditions for retesting mentioned above cannot be met, a new serological survey should be carried out in the holding after an adequate period of time, repeating the application of the primary survey design and ensuring that all animals tested are individually identified. These animals should remain in the holding and should not be vaccinated, so that they can be retested after an adequate period of time.

b) Following clinical examination, serum samples should be collected from representative numbers of cattle that were in physical contact with the primary sampling unit. The magnitude and prevalence of antibody reactivity observed should not differ in a statistically significant manner from that of the primary sample if virus is not circulating.

c) Following clinical examination, epidemiologically linked herds should be serologically tested and satisfactory results should be achieved if virus is not circulating.

d) Sentinel animals can also be used. These can be young, unvaccinated animals or animals in which maternally conferred immunity has lapsed and belonging to the same species resident within the positive initial sampling units. They should be serologically negative if virus is not circulating. If other susceptible, unvaccinated ruminants (sheep, goats) are present, they could act as sentinels to provide additional serological evidence.

Laboratory results should be examined in the context of the epidemiological situation. Corollary information needed to complement the serological survey and assess the possibility of viral circulation includes but is not limited to:

– characterization of the existing production systems;

– results of clinical surveillance of the suspects and their cohorts;

– quantification of vaccinations performed on the affected sites;

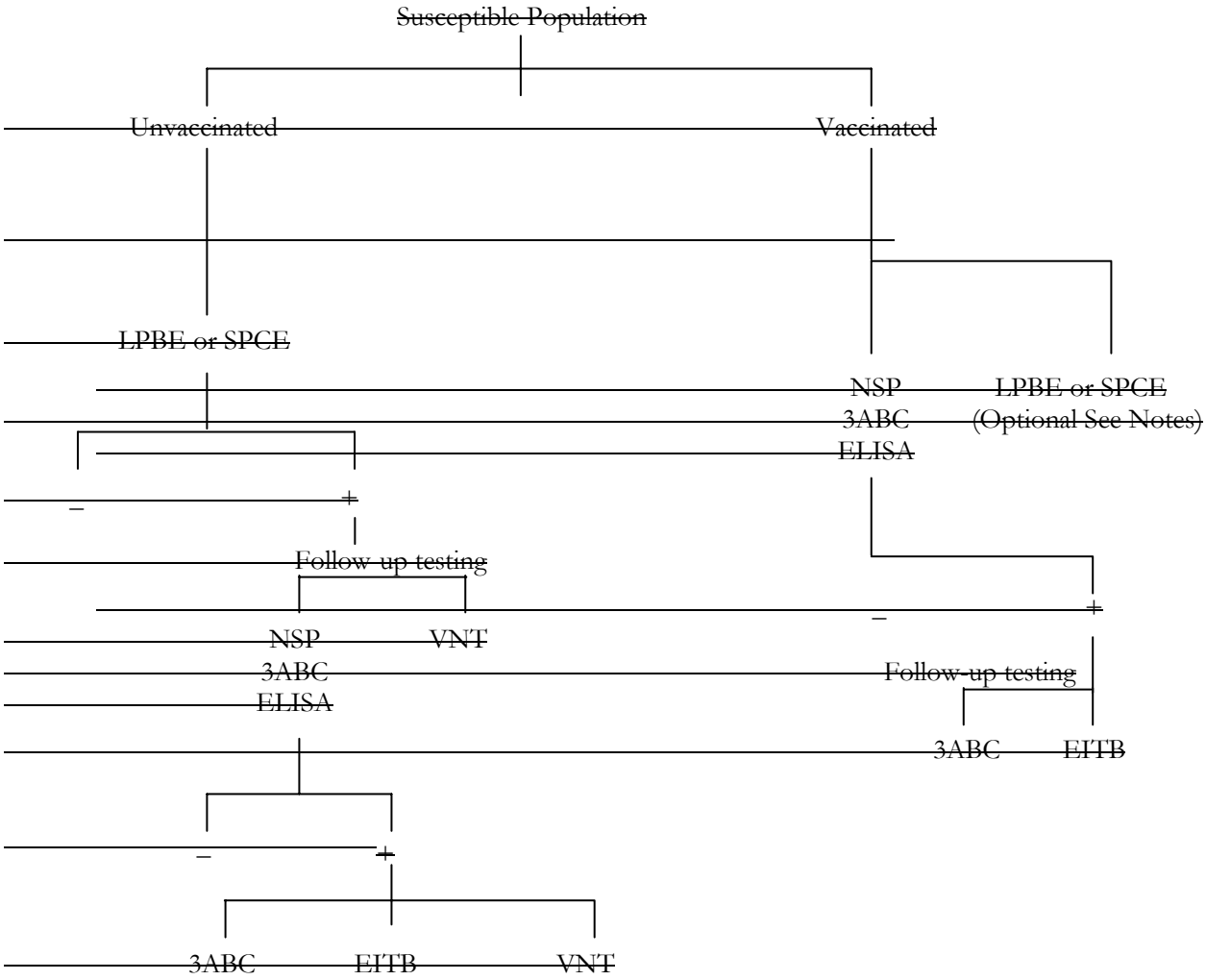
– sanitary protocol and history of the establishments with positive reactors;

– control of animal identification and movements;

– other parameters of regional significance in historic FMDV transmission.

The entire investigative process should be documented as standard operating procedure within the surveillance programme.

Figure 1 ***Schematic representation of laboratory tests for determining evidence of FMDV infection through or following serological surveys***

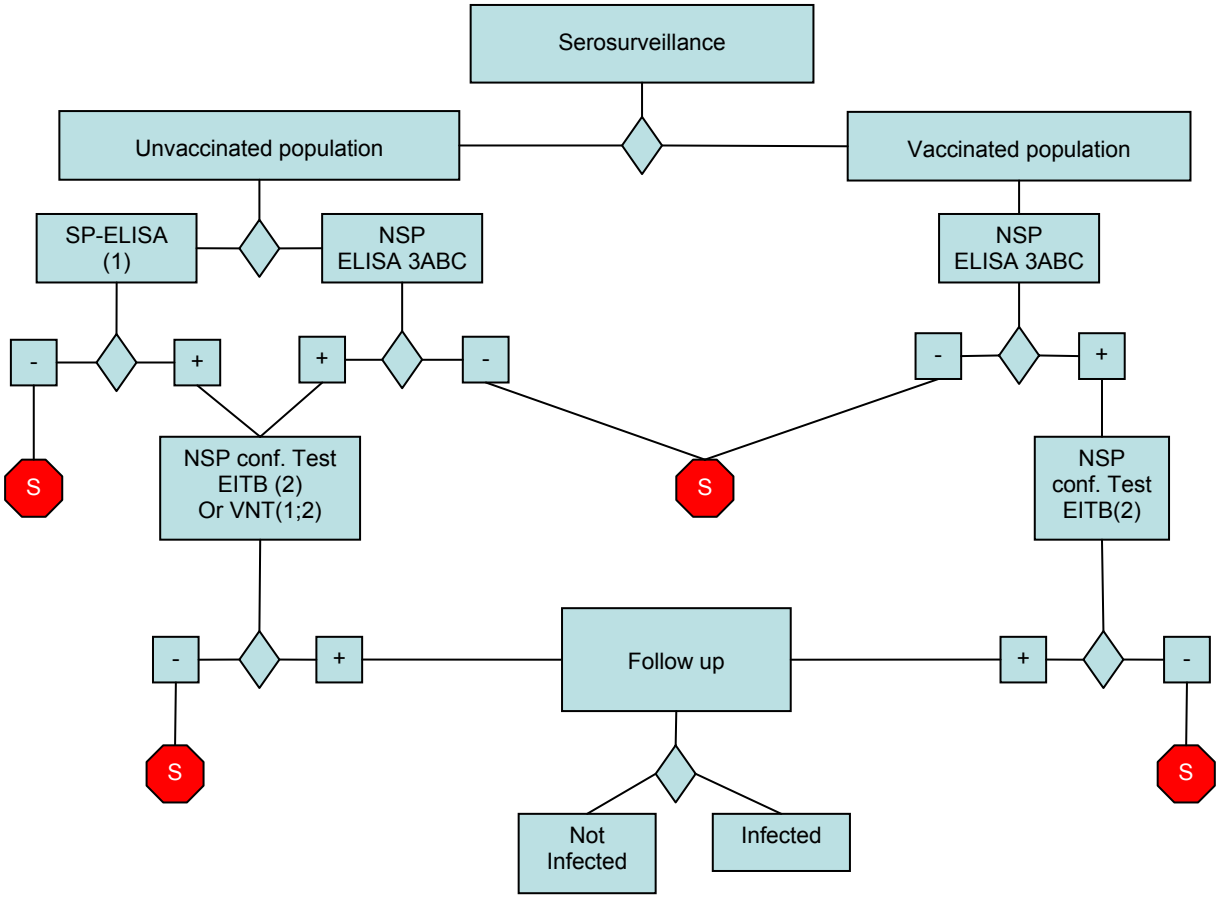


The above diagram indicates the tests which are recommended for use in the investigation of sampling units in which a positive test result has been obtained.

When feasible, detection of virus in OP fluid can also be used as complementary test on units in which positive NSP test result has been obtained.

Appendix VIII (contd)

Figure 1 ***Schematic representation of laboratory tests for determining evidence of FMDV infection through or following serological surveys***



Key:

ELISA	Enzyme-linked immunosorbent assay
VNT	Virus neutralisation test
NSP	Nonstructural protein(s) of foot and mouth disease virus (FMDV)
3ABC	NSP antibody test
EITB	Electro-immuno transfer blotting technique (Western blot for NSP antibodies of FMDV)
OP	Oesophageal–pharyngeal sample
SP	Structural protein test
S	No evidence of FMDV

Community position:

There appears to be abbreviations listed above which do not appear on the flow chart i.e. OP

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

—— text deleted

Appendix IX

CHAPTER 2.2.13.

BLUETONGUE

Article 2.2.13.1.

Community position:
The Community can support this proposal but would like the points given in the text below taken on board. In addition the Community request the OIE to study further and promote research on the length of vireamia in different species and the use of inactivated and attenuated vaccines and the time for immunity to be achieved. It would be useful to determine the maximum length of time for vireamia in an animal infected with bluetongue virus and then vaccinated shortly afterwards.
Furthermore however, the Commission would like a reasoned argument as to how the OIE reached its decision concerning the reduction of the infective period for bluetonge from 100 days to 60 days at least for bovines when the EC supporting document highlighted elements that contradicted this reduction.

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

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

In the absence of clinical disease in a country or zone within this part of the world, its BTV status should be determined by an ongoing surveillance and monitoring programme (in accordance with ~~Chapter 1.3.6~~ Appendix 3.8.1.) designed in accordance with the epidemiology of the disease, i.e. focusing on climatic and geographical factors, the biology and likely competence of *Culicoides* and/or serology of susceptible animals. The programme may need to be adapted to target parts of the country or zone at a higher risk due to historical, geographical and climatic factors, ruminant population data and *Culicoides* ecology, or proximity to enzootic or incursional zones as described in Appendix 3.8.1. ~~Random and targeted serological surveillance should provide at least a 95% level of confidence of detecting an annual seroconversion incidence of 2% in cattle (or other ruminant species if sufficient cattle are not available).~~

Community position:
Criteria in appendix 3.8.1. are too generic and possibly do not provide enough guarantees for an early detection of virus circulation however the proposed new guidelines developed during the meeting of the OIE Ad-hoc group on bluetongue surveillance in February 2005 should cover these aspects.

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

Community position:
As stated before the Community believes a more flexible approach is needed It suggests the following wording to replace the above paragraph" All countries adjacent to an infected or unknown status zone and in an at risk zone should carry out surveillance on that part of the territory at risk within a 100 km distance the of

known infection front but a lesser distance could be acceptable if there are relevant **ecological or geographical features likely to interrupt the transmission of BTV. The front of the disease is the limit of the possible zone where the virus is known to be circulating which must be based on appropriate surveillance data. It must include those areas where the virus has been thought to have been circulating during the last 2 years and in any case those areas where the infection is historically present or is unknown. A number of factors must be taken into account when establishing such a zone such geography, climate epidemiology and entomology."**

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

Article 2.2.13.2.

BTV free country or zone

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

   a) the country or zone lies wholly north of 5040°N or south of 35°S, and is not adjacent to a country or zone not having a free status; or

Community position:
Please see the Community position highlighted above and th.

   b) a surveillance and monitoring programme as described in Chapter 1.3.6Appendix 3.8.1 Article 2.2.13.1. has demonstrated no evidence of BTV in the country or zone during the past 2 years, nor have any ruminants been vaccinated against bluetongue in the country or zone during the past 12 months; or

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

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

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

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

   a) the animals have been vaccinated in accordance with the *Terrestrial Manual* at least 30 60 days prior to dispatch with a vaccine which covers all serotypes whose presence in the source population has been demonstrated through a surveillance and monitoring programme as described in Chapter 1.3.6Appendix 3.8.1, and that the animals are identified in the accompanying certification as having been vaccinated; or

   b) the animals are not vaccinated, and a surveillance and monitoring programme as described in Chapter 1.3.6Appendix 3.8.1 has been in place in the source population for a period of 60 days immediately prior to dispatch, and no evidence of BTV transmission has been detected.

4) A BTV free country or zone adjacent to an infected country or zone should include a *surveillance* zone in which surveillance is conducted as described in Appendix 3.8.1 Article 2.1.9.1. Animals

within this ~~the *surveillance*~~ zone must be subjected to continuing surveillance. The boundaries of ~~the *surveillance*~~ this zone must be clearly defined, and must take account of geographical and epidemiological factors that are relevant to BTV transmission ~~infection~~.

Article 2.2.13.3.

BTV seasonally free zone

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

For the application of Articles 2.2.13.7., 2.2.13.10. and 2.2.13.14., the seasonally free period is taken to commence the day following the last evidence of BTV transmission (as demonstrated by the surveillance and monitoring programme), or of the cessation of activity of adult *Culicoides* likely to be competent BTV vectors.

For the application of Articles 2.2.13.7., 2.2.13.10. and 2.2.13.14., the seasonally free period is taken to conclude either:

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

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

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

Article 2.2.13.4.

BTV infected country or zone

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

Article 2.2.13.5.

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

1) ruminants and other BTV susceptible herbivores;

2) semen of these species;

3) embryos/ova of these species;

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

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

Article 2.2.13.6.

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

for ruminants and other BTV susceptible herbivores

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

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

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

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

4) the animals:

   a) were kept in a BTV free country or zone for at least 7 days;

   b) were vaccinated in accordance with the *Terrestrial Manual* ~~30~~ 60 days before introduction into the free country or zone against all serotypes whose presence in the source population has been demonstrated through a surveillance and monitoring programme as described in Appendix 3.8.1.;

   c) were identified as having been vaccinated and

   d) remained in the BTV free country or zone until shipment;

AND

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

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

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

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

Article 2.2.13.7.

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

for ruminants and other BTV susceptible herbivores

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

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

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

Community position:
The guarantees for the importing country are given by the combination of the protection from Culicoides attack, the standstill and the negative serological test performed after the maximum time for the seroconversion.
No added guarantee is obtained from the second test if the animal is protected from the Culicoides attack after the first test.

Proposed text: "were kept during the BTV seasonally free period in a BTV seasonally free zone for at least 28 days prior to shipment, and were subjected during the residence period in the zone to a serological test to detect antibody to the BTV group, according to the *Terrestrial Manual* ~~such as the BT competition ELISA or the BT AGID test~~, with negative results on carried out at least 28 days after the commencement of the residence period;
This is because although one test is sufficient 28 days is needed to enuser sero-conversion has occurred see papers "Studies on the safety and immunogenicity of the South African bluetongue virus serotype 2 monovalent vaccinates: the specific detection of of vaccinates strain genomes by RT-PCR" by S. Hammoumi, E. Bread, C. Sailleau, P.Russo, C. Grillet, C. Cetre-Sossah, E. Albina, R. Sanchos, M. Pepin, J.M. Guibert and S. Zientara; Journal of Veterinary Medicine B (2003) 50 (7) pages 316-321.

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

Community position:
The guarantees for the importing country are given by the combination of the protection from Culicoides attack, the standstill and the negative virological test performed after the minimum time for the beginning of the viraemic period.
No added guarantee is obtained from the second test if the animal is protected from the Culicoides attack after the first test and 7 days is sufficient time. This is consistent with the time interval laid in Article 2.2.13.6. and the time before the first testing in the proposed protocol.
Proposed text: "were kept during the BTV seasonally free period in a BTV seasonally free zone for at least 7 days prior to shipment, and were subjected during the residence period in the zone to an agent identification test according to the *Terrestrial Manual* ~~to a BTV isolation test or polymerase chain reaction test,~~ with negative results carried out at least 7 days after the commencement of the residence period.

4) were kept during the seasonally free period in a BTV seasonally free zone, and were vaccinated in accordance with the *Terrestrial Manual* ~~30~~ 60 days before introduction into the free country or zone against all serotypes whose presence in the source population has been demonstrated through a surveillance and monitoring programme as described in Appendix 3.8.1, were identified as having been vaccinated and remained in the BTV free country or zone until shipment;

AND

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

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

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

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

Article 2.2.13.8.

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

for ruminants and other BTV susceptible herbivores

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

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

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

Community position:
The guarantees for the importing country are given by the combination of the protection from Culicoides attack, the standstill and the negative serological test performed after the maximum time for the seroconversion.
No added guarantee is obtained from the second test if the animal is protected from the Culicoides attack after the first test.

Proposed text: "were protected from attack from *Culicoides* likely to be competent BTV vectors for at least 28 days prior to shipment, and were subjected during that period to a serological test to detect antibody to the BTV group, according to the *Terrestrial Manual* ~~such as the BT competition ELISA or the BT AGID test~~, with negative results on carried out at least 28 days after the introduction into the *quarantine station or*;

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

Community position:
The guarantees for the importing country are given by the combination of the protection from Culicoides attack, the standstill and the negative virological test performed after the minimum time for the beginning of the viraemic period.
No added guarantee is obtained from the second test if the animal is protected from the Culicoides attack after the first test and 7 days is sufficient time. This is consistent with the time interval laid in Article 2.2.13.6. and the time before the first test in the proposed protocol.
Proposed text: "were protected from attack from *Culicoides* likely to be competent BTV vectors for at least 7 days prior to shipment, and were subjected during the residence period in the zone to an agent identification test according to the *Terrestrial Manual* ~~to a BTV isolation test or polymerase chain reaction test,~~ with negative results carried out at least 7 days after introduction into the *quarantine station*; or"

4) were vaccinated in accordance with the *Terrestrial Manual* at least ~~30~~ 60 days before shipment, against all serotypes whose presence in the source population has been demonstrated through a

surveillance and monitoring programme as described in Appendix 3.8.1, and were identified in the accompanying certification as having been vaccinated; or

5) are not vaccinated, a surveillance and monitoring programme as described in Appendix 3.8.1. has been in place in the source population for a period of 60 days immediately prior to shipment, and no evidence of BTV transmission has been detected;

AND

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

7) were vaccinated ~~30~~ 60 days before shipment or had antibodies against all serotypes whose presence in the zones of transit has been demonstrated through a surveillance and monitoring programme as described in Appendix 3.8.1.

Article 2.2.13.9.

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

for semen of ruminants and other BTV susceptible herbivores

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

1) the donor animals:

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

   b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, ~~such as the BT competition ELISA or the BT AGID test,~~ between ~~28~~ 21 and 60 days after the last collection for this consignment, with negative results; or

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

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

Article 2.2.13.10.

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

for semen of ruminants and other BTV susceptible herbivores

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

1) the donor animals:

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

   b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group ~~such as the BT competition ELISA or the BT AGID test~~, with negative results, at least every 60 days throughout the collection period and between ~~28~~ 21 and 60 days after the final collection for this consignment; or

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

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

Article 2.2.13.11.

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

for semen of ruminants and other BTV susceptible herbivores

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

1) the donor animals:

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

b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group ~~such as the BT competition ELISA or the BT AGID test~~, with negative results, at least every 60 days throughout the collection period and between ~~28~~ 21 and 60 days after the final collection for this consignment; or

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

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

Article 2.2.13.12.

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

for *in vivo* derived bovine embryos/oocytes

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

Article 2.2.13.13.

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

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

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

1) the donor females:

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

b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, ~~such as the BT competition ELISA or the BT AGID test~~, between ~~28~~ 21 and 60 days after collection, with negative results; or

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

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

Article 2.2.13.14.

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

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

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

1) the donor females:

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

b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, ~~such as the BT competition ELISA or the BT AGID test~~, between ~~28~~ 21 and 60 days after collection, with negative results; or

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

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

Article 2.2.13.15.

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

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

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

1) the donor females:

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

b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, ~~such as the BT competition ELISA or the BT AGID test~~, between ~~28~~ 21 and 60 days after collection, with negative results; or

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

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

Article 2.2.13.16.

Protecting animals from Culicoides attack

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

~~Strategies to protect animals from attack from *Culicoides* likely to be competent BTV vectors during~~

~~transport through an infected country or zone should take into account the local ecology of the vector.~~

Potential risk management strategies include:

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

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

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

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

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

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

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

ANNEX III

DIAGNOSTIC MANUAL COMMENTS

ADVICE FOR MEMBER COUNTRY COMMENTS

Chapter Number and Title: I.1.1. **Sampling methods**

Country making the comments: COMMUNITY

Date : 19/03/05

General Comments:

Part B of the Chapter on sample size is useful

Part D on shipment of samples is also very informative. However a practical approach indicating clearly the type of packaging required for sending material for diagnosis of OIE notifiable diseases and where this specific containers can be ordered would be more useful to the member states.

Example: which containers should be used and which precaution taken to send material from suspected animal to the Reference laboratories?

The presented document should be adapted to the new Definition 3.6.1.3 of ADENDUM II (22th of March 2005) of the IATA, Dangerous Goods Regulations (46th Edition, effective from 1st January 2005). In addition, the changes concerning class 6.2 dangerous goods or UN3373 should be included.

(New 3,6.2.1.4 Patient specimens are human or animal materials, collected directly from humans or animals, including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluid swabs, and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment and prevention.

3.6.2.2.2.2 Category B: An infectious substance which does not meet the criteria for inclusion in Category A. Infectious substances in Category B must be assigned to UN 3373. Note: The proper shipping name of UN 3373 is Diagnostic specimens, Clinical specimens or Biological substance, category B. On 1 January 2007, it is anticipated that the use of the shipping names Diagnostic specimens and Clinical specimens will no longer be permitted)

Specific Comments (add continuation sheets if required)

Lines 68-70: An alternative method for collecting and transporting blood that is to be used for serology is to place a drop of blood on to filter paper, the blood is dried at room temperature and the sample can then be shipped un-refrigerated. All tests are not validated with sera collected on filter paper therefore the utilisation of blotting paper for collecting sera is not always recommended. The preliminary agreement of the destination laboratory should be ensured prior to collecting bloods/sera for serological test with this method.

Lines 282 and following : referring to table 1 and table 2 :

- Avian influenza is not indicated in any of the tables ;
- The wording: “cultures only” is not clear. Does it means that the specimen collected from suspected animals are not considered as virulent material under UN 2814 and UN 2900 ? Should they be considered as diagnostic specimen or biological substance under UN 3373 ?

Page 8 line 295 et seqq.: should be adapted to the new IATA Dangerous Goods Regulations

ADVICE FOR MEMBER COUNTRY COMMENTS

Chapter Number and Title: I.1.9. The role of official bodies in the international regulation of veterinary biologicals

Country making the comments: Community

Date: 8-4-05

General Comments

NONE

Specific Comments (add continuation sheets if required)

NONE

line:

ADVICE FOR MEMBER COUNTRY COMMENTS

Chapter Number and Title: I.1.11. **Guidelines for international standards for vaccine banks**

Country making the comments : Community

Date 19 03 2005

General Comments:

This chapter should be harmonised with chapter 2.2.10.

Some of the statements in this chapter are specific to FMD vaccine antigen bank and it is suggested that those specific statements be put under Chapter 2210 instead of this chapter which is generic to vaccine banks (for example lines 179-184).

Specific Comments (add continuation sheets if required)

Lines 9-28 : the definitions of the different types of vaccination should be consistent between the Manual and the Code.

Suggest deletion of lines 66, 67 68 : such delays in the production and despatch of emergency vaccine to control an outbreak inevitably lead to wider spread of the disease and further difficulty in its control.

Page 3 lines 137 to 157 : one of the problems related to the vaccine bank is to have the guarantee, when the vaccine will be needed in an emergency situation, that it will comply with the requirements mainly related to the quality and efficacy standards. In consequences this chapter does not insist enough about the need of regular controls to be carried out on the vaccines stored.

The controls will depend on the type of the vaccine bank. So, we would like to suggest the following additions to the test:

"Precise procedures have to be implemented to carry out, on a regular basis, controls of the antigens or vaccines stored. These procedures have to take into consideration the type of the vaccine bank. If, e.g., antigen is stored, quality controls on representative samples have to be done regularly and the competent authorities have to ensure the manufacturers remain capable to produce the finished product to allow the expected protection of the animal population intended to be vaccinated in emergency conditions. If vaccines are stored, safety controls have to be carried out at the beginning of the storage period. Quality and potency controls have to be carried out on a regular basis during the storage period. It is recommended that the results of these control tests could be shared regularly by all the competent authorities involved in the regional bank."

> *Suggest deletion of lines 143-145 : this makes the issue of an authorised product even more important, particularly where vaccinated animals are intended for the food chain and require the support of agencies responsible for human health.*

Suggest deletion of line 169 : where low temperature is not necessarily important.

ADVICE FOR MEMBER COUNTRY COMMENTS

Chapter Number and Title: I.1.11. **Guidelines for international standards for vaccine banks**

Country making the comments : Community

Date 19 03 2005

General Comments:

This chapter should be harmonised with chapter 2.2.10.

Some of the statements in this chapter are specific to FMD vaccine antigen bank and it is suggested that those specific statements be put under Chapter 2210 instead of this chapter which is generic to vaccine banks (for example lines 179-184).

Specific Comments (add continuation sheets if required)

Lines 9-28 : the definitions of the different types of vaccination should be consistent between the Manual and the Code.

Suggest deletion of lines 66, 67 68 : such delays in the production and despatch of emergency vaccine to control an outbreak inevitably lead to wider spread of the disease and further difficulty in its control.

Page 3 lines 137 to 157 : one of the problems related to the vaccine bank is to have the guarantee, when the vaccine will be needed in an emergency situation, that it will comply with the requirements mainly related to the quality and efficacy standards. In consequences this chapter does not insist enough about the need of regular controls to be carried out on the vaccines stored.

The controls will depend on the type of the vaccine bank. So, we would like to suggest the following additions to the test:

"Precise procedures have to be implemented to carry out, on a regular basis, controls of the antigens or vaccines stored. These procedures have to take into consideration the type of the vaccine bank. If, e.g., antigen is stored, quality controls on representative samples have to be done regularly and the competent authorities have to ensure the manufacturers remain capable to produce the finished product to allow the expected protection of the animal population intended to be vaccinated in emergency conditions. If vaccines are stored, safety controls have to be carried out at the beginning of the storage period. Quality and potency controls have to be carried out on a regular basis during the storage period. It is recommended that the results of these control tests could be shared regularly by all the competent authorities involved in the regional bank."

> *Suggest deletion of lines 143-145 : this makes the issue of an authorised product even more important, particularly where vaccinated animals are intended for the food chain and require the support of agencies responsible for human health.*

Suggest deletion of line 169 : where low temperature is not necessarily important.

Page 2, chapter "Definition of a vaccine bank". Add at line 76 the following sentence: "The economic benefit of ready-to-use vaccines could be much higher in case of spray-dried or freeze-dried vaccines, usually endued with a long shelf life."

Page 2, chapter "Types of vaccine banks". Add at line 85 the following sentence: "*Ad hoc* legislation could regulate the use of vaccines without a marketing licence in case of emergency, if need be".

Page 3, chapter "Types of vaccine banks". Add at line 100 the following sentence: "These parameters should be assessed preferably by an independent research laboratory or control agency".

Page 3, chapter "Quantities of vaccines for a bank". Add at line 136 the following sentence: "Therefore, the number of vaccine doses should be adjusted according to the worst case scenario of a primary outbreak within an area of high livestock density.

Page 3, chapter "Acquirement of vaccines for a bank". Delete lines 147- 159 (too many details and the overall picture is ill-defined).

Page 4, chapter "Regulatory standards - safety, efficacy and quality". Delete lines 161-169: the content is too specific for the EU Member States. The hint to articles 7 and 8 of the EU Directive on FMD may be inserted into the above *addendum* at line 85.

Page 4, chapter "Storage of vaccines/antigens in a bank". Delete the word "vaccines" at line 183 (there is no need for a GMP facility in case of fully formulated, ready-to-use vaccines).

Page 9, chapter "Potency tests". The contents are ill-defined; potency may be mistaken for efficacy, dealt with in another chapter on page 8. The whole chapter could be deleted or a preliminary sentence should better specify the scope of this heading.

Page 10, chapter "Stability tests". At line 470 replace "…potency test …." with "…acceptable parameter…."

ADVICE FOR MEMBER COUNTRY COMMENTS

Chapter Number and Title: 2.2.10. **Foot and mouth disease**

Country making the comments: Community

Date : 05/04/2005

General Comments
Some statements of this chapter 2.2.10.6 should be harmonised with those of chapter 1.1.11.

In general all the statements specific to FMD vaccine of chapter 1.1.11 should be transferred to this chapter.

The current text uses the term 'Safety' to apply both to innocuity (i.e. freedom from infectious virus) and safety in terms or freedom from local or systemic toxicity. The term innocuity is well recognised in regulatory circles and should be used appropriately here. Likewise, the text is incorrect in terms of 'batch tests' (i.e. tests applied to every batch for the purposes of batch release) and 'final product tests' (which should here refer to tests conducted once for the purposes of obtaining a licence or authorisation for the product from the regulatory agency). In the proposed amendments the terms have been used correctly and the tests moved to their appropriate section.

Section 5 (a) – The intradermolingual test for innocuity is generally now considered to be outdated and should not be recommended because of its adverse animal welfare implications. It is now accepted that innocuity is better tested in vitro by testing the inactivated (concentrated) antigen and that safety (lack of local or systemic toxicity) is better tested by administration of the vaccine by one of the recommended routes of administration, preferably in overdose. There is no benefit to be gained from intradermolingual inoculation of the finished product. This test has now been removed from the Ph. Eur. monograph for inactivated FMD vaccines and should certainly be removed from this text.

Specific Comments (add continuation sheets if required)

line: see attached text with track changes

BBSECTION 2.1.

LIST A DISEASES

CHAPTER 2.1.1.

FOOT AND MOUTH DISEASE

SUMMARY

Foot and mouth disease (*FMD*) *is the most contagious disease of mammals and has a great potential for causing severe economic loss in susceptible cloven-hoofed animals. There are seven serotypes of FMD virus, namely, O, A, C, SAT 1, SAT 2, SAT 3 and Asia 1. Infection with one serotype does not confer immunity against another. FMD cannot be differentiated clinically from other vesicular diseases, including swine vesicular disease, vesicular stomatitis, and vesicular exanthema. Laboratory diagnosis of any suspected FMD case is therefore a matter of urgency.*

Typical cases of FMD are characterised by a vesicular condition of the feet, buccal mucosa and, in females, the mammary glands. Clinical signs can vary from mild to severe and fatalities may occur, especially in young animals. In some species the infection may be subclinical, e.g. African buffalo (Syncerus caffer). *The preferred tissue for diagnosis is epithelium from unruptured or freshly ruptured vesicles or vesicular fluid. Where this is not possible, blood and/or oesophageal–pharyngeal fluid samples taken by probang cup in ruminants or throat swabs from pigs provide an alternative source of virus. Myocardial tissue or blood can be submitted from fatal cases, but vesicles are again preferable if present.*

It is vital that samples from suspected cases be transported under secure conditions and according to international regulations. They should only be dispatched to authorised laboratories.

Diagnosis of FMD is by virus isolation or by the demonstration of FMD viral antigen or nucleic acid in samples of tissue or fluid. Detection of specific humoral antibody can also be used for diagnosis. Serodiagnosis is enhanced by the newly developed nonstructural protein (*NSP*) *assays that enable detection of past or current infection, irrespective of vaccination status.*

Identification of the agent: *The demonstration of FMD viral antigen is sufficient for a positive diagnosis. Due to the highly contagious nature and economic importance of FMD, the laboratory diagnosis and serotype identification of the virus should be done in a virus-secure laboratory.*

Complement fixation (*CF*) *has been replaced in many laboratories by the enzyme-linked immunosorbent assay* (*ELISA*), *as it is more specific and sensitive and is not affected by pro- or anti-complementary factors. If the sample is inadequate or the test result inconclusive, it will be necessary to grow the virus in cell cultures or in 2–7-day old unweaned mice. The cultures should preferably be of primary bovine thyroid, but pig, lamb or calf kidney cells, or cell lines of comparable sensitivity may be used. When a cytopathic effect* (*CPE*) *appears in the cultures, the fluids can be used in CF tests or ELISAs. Similar tests can be performed on homogenised suspensions of the dissected musculo-skeletal tissues of any mice that die. In the absence of CPE or any dead mice, a further passage should be made at a 48-hour interval, with freeze–thawing of the cells, before the sample is declared to be negative.*

Nucleic acid recognition tests, such as the polymerase chain reaction, are being used increasingly as rapid and sensitive diagnostic methods. Electron microscopic examination of lesion material is sometimes useful to differentiate FMD from disease caused by other viruses.

Serological tests: *The demonstration of specific antibodies to structural proteins in nonvaccinated animals, where a vesicular condition is present, is sufficient for a positive diagnosis. This is particularly useful in mild cases or where epithelial tissue cannot be collected. Tests for antibodies to some NSPs of FMD virus are useful in providing evidence of previous or current viral replication in the host, irrespective of vaccination status. NSPs, unlike structural proteins, are not serotype specific and as a consequence, the detection of these antibodies is not serotype restricted.*

Virus neutralisation (*VN*) *tests and ELISAs for antibodies to structural proteins are used as serotype-specific serological tests. VN tests depend on tissue cultures and are therefore more prone to variability than ELISAs; they are also slower and subject to contamination. ELISAs for antibodies have the advantage of being faster, and are not dependent on cell cultures. The ELISA can be performed with inactivated antigens, thus requiring less restrictive biocontainment facilities.*

Requirements for vaccines and diagnostic biologicals: *Inactivated virus vaccines of varying composition are available commercially. Typically, virus is used to infect a suspension or monolayer cell culture and the resulting preparation is clarified, inactivated with ethyleneimine and blended with adjuvant. Many FMD vaccines are multivalent to provide cover against the different serotypes likely to be encountered in a given field situation.*

The finished vaccine must be shown to be free from residual live virus. This is most effectively done using in-vitro *tests on concentrated inactivated virus preparations and freedom from live virus is subsequently confirmed during* in-vivo *tests on the finished vaccine. Challenge tests are also conducted in vaccinated cattle to establish a* PD_{50} (*50% protective dose*) *value or protection against generalised foot infection* (*PGP*), *although a serological test is considered to be satisfactory where the vaccine producer has established a valid correlation between protection and specific antibody response.*

FMD vaccine production facilities should also meet the OIE requirements for Containment Group 4 pathogens.

Diagnostic and reference reagents are available from the OIE Reference Laboratories for FMD or the FAO (*Food and Agriculture Organization of the United Nations*) *World Reference Laboratory for FMD*[1]*. The Pirbright Laboratory* (*see footnote 1*) *has dual designations as both the World Reference Laboratory and an OIE Reference Laboratory for FMD.*

A. INTRODUCTION

Foot and mouth disease (FMD) is caused by a virus of the genus Aphthovirus, family Picornaviridae. There are seven serotypes of FMD virus, namely O, A, C, SAT 1, SAT 2, SAT 3, and Asia 1, that infect cloven-hoofed animals. Infection with any one serotype does not confer immunity against another. Within serotypes, many strains can be identified by biochemical and immunological tests.

In Africa, FMD viruses are maintained by cattle and African buffalo (*Syncerus caffer*). Available evidence indicates that although other domestic and wild species become infected, they are unable to maintain the infection for more than a few months in the absence of cattle or African buffalo. Elsewhere in the world cattle are usually the main reservoir, although in some instances the viruses involved appear to be specifically adapted to domestic pigs or sheep and goats. It is probable that these adapted viruses are able to modify their adaptation and affect other species if given the opportunity. However, the pig-adapted Cathay strain of FMD virus apparently does not infect large ruminants in the field or experimentally and requires cells of porcine origin for primary isolation. Wildlife outside Africa has not, so far, been shown to be able to maintain FMD viruses. The evidence indicates that infection of deer in the past was derived from contact, direct or indirect, with infected domestic animals.

Of the domesticated species, cattle, pigs, sheep, goats and buffalo are susceptible to FMD (21). In addition, many species of cloven-hoofed wildlife, such as deer, antelope and wild pigs may become infected, although, apart from the African buffalo their involvement in the epidemiology of FMD in the domesticated species is not certain. Strains of FMD virus that infect cattle have been isolated from wild pigs and deer. For the diagnosis of FMD in wild species, procedures similar to those described for farm animals can be applied.

1 FAO World Reference Laboratory for FMD, Pirbright Laboratory, Ash Road, Pirbright, Woking, Surrey GU24 0NF, United Kingdom.

Infection of susceptible animals with FMD virus leads to the appearance of vesicles on the feet, in and around the oral cavity, and on the mammary glands of females. Vesicles can also occur at other sites, such as inside the nostrils and at pressure points on the limbs – especially in pigs. The severity of clinical signs varies with the strain of virus, the exposure dose, the age and breed of animal, the host species and its degree of immunity (32). The signs can range from a mild or inapparent infection to one that is severe. Death may result in some cases. Mortality from a multifocal myocarditis is most commonly seen in young animals: myositis may also occur in other sites. Adult animals may occasionally succumb.

On premises with a history of sudden death in young cloven-hoofed livestock, close examination of adult animals may often reveal the presence of vesicular lesions if FMD is involved. The presence of vesicles in fatal cases is variable.

In animals with a history of vesicular disease, the detection of FMD virus in samples of vesicular fluid, epithelial tissue, milk, or blood is sufficient to establish a diagnosis. Diagnosis may also be established by the isolation of FMD virus from the blood, heart or other organs of fatal cases. A myocarditis may be seen macroscopically in a proportion of fatal cases.

FMD virus can replicate and be excreted from the respiratory tract of animals. Airborne excretion of virus occurs during the acute phase of infection. FMD viruses may occur in all the secretions and excretions of acutely infected animals including expired air. Transmission is generally effected by contact between infected and susceptible animals or, more rarely, exposure of susceptible animals to the excretions and secretions of acutely infected animals. Following recovery from the acute stage of infection, infectious virus disappears from all secretions and excretions with the exception, in the case of ruminants, of those of oesophageal–pharyngeal (OP) origin. Animals in which the virus persists in the OP for more than 28 days after infection are referred to as carriers. Pigs do not become carriers. Circumstantial evidence indicates that carriers are able, on rare occasions, to transmit the infection to susceptible animals with which they come in close contact: the mechanism involved is unknown. The carrier state in cattle usually does not persist for more than 6 months, although in a small proportion it may last up to 3 years. In African buffalo individual animals have been shown to harbour the virus for at least 5 years, but it is probably not a lifelong phenomenon. Within a herd of buffalo, the virus may be maintained for 24 years or longer. There is no information on the duration of the carrier state in another domestic buffalo, the swamp buffalo of East Asia. Domestic buffalo, sheep and goats do not usually carry FMD viruses for more than a few months.

Due to the highly contagious nature and economic importance of FMD, the laboratory diagnosis and serotype identification of the virus should be done in a virus-secure laboratory. The facility should meet the requirements for Containment Group 4 pathogens as outlined in Appendix .1.6.1 of Chapter I.1.6. of this *Terrestrial Manual.* Countries lacking access to such a specialised national or regional laboratory should send specimens to an OIE FMD Reference Laboratory. Vaccine production facilities should also meet the requirements for Containment Group 4 pathogens.

Diagnostic and standard reagents are available in kit form or as individual items from the FAO WRL for FMD. The use of inactivated antigens in the enzyme-linked immunosorbent assay (ELISA), as controls in the antigen-detection test or to react with test sera in the liquid-phase blocking or solid-phase competitive ELISA, reduces the disease security risk involved in the use of live virus. Reagents are supplied freeze-dried or in glycerol and can remain stable at 4°C or at –20°C, respectively, for many years. The International Atomic Energy Agency[2] has produced a manual that includes a recommended test and quality control protocols.

B. DIAGNOSTIC TECHNIQUES

For laboratory diagnosis, the tissue of choice is epithelium or vesicular fluid. Ideally, at least 1 g of epithelial tissue should be collected from an unruptured or recently ruptured vesicle. To avoid injury to personnel collecting the samples, as well as for animal welfare reasons, it is recommended that animals be sedated before any samples are obtained.

Epithelial samples should be placed in a transport medium composed of equal amounts of glycerol and 0.04 M phosphate buffer, pH 7.2–7.6, preferably with added antibiotics (penicillin [1000 International Units (IU)], neomycin sulphate [100 IU], polymyxin B sulphate [50 IU], mycostatin [100 IU]). If 0.04 M phosphate buffer is not available, tissue culture medium or phosphate buffered saline (PBS) can be used instead, but it is important that the final pH of the glycerol/buffer mixture be in the range pH 7.2–7.6. Samples should be kept refrigerated or on ice until received by the laboratory.

2 International Atomic Energy Agency, Wagramerstrasse 5, P.O. Box 100, A-1400 Vienna, Austria.

Where epithelial tissue is not available from ruminant animals, for example in advanced or convalescent cases, or where infection is suspected in the absence of clinical signs, samples of OP fluid can be collected by means of a probang (sputum) cup (or in pigs by swabbing the throat[3]) for submission to a laboratory for virus isolation.

Before the collection of OP samples from cattle or large ruminants (e.g. buffaloes), 2 ml transport fluid (composed of 0.08 M phosphate buffer containing 0.01% bovine serum albumin, 0.002% phenol red, antibiotics [1000 units/ml penicillin, 100 units/ml mycostatin, 100 units/ml neomycin, and 50 units/ml polymyxin], and adjusted to pH 7.2) should be added to a container of around 5 ml capacity capable of withstanding freezing above solid carbon dioxide (dry ice) or liquid nitrogen.

After collection of OP fluid by probang, the contents of the cup should be poured into a wide-necked transparent bottle of around 20 ml capacity. The fluid is examined, and should contain some visible cellular material. Of this, 2 ml is then added to the 2 ml of transport fluid, ensuring that cellular material is transferred; the mixture is shaken gently and should have a final pH of around pH 7.6. Samples contaminated with ruminal contents may be unsuitable for culture. Samples seen to contain blood are not entirely satisfactory. Repeat sampling can be done after the mouth and throat of the animal have been rinsed with water or PBS.

OP samples from small ruminants are collected by putting 2 ml of transport fluid into a wide-necked bottle of about 20 ml capacity and, after collection, rinsing the probang cup in this transport fluid to discharge the OP sample. This is then transferred to a container of about 5 ml capacity for transport. The small container should be capable of withstanding freezing above solid carbon dioxide or liquid nitrogen (27).

Samples of OP fluid should be refrigerated or frozen immediately after collection. If they are to remain in transit for more than a few hours, they should be frozen by being placed either above solid carbon dioxide or liquid nitrogen. Before freezing, the containers should be carefully sealed using airtight screw caps or silicone. This is particularly important when using solid carbon dioxide, as introduction of CO_2 into the OP sample will lower its pH, inactivating any FMD virus that may be in the samples. Glass containers should not be used because there is a risk that they will explode on defrosting in the event of liquid nitrogen leaking into them. Samples should reach the laboratory in a frozen state.

Special precautions are required when sending perishable suspect FMD material both within and between countries. The International Air Transport Association (IATA), Dangerous Goods Regulations (DGR) has explicit requirements for packaging and shipment of diagnostic specimens by all commercial means of transport. These are summarised in Chapter 1.1.1. Sampling methods.

1. Identification of the agent

a) Virus isolation

The epithelium sample should be taken from the PBS/glycerol, blotted dry on absorbent paper to reduce the glycerol content, which is toxic for cell cultures, and weighed. A suspension should be prepared by grinding the sample in sterile sand in a sterile pestle and mortar with a small volume of tissue culture medium and antibiotics. Further medium should be added until a final volume of five times that of the epithelial sample has been added, giving a 20% suspension. This is clarified on a bench centrifuge at 2000 ***g*** for 10 minutes. Once clarified, such suspensions of field samples suspected to contain FMD virus are inoculated into cell cultures or unweaned mice. Sensitive cell culture systems include primary bovine thyroid cells and primary pig, calf or lamb kidney cells. Established cell lines, such as BHK-21 (baby hamster kidney) and IB-RS-2 cells, may be used but are less sensitive than primary cells for detecting low amounts of infectivity (10). The cell cultures should be examined for cytopathic effect (CPE) for 48 hours. If no CPE is detected, the cells should be frozen and thawed, used to inoculate fresh cultures and examined for CPE for another 48 hours. Unweaned mice are an alternative to cell cultures and should be 2–7 days old and of selected inbred strains. Some field viruses may require several passages before they become adapted to mice (38).

b) Immunological methods

- **Enzyme-linked immunosorbent assay**

At the FAO WRL for FMD (see footnote 1), the preferred procedure for the detection of FMD viral antigen and identification of viral serotype is the ELISA (20, 36). This is an indirect sandwich test in which different rows in multiwell plates are coated with rabbit antisera to each of the seven serotypes of FMD virus. These are the 'capture' sera. Test sample suspensions are added to each of the rows, and appropriate controls are also included. Guinea-pig antisera to each of the serotypes of FMD virus are added next, followed by rabbit anti-guinea-pig serum conjugated to an enzyme. Extensive washing is carried out between each stage to remove unbound reagents. A colour reaction on the addition of enzyme substrate and chromogen, indicates

[3] The pig should be properly restrained, ideally held on its back in a wooden cradle with its neck extended. Holding a swab in a suitable instrument, such as an artery forceps, the swab is pushed to the back of the mouth into the pharynx.

a positive reaction. With strong positive reactions this will be evident to the naked eye, but results can also be read spectrophotometrically at an appropriate wavelength. In this case, an absorbance reading greater than 0.1 above background indicates a positive reaction; the serotype of FMD virus can also be identified. Values close to 0.1 should be confirmed by retesting or by amplification of the antigen by tissue culture passage and testing the supernatant once a CPE has developed. A suitable protocol is given below.

Depending on the species affected and the geographical origin of samples, it may be appropriate to simultaneously test for swine vesicular disease (SVD) virus or vesicular stomatitis (VS) virus. Ideally a complete differential diagnosis should be undertaken in all vesicular conditions.

Rabbit antiserum to the 146S antigen of each of the seven serotypes of FMD virus (plus SVD virus if required) is used as a trapping antibody at a predetermined optimal concentration in carbonate/bicarbonate buffer, pH 9.6.

Control antigens are prepared from selected strains of each of the seven types of FMD virus (plus SVD virus if appropriate) grown on monolayer cultures of BHK-21 cells (IB-RS-2 cells for SVD virus). The unpurified supernatants are used and pretitrated on ELISA plates. The final dilution chosen is that which gives an absorbance at the top of the linear region of the titration curve (optical density approximately 2.0), so that the five-fold dilutions of the control antigens used in the test give two additional lower optical density readings from which the titration curve can be derived. PBS containing 0.05% Tween 20 and phenol red indicator is used as a diluent (PBST).

Guinea-pig antisera prepared by inoculating guinea-pigs with 146S antigen of one of the seven serotypes of FMD virus (plus SVD virus if required) and preblocked with normal bovine serum (NBS) is used as the detecting antibody. Predetermined optimal concentrations are prepared in PBS containing 0.05% Tween 20, and 5% dried, nonfat skimmed milk (PBSTM).

Rabbit (or sheep) anti-guinea-pig immunoglobulin conjugated to horseradish peroxidase and preblocked with NBS is used at a predetermined optimum concentration in PBSTM. As an alternative to guinea-pig or rabbit antisera, suitable monoclonal antibodies (MAbs) can be used coated to the ELISA plates as capture antibody or peroxidase-conjugated as detecting antibody.

- **Test procedure**

i) ELISA plates are coated with 50 µl/well rabbit antiviral sera in carbonate/bicarbonate buffer, pH 9.6. Rows A to H receive, respectively, antisera to serotypes O, A, C, SAT 1, SAT 2, SAT 3, Asia 1 and SVD virus (optional).

ii) Leave overnight at 4°C in a stationary position or place on an orbital shaker set at 100–120 revolutions per minute in a 37°C incubator for 1 hour.

iii) Prepare test sample suspension (with 20% original sample suspension or undiluted clarified cell culture supernatant fluid).

iv) The ELISA plates are washed five times in PBS.

v) On each plate, load wells of columns 4, 8 and 12 with 50 µl PBST. Additionally, add 50 µl of PBST to wells 2 and 3 of rows A to H on plate 1. To well 1 of row A of plate 1 add 50 µl of control antigen type O, and to well 2 of row A add 12.5 µl of control antigen type O. Mix antigen and diluent in well 2 and transfer 12.5 µl from well 2 to well 3 of row A. Mix and discard 12.5 µl from well 3 (this gives a five-fold dilution series of antigen O). Similarly repeat with antigen A, adding 50 µl of antigen type A to well 1 of row B, and 12.5 µl of antigen type A to well 2, and then mix and transfer 12.5 µl to well 3 (as done before with antigen type O), and continue for types C, SAT 1, SAT 2, SAT 3, Asia 1 and SVD (if appropriate). It is only necessary to change pipette tips on the micropipette between antigens. The remainder of the plate can be loaded with the test sample(s). Add 50 µl of sample one to wells 5, 6 and 7 of rows A to H, the second sample is placed similarly in columns 9, 10 and 11, rows A to H.

   If more than two samples are to be tested at the same time, the other ELISA plates should be used as follows:

   Dispense 50 µl of the PBST to the wells (rows A to H) of columns 4, 8 and 12 (buffer control columns). Note that the control antigens are not required on these plates. These test samples may be added in 50 µl volumes in rows A to H to columns 1, 2, 3; 5, 6, 7; 9, 10, 11, respectively.

vi) Cover with lids and place on an orbital shaker at 37°C for 1 hour.

vii) Wash the plates by flooding with PBS – wash three times as before and empty residual wash fluid. Blot the plates dry.

viii) Transfer 50 µl volumes of each guinea-pig serum dilution to each plate well in the appropriate order, e.g. rows A to H receive, respectively, antisera to serotypes O, A, C, SAT 1, SAT 2, SAT 3, Asia 1 and SVD virus (optional).

ix) Cover the plates with lids and replace on the orbital shaker. Incubate at 37°C for 1 hour.

x) The plates are washed again three times, and 50 µl of rabbit anti-guinea-pig immunoglobulin conjugated to horseradish peroxidase is added to each well. The plates are incubated at 37°C for 1 hour on a rotary shaker.

xi) The plates are washed again three times, and 50 µl of substrate solution, containing 0.05% % H_2O_2 plus orthophenylene diamine or a suitable alternative chromogen, is added to each well.

xii) The reaction is stopped after 15 minutes by the addition of 50 µl of 1.25 M sulphuric acid. The plates are read at 492 nm on a spectrophotometer linked to a computer.

- **Complement fixation test**

The ELISA is preferable to the complement fixation (CF) test because it is more sensitive and it is not affected by pro- or anti-complementary factors. If ELISA reagents are not available, however, the CF test may be performed as follows:

Antisera to each of the seven types of FMD virus are diluted in veronal buffer diluent (VBD) in 1.5-fold dilution steps from an initial 1/16 dilution to leave 25 µl of successive antiserum dilutions in U-shaped wells across a microtitre plate. To these are added 50 µl of 3 units of complement, followed by 25 µl of test sample suspension(s). The test system is incubated at 37°C for 1 hour prior to the addition of 25 µl of 1.4% standardised sheep red blood cells (SRBC) in VBD sensitised with 5 units of rabbit anti-SRBC. The reagents are incubated at 37°C for a further 30 minutes and the plates are subsequently centrifuged and read. Appropriate controls for the test suspension(s), antisera, cells and complement are included. CF titres are expressed as the reciprocal of the serum dilution producing 50% haemolysis. A CF titre $\geq$36 is considered to be a positive reaction. Titre values of 24 should be confirmed by retesting an antigen that has been amplified through tissue culture passage.

c) Nucleic acid recognition methods

The polymerase chain reaction (PCR) can be used to amplify the genome fragments of FMD virus in diagnostic material (2, 8). Specific primers have been designed to distinguish between each of the seven serotypes. *In situ* hybridisation techniques have been developed for investigating the presence of FMD virus RNA in tissue samples (44). These techniques are only in use in specialised laboratories.

The molecular epidemiology of FMD is based on the comparison of genetic differences between virus isolates. Dendrograms showing the genomic relationship between vaccine and field strains for all seven serotypes based on sequences derived from the 1D gene have been published. Reverse-transcription PCR (RT-PCR) amplification of FMD virus RNA, followed by nucleotide sequencing, is the current preferred option for generating the sequence data to perform these comparisons. The WRL and other laboratories have developed techniques for performing these studies, and a database of over 3000 sequences is currently held.

The recommended method is to:

i) Extract FMD virus RNA directly from epithelial suspensions, or from a low cell culture passage.

ii) Perform an RT-PCR of the complete VP1 gene (or if only part of the VP1 gene, then the 3' end of the gene is more useful).

iii) Determine the nucleotide sequence of the PCR product (or at least 170 nucleotides [preferably 420 for the SAT types] at the 3' end of the gene).

A protocol, complete with primer sequences, is available from the WRL on request or can be downloaded from the following World Wide Web URL:

http://www.iah.bbsrc.ac.uk/virus/picornaviridae/aphthovirus/fmd.htm

2. Serological tests

FMD virus infection can be diagnosed by the detection of a specific antibody response. The tests generally used are virus neutralisation (VN) and ELISA (24, 25, 41). These are also the prescribed tests for trade. The VN test is serotype specific, requires cell culture facilities and takes 2–3 days to provide results. The ELISA is a blocking- or competitive-based assay that uses serotype-specific polyclonal or monoclonal antibodies. It is therefore serotype specific, sensitive and quantitative, and has the advantage that it is quicker to perform, is less variable, and is not dependent on tissue culture systems. Low titre false-positive reactions can be expected in a small proportion of the sera in either test. An approach combining screening by ELISA and confirming the positives by the VN test

minimises the occurrence of false-positive results. The OIE has coordinated the production of reference sera to standardise the FMD serological tests; these are available from the WRL.

The detection of antibody to the nonstructural proteins (NSPs) of FMD virus has been used to identify past or present infection with any of the seven serotypes of the virus, whether or not the animal has also been vaccinated. Conventionally this has been carried out by measuring antibody to the virus infection-associated antigen (VIAA; the viral RNA polymerase protein 3D) using agar gel immunodiffusion (AGID) (31). Although relatively insensitive, the test is inexpensive, easy to perform and has been used extensively in South America to detect viral activity on a population basis during FMD eradication campaigns. The VIAA test has now largely been superseded by assays that measure antibody to FMD virus NSPs produced by recombinant techniques in a variety of *in-vitro* expression systems. Antibody to the polyproteins 3AB or 3ABC are generally considered to be the most reliable indicators of infection (11, 30, 39). In animals seropositive for antibody to 3AB or 3ABC, antibody to one or more of the other NSPs including the L, 2C, 3A, 3B or 3D protein is further confirmation of infection (9, 30, 39). The test can be used to detect FMD virus infection in vaccinated and unvaccinated populations. However, vaccine purity is an import consideration as the presence of trace amounts of NSPs in some vaccine preparations may result in false-positive reactions in animals that have been repeatedly vaccinated. Conversely, there is experimental evidence that a few animals, vaccinated and subsequently challenged with live virus and confirmed persistently infected, may not be detected in some anti-NSP tests, causing false-negative results (28). Therefore, NSP assays may be used on a herd but not on an individual animal basis to detect FMD virus circulation in vaccinated populations.

a) Virus neutralisation (a prescribed test for international trade)

The quantitative VN microtest for FMD antibody is performed with IB-RS-2, BHK-21, lamb or pig kidney cells in flat-bottomed tissue-culture grade microtitre plates.

Stock virus is grown in cell monolayers and stored at –20°C after the addition of 50% glycerol. (Virus has been found to be stable under these conditions for at least 1 year.) The sera are inactivated at 56°C for 30 minutes before testing. The control standard serum is 21-day convalescent serum (usually pig). A suitable medium is Eagle's complete medium/LYH (Hank's balanced salt solution with yeast lactalbumin hydrolysate) with antibiotics.

The test is an equal volume test in 50 µl amounts.

- **Test procedure**

i) Starting from a 1/4 dilution, sera are diluted in a twofold dilution series across the plate, using at least two rows of wells per serum, preferably four rows, and a volume of 50 µl.

ii) Previously titrated virus is added; each 50 µl unit volume of virus suspension should contain about 100 $TCID_{50}$ (50% tissue culture infective dose) within an accepted range (e.g. 35–350 $TCID_{50}$).

iii) Controls include a standard antiserum of known titre, a negative serum, a cell control, a medium control, and a virus titration used to calculate the actual virus titre used in the test.

iv) Incubate at 37°C for 1 hour with the plates covered.

v) A cell suspension at 10^6 cells/ml is made up in medium containing 10% bovine serum (specific antibody negative) for cell growth. A volume of 50 µl of cell suspension is added to each well.

vi) Plates are sealed with pressure-sensitive tape and incubated at 37°C for 2–3 days. Alternatively, the plates may be covered with loosely fitting lids and incubated in an atmosphere of 3–5% carbon dioxide at 37°C for 2–3 days.

vii) Microscope readings may be feasible after 48 hours. The plates are finally fixed and stained routinely on the third day. Fixation is effected with 10% formol/saline for 30 minutes. For staining, the plates are immersed in 0.05% methylene blue in 10% formalin for 30 minutes. An alternative fixative/stain solution is naphthalene blue black solution (0.4% [w/v] naphthalene blue black, 8% [w/v] citric acid in saline) (23). The plates are rinsed in tap water.

viii) Positive wells (where the virus has been neutralised and the cells remain intact) are seen to contain blue-stained cells sheets; the negative wells (where virus has not been neutralised) are empty. Titres are expressed as the final dilution of serum present in the serum/virus mixture at the 50% end-point, as per the Kärber method. The test is considered to be valid when the amount of virus used per well is in the range $\log_{10}$ 1.5–2.5 $TCID_{50}$, and the positive standard serum is within twofold of its expected titre.

ix) Interpretation of tests can vary between laboratories in regard to end-points taken. Laboratories should establish their own criteria by reference to standard reagents that can be obtained from the FAO WRL for FMD (see footnote 1). At the WRL, a titre of 1/45 or more of the final serum dilution in the serum/virus mixture is regarded as positive. Titres of 1/16 to 1/32 are considered to be doubtful, and

further serum samples are requested for testing. Animals are considered to be positive if the second sample has a titre of 1/16 or greater. A titre of 1/8 or less is considered to be negative.

b) Solid-phase competitive enzyme-linked immunosorbent assay (a prescribed test for international trade)

Rabbit antiserum to the 146S antigen of one of the seven types of FMD virus is used as the trapping antibody at a predetermined[4] optimal concentration in carbonate/bicarbonate buffer, pH 9.6.

Antigens are prepared by inactivating viruses propagated in cell culture with ethyleneimine using the procedures described for vaccine manufacture. The final dilution chosen is that which, after addition of an equal volume of diluent, gives an absorbance on the upper part of the linear region of the titration curve (optical density approximately 1.5). PBS containing 0.05% Tween 20 and phenol red indicator is used as a diluent (PBST).

Guinea-pig antisera, prepared by inoculating guinea-pigs with 146S antigen of one of the seven serotypes and preblocked with normal bovine serum, is used as the detecting antibody. Predetermined optimal concentrations are prepared in PBS containing 0.05% Tween 20, and 5% dried, nonfat skimmed milk (PBSTM).

Rabbit (or sheep) anti-guinea-pig immunoglobulin conjugated to horseradish peroxidase and preblocked with NBS is used at a predetermined optimum concentration in PBSTM.

Test sera are diluted in PBST.

Collaborative studies have shown that the solid-phase competitive ELISA is more specific but as sensitive as the liquid-phase blocking ELISA (29).

- **Test procedure**

i) ELISA plates are coated with 50 µl/well rabbit anti-FMD virus antigen diluted in carbonate/bicarbonate buffer, pH 9.6, and left overnight in a humid chamber at 4°C.

ii) The ELISA plates are washed five times with PBS.

iii) Then 50 µl of the FMD virus antigen diluted in blocking buffer is added to each well of the ELISA plates. (Blocking buffer: 0.05% [w/v] Tween 20, 10% [v/v] normal bovine serum, 5% [v/v] normal rabbit serum.) The plates are covered and placed on an orbital shaker at 37°C for 1 hour, with continuous shaking.

iv) After washing five times with PBS, 40 µl of blocking buffer is added to each well, followed by 10 µl of test sera (or control sera), giving an initial serum dilution of 1/5.

v) Immediately 50 µl of guinea-pig anti-FMD virus antiserum diluted in blocking buffer is added, giving a final serum dilution of 1/10.

vi) The plates are covered and incubated on an orbital shaker at 37°C for 1 hour.

vii) After washing five times with PBS, 50 µl of anti-guinea-pig Ig conjugate diluted in blocking buffer is added. The plates are covered and incubated for 1 hour at 37°C on an orbital shaker.

viii) After washing five times with PBS, 50 µl of substrate solution, containing 0.05% H_2O_2 plus orthophenylene diamine or a suitable alternative chromogen, is added to each well.

ix) The reaction is stopped after 10 minutes by the addition of 50 µl of 2 M sulphuric acid. The plates are read at 492 nm on a spectrophotometer linked to a computer.

x) *Controls:* On each plate two wells are used for conjugate control (no guinea-pig serum), four wells each for strong and weak positive sera, two wells for negative sera, and four wells for 0% competition (no test sera).

xi) *Interpretation of the results:* A percentage of inhibition is calculated for each well, either visually or using a suitable computer programme (100 – [optical density of each test or control value/mean optical density of the 0% competition] × 100%), representing the competition between the test sera and the guinea-pig anti-FMD virus antisera for the FMD virus antigen on the ELISA plate. Greater than 60% inhibition is positive (35).

---

[4] A chequerboard titration of the rabbit-trapping antiserum, the guinea-pig antiserum and the anti-guinea-pig antiserum is performed. Before using the antigen-trapping ELISA or the liquid-phase blocking ELISA, each of these reagents is titrated, one against another, keeping the third reagent at a fixed concentration. In this way the optimal dilutions (for positive colour and low background colour) can be determined. These 'predetermined' dilutions are then used for all future tests using these particular batches of reagents.

c) Liquid-phase blocking enzyme-linked immunosorbent assay

Antigens are prepared from selected strains of FMD virus grown on monolayers of BHK-21 cells. The unpurified supernatants are used and pretitrated in a twofold dilution series but without serum. The final dilution chosen is that which, after addition of an equal volume of diluent (see below), gives an absorbance on the upper part of the linear region of the titration curve (optical density approximately 1.5). PBS containing 0.05% Tween 20 and phenol red indicator is used as a diluent (PBST). The other reagents used in the test are the same as those in the solid-phase blocking ELISA.

- **Test procedure**

i) ELISA plates are coated with 50 µl/well rabbit antisera to the 14S antigen being tested for and left overnight in a humid chamber at room temperature.

ii) The ELISA plates are washed five times with PBS.

iii) In U-bottomed multiwell plates (carrier plates) 50 µl of a duplicate, twofold series of each test serum is prepared, starting at 1/4. To each well, 50 µl of a constant dose of viral antigen that is homologous to the rabbit antisera used to coat the plates is added and the mixtures are left overnight at 4°C, or incubated at 37°C for 1 hour. The addition of the antigen increases the starting serum dilution to 1/8.

iv) Then 50 µl of serum/antigen mixtures is transferred from the carrier plates to the rabbit-serum coated ELISA plates and the plates are incubated at 37°C for 1 hour on a rotary shaker.

v) After washing, 50 µl of guinea-pig antiserum homologous to the viral antigen used in the previous step (iv) is added to each well. The plates are then incubated at 37°C for 1 hour on a rotary shaker.

vi) The plates are washed and 50 µl of rabbit anti-guinea-pig immunoglobulin conjugated to horseradish peroxidase is added to each well. The plates are incubated at 37°C for 1 hour on a rotary shaker.

vii) The plates are washed again three times and 50 µl of substrate solution, containing 0.05% H_2O_2 plus orthophenylene diamine or a suitable alternative chromogen, is added to each well.

viii) The reaction is stopped after 15 minutes by the addition of 50 µl of 1 M sulphuric acid. The plates are read at 492 nm on a spectrophotometer linked to a computer.

ix) *Controls:* A minimum of four wells each of strong positive, weak positive and negative bovine reference sera at a final dilution of 1/32 should be included on each plate together with an equivalent number of reaction (antigen) control wells containing antigen in diluent alone without serum. For end-point titration tests, duplicate twofold dilution series of positive and negative homologous bovine reference sera should be included on at least one plate of every run.

x) *Interpretation of the results:* Antibody titres are expressed as the 50% end-point titre, i.e. the dilution at which the reaction of the test sera results in an optical density equal to 50% inhibition of the median optical density of the reaction (antigen) control wells (Kärber). The median is calculated as the mean of two mid-values of the reaction control wells, eliminating from the calculation the highest and lowest values (alternatively, the mean value can be used after setting suitable tolerance limits to control for inter-well variation). Titres greater than 1/40 are considered to be positive. Titres close to 1/40 should be retested using the VN test.

d) Nonstructural protein antibody tests

Antibody to expressed, recombinant FMD virus NSPs can be measured by ELISA or immunoblotting. In a number of laboratories, several indirect ELISAs have been shown to be sensitive, specific and reliable. These ELISAs either use purified antigens absorbed directly to microplates or use polyclonal or monoclonal antibodies to trap specific antigens from semi-purified preparations (9, 11, 30). A competitive ELISA has also been developed (39). Examples of an ELISA and an immunoblotting technique are described in detail below.

As mentioned previously, the AGID test to detect antibody to the VIAA (viral RNA polymerase protein 3D) has been widely used in South America (31). It has now been largely replaced by the ELISA or immunoblot.

- **Indirect enzyme-linked immunosorbent assay**

- **Preparation of recombinant antigens (see Section B.2.d. Enzyme-linked immunoelectrotransfer blot assay below)**

- **Test procedure**

i) Microplates are coated overnight at 4°C with 1 µg/ml of the fusion antigen 3ABC in carbonate/ bicarbonate buffer, pH 9.6 (100 µl per well). Antigen 3ABC was expressed and purified as indicated for the EITB tests (33).

ii) The plates are washed six times with PBS, pH 7.2, supplemented with 0.05% Tween 20 (PBST).

iii) Test sera (100 µl per well) are added in a 1/20 dilution in blocking buffer consisting of PBS, 0.05% Tween 20, 5% nonfat dry milk, 10% equine sera and 0.1% *Escherichia coli* lysate. Each plate includes a set of strong and weak positive and negative controls calibrated against the International Standard Sera described below.

iv) The plates are incubated for 30 minutes at 37°C and washed six times in PBST.

v) Horseradish-peroxidase-conjugated rabbit anti-species IgG is diluted optimally in the blocking buffer, added at 100 µl per well and the plates are incubated for 30 minutes at 37°C.

vi) After six washings, each well is filled with 100 µl of 3'3', 5'5'-tetramethylbenzidine plus 0.004% (w/v) H_2O_2 in phosphate/citrate buffer, pH 5.5.

vii) The reaction is stopped after 15 minutes of incubation at room temperature by adding 100 µl of 0.5 M H_2SO_4. Absorbance is read at 450 nm and at 620 nm for background correction.

viii) *Interpreting the results:* Test results are expressed as per cent positivity relative to the strong positive control [(optical density of test or control wells/optical density of strong positive control) × 100]. Cut-off values, with or without suspicious zones, need to be determined by individual laboratories with consideration being given to the purpose of testing and the intended target population.

- **International Standard Sera**

International standard sera are currently being developed based on the test method described above. Three standard sera: a strong positive, a weak positive and a negative are being developed according to the OIE Guidelines (34). These sera will act as reference materials for the calibration of other test methods and reagents and as prototypes for the production of national and working standards. The strong positive standard will represent the upper range of antibody detection. The weak positive standard will represent the lower range of detection or the analytical sensitivity of the test method. It is important to note that the dilution of the weak positive standard must be chosen such that it is unequivocally positive in all runs of the assay. The negative standard, used to prepare dilutions of the positive standards, will act as a baseline or background control for the positive standards.

- **Enzyme-linked immunoelectrotransfer blot assay (EITB)**

The EITB assay has been widely applied in South America for serosurveillance and risk assessment associated with animal movement. Currently, the procedure is to perform an initial screening test using an indirect ELISA for antibody to 3ABC, and to follow that by a confirmatory EITB assay if samples give positive or suspect results. This combination of tests is particularly recommended when serosurveillance involves a large number of samples. Further information is available from the OIE Reference Laboratory in Brazil (see Table given in Part 3 of this *Terrestrial Manual*).

- **Preparation of test strips containing the recombinant antigens**

i) The five bioengineered FMD virus NSPs 3A, 3B, 2C, 3D and 3ABC are expressed in *E. coli* C600 by thermo-induction. The 3D polypeptide is expressed in its complete form (33), whereas the rest of the proteins are obtained as fusions to the N-terminal part of the MS-2 polymerase gene (40).

ii) The expressed polymerase is purified over phosphocellulose, followed by poly(U) Sepharose columns. The fused proteins 3A, 3B, 2C and 3ABC are purified by sequential extraction of the bacterial extracts with increasing concentrations of urea. The 7M fraction containing the fusion proteins is further purified on a preparative 10% SDS-PAGE (sodium dodecyl sulphate-polyacrylamide gel electrophoresis). The fusion protein band is excised from the gel and electroeluted (33).

iii) A mixture containing 20 ng/ml of each one of the purified recombinant polypeptides is separated on 12.5% SDS-PAGE and electrophoretically transferred to nitrocellulose (33).

- **Test procedure**

i) The required amount of test strips should be assessed, taking into account that for each nitrocellulose sheet, which defines one transferred gel, a positive, a weakly positive, a cut-off and a negative control serum should be assayed. In general, 24 nitrocellulose strips, each 3 mm wide, should result from a gel.

ii) A volume of 0.8 ml of saturation buffer (50 mM Tris-HCl, pH 7.5; 150 mM NaCl; 0.2% Tween 20; 5% nonfat dry milk; and 0.05% bacterial *E. coli* lysate) is added to each well. The antigen-coated strips are blocked by placing the trays on a rocker and agitating for 30 minutes at room temperature (20–22°C).

iii) A dilution of 1/200 of test sera and of each of the controls is added to the appropriate trough. The strips must be completely submerged and facing upwards, and maintained in that position during the whole process.

iv) Strips are incubated for 60 minutes on a rocker at room temperature.

v) Liquid is removed from the trays, and each test strip is washed three times with washing solution (50 mM Tris-HCl, pH 7.5; 150 mM NaCl; and 0.2% Tween 20) by agitation for 5 minutes.

vi) The alkaline-phosphatase-conjugated rabbit anti-bovine solution is added to each test well, and the strips are incubated with shaking for 60 minutes at room temperature.

vii) The liquid is removed from the trays and each test strip is washed three times with washing solution as above.

viii) Substrate solution (0.015% bromochloroindolylphosphate/0.03% nitroblue tetrazolium) is prepared in substrate buffer (100 mM NaCl; 5 mM $MgCl_2$; and 100 mM Tris-HCl, pH 9.3), and is added to each test well.

ix) Strips are incubated by placing the test tray on the orbital mixer and agitating until the cut-off control shows five distinct, discernible bands. Strips are washed with running deionised water and air-dried.

x) *Interpreting the results:* The EITB may be scanned with a densitometer but visual reading, although more subjective, is considered suitable as well. Individual control sera are run that exhibit minimal but consistent staining for each of the four antigens. A test sample is considered positive if antigens 3ABC, 3A, 3B and 3D (±2C) demonstrate staining densities equal to or higher than that of their appropriate controls. A sample is considered negative if two or more antigens demonstrate densities below their control sera. Test samples not fitting either profile are considered indeterminate.

C. REQUIREMENTS FOR VACCINES AND DIAGNOSTIC BIOLOGICALS

The control of FMD is usually a national responsibility and, in many countries, the vaccine may be used only under the control of the competent authority.

Guidelines for the production of veterinary vaccines are given in Chapter I.1.7. Principles of veterinary vaccine production. The guidelines given here and in Chapter I.1.7 are intended to be general in nature and may be supplemented by national and regional requirements.

Virulent FMD virus must be used to produce FMD vaccine; consequently, the FMD vaccine production facility should operate under the appropriate biosecurity procedures and practices. The facility should meet the requirements for Containment Group 4 pathogens as outlined in Appendix I.1.6.1 of Chapter I.1.6 of this *Terrestrial Manual.*

Routine vaccination against FMD is used in many countries where the disease is endemic. In contrast, a number of disease-free countries have never vaccinated their livestock but have preferred the use of strict movement controls and slaughter of infected and contact animals when outbreaks have occurred. Nevertheless, many disease-free countries maintain the option to vaccinate and have their own strategic reserves of highly concentrated inactivated virus preparations. Such antigen reserves offer the potential of supplying formulated vaccine in an 'emergency' at short notice (17).

FMD vaccines are chemically inactivated cell-culture-derived preparations of the virus that have been blended with a suitable adjuvant. In the case of vaccines destined for use in swine, oil adjuvants are preferred. Live FMD vaccines are not acceptable due to the danger of reversion to virulence and as their use would prevent the differentiation of infected from vaccinated animals.

Because of the presence of multiple serotypes of the virus, many FMD vaccines are multivalent and it is common practice to prepare vaccines from two or more different virus strains. In areas where the disease is maintained by free-living buffalo, it is necessary to include more than one virus per serotype to ensure broad antigenic coverage against prevailing viruses.

1. Seed management

a) Characteristics of the seed

Selection of seed viruses should ideally be based on their ease of growth in cell culture, virus yield, stability and broad antigenic spectrum (37). The production strains should be characterised and distributed by the

official control laboratories; they should be selected in accordance with the epidemiological importance of each variant.

b) Method of culture

Many manufacturers of FMD vaccines derive their vaccine strains from local field isolates and, for those grown in cell culture, adapt them for growth in suspension or monolayer cells by serial passage. In order to remove the risk of any contaminating lipid-containing viruses in these field isolates, it is recommended that they undergo organic solvent treatment prior to, or during, adaptation. It is preferable to keep the number of passages in cell culture to a minimum as there is evidence of antigenic 'drift' of FMD virus during this procedure.

c) Validation as a vaccine

Seed viruses must be antigenically characterised and proven to be free from all extraneous agents listed by the appropriate licensing authorities, to establish homology to the original candidate isolates, purity and effectiveness against the circulating strains for which they were developed. This often encompasses a number of methods, but to establish applicability to field strains a VN test is often used. Seed viruses may be stored at –20°C if glycerinated or at a lower temperature (e.g. –70°C) if not glycerinated. Working seed viruses may be expanded in one or a few more passages from the master seed stock and used to infect the final cell culture at an approximate rate of 1 PFU (plaque-forming unit) per 100 cells.

2. Method of manufacture

FMD virus is usually produced in large-scale suspension cell systems under aseptic conditions. It is essential that all pipework and vessels be thoroughly sterilised ensuring that no areas in the system harbour microorganisms. In addition to general considerations of sterility, it is important to note that the virus is vulnerable to attack by proteolytic enzymes, such as those produced by microorganisms (13). Control of pH and temperature are also critical because of the acid and temperature lability of the virus (12). Optimum temperature for cell, virus growth and inactivation, normally around 37°C and 26°C, respectively, should be precisely controlled. During other stages of manufacture, the temperature should be reduced to 4–6°C. Virus should be maintained at approximately pH 7.6 and should never be below pH 7.0. Explant culture of tongue epithelium (the 'Frenkel' Method) are no longer considered suitable for growth of FMD virus for vaccine production as the use of this type of primary cell culture is not compliant with the requirements of Goof Manufacturing Practice.

A suitable strain of the virus is used to infect a suspension of a transformed cell line, such as BHK. Such cell cultures should be proven to be free from contaminating microorganisms. It is common practice to keep stocks of BHK cells over liquid nitrogen and revive as necessary. On revival, they are expanded in nutrient medium to a volume and cell density appropriate to seeding the main culture. As an approximation, the main culture is seeded to give an initial density of 0.2–0.5 × 10^6 cells/ml, which is allowed to multiply to 2–3 × 10^6 cells/ml before being infected with virus.

When the virus has reached its maximum titre, which is variously determined by infectivity, CF or other tests, the culture is clarified and filtered, often by centrifugation. The virus is subsequently inactivated by addition of ethyleneimine (EI), usually in the form of binary ethyleneimine (BEI). This is usually prepared by dissolving, to a concentration of 0.1 M, 2-bromoethylamine hydrobromide in 0.2 N sodium hydroxide solution, and incubating at 37°C for 1 hour (4, 5). The BEI formed is then added to a virus suspension held at 26°C, to give a final concentration of 3 mM. Inactivation is usually continued for 24 hours, followed by a second dose of BEI for a further 24 hours. After inactivation any residual BEI in the harvest can be neutralised by adding sodium thiosulphate solution to a final concentration of 2%. To decrease the likelihood of live virus failing to contact the EI at the second application, it is essential to transfer the vessel contents immediately to a second sterile vessel where inactivation is allowed to go to completion at 48 hours.

The inactivated virus may be concentrated by ultrafiltration, polyethylene glycol precipitin or polyethylene oxide adsorption (1, 43). These concentrated antigens can be kept at –70°C or lower temperatures for many years, if necessary, and made into vaccine when required by dilution in a suitable buffer and addition of adjuvants (15).

Conventional FMD vaccines are usually formulated in one of two ways. The vaccine most commonly used for cattle is prepared by adsorbing the virus on to aluminium hydroxide gel, one of the adjuvant constituents of the final vaccine blend. Other components of the final blend include antifoam, phenol red dye (if permitted by the country requiring vaccine), lactalbumin hydrolysate, tryptose phosphate broth, amino acids, vitamins and buffer salts. A second adjuvant, saponin, derived from the South American tree *Quillaja saponaria mollina*, is also incorporated, as well as merthiolate/chloroform as a preservative.

An alternative formulation uses mineral oils, such as Marcol and Drakeol, as adjuvants. These preparations offer a number of advantages over the standard aluminium hydroxide/saponin vaccine, not least of which is their

efficacy in pigs. They are widely used for vaccinating cattle in South America because of the longer duration of immunity obtained. The mineral oil is usually premixed with an emulsifying agent, such as mannide monooleate, before the addition of an equal volume of the aqueous phase of the vaccine, and emulsified by use of a colloid mill or continuous mechanical or flow ultrasonic emulsifier. More complex double emulsions (water/oil/water) may be produced by emulsifying once more in an aqueous phase containing a small amount of Tween 80 (26).

Significant advances made in recent years have seen the introduction of alternative 'ready-to-use' oil adjuvants. Oils containing esters of octadecenoic acid and 2,5 anhydro-d-mannitol, for example, readily form double or mixed emulsions (water/oil/water) that are both stable and of low viscosity, without the requirement of sophisticated emulsification equipment (6, 17).

3. In-process control

In general, virus titres reach optimum levels within about 24 hours of the cell culture being infected. The time chosen to harvest the culture may be based on a number of assays; for instance cell death. Virus concentration may be assessed by infectivity test, sucrose density gradient (14) or serological techniques. It is preferable to use a method for measuring antigenic mass, such as sucrose density gradient analysis, as well as one that measures infectivity, as the two properties do not necessarily coincide and the different methods may complement one another.

During inactivation of the virus, timed samples should be taken at regular intervals for the purpose of monitoring the rate and linearity of the inactivation process. Virus titres in the samples are determined by inoculation of cell cultures proven to be highly susceptible to FMD virus, e.g. BHK or bovine thyroid cells. Such cultures permit the testing of statistically meaningful samples under reproducible conditions. The $\log_{10}$ infectivities of the timed samples are plotted against time, and the inactivation procedure is not considered to be satisfactory unless at least the latter part of the slope of the line is linear and extrapolation indicates that there would be less than one infectious particle per 10^4 litres of liquid preparation at the end of the inactivation period.

4. Tests on the final product

a) Safety

Tests for innocuity (non-infectivity) are most effectively carried out on the bulk, concentrated, inactivated viral harvest (see Sections 3 and 5.b, below). Although it may be possible to confirm innocuity by testing virus eluted from the vaccine, this is not universally applicable to all formulations and is not as reliable as testing concentrated antigens. For example, saponin influences greatly the elution of FMD virus from aluminium hydroxide/saponin vaccines (16). If the elution procedure is appropriate to a particular formulation, then it may be validated by seeding parallel samples of vaccine with trace amounts of live virus (7).

For the purposes of gaining regulatory approval, a trial batch of vaccine should be tested for local and systemic toxicity by each recommended route of administration in an *in-vivo* test in an appropriate number of cattle (18). Double dose and repeat dose tests using vaccines formulated to contain the maximum permitted amount and number of antigens should be conducted using a similar protocol described below for batch safety tests..

b) Potency

Cattle of at least 6 months of age, obtained from areas free from FMD, that have not previously been vaccinated against FMD and are free from antibodies to the different types of FMD virus should be used. Three groups of no fewer than five cattle per group should be vaccinated by the route recommended by the manufacturer. The vaccine should be administered at different doses per group by injecting different volumes of the vaccine. For example, if the label states that the injection of 2 ml corresponds to the administration of 1 dose of vaccine, a 1/4 dose of vaccine would be obtained by injecting 0.5 ml, and a 1/10 dose would be obtained by injecting 0.2 ml. These animals and a control group of two nonvaccinated animals are challenged 3 weeks after vaccination with a suspension of bovine virus that is fully virulent and appropriate to the virus types in the vaccine under test by inoculating a total of 10,000 ID_{50} (50% infectious dose) intradermally into two sites on the upper surface of the tongue (0.1 ml per site). Animals are observed for 8–10 days. Unprotected animals show lesions at sites other than the tongue. Control animals must develop lesions on at least three feet. From the number of animals protected in each group, the PD_{50} (50% protective dose) content of the vaccine is calculated. There are a variety of methods for calculating PD_{50} (22), but procedures based on Kärber are generally preferred. The vaccine should contain at least 3 PD_{50} per dose for cattle, when employed for routine prophylactic use, although 6 PD_{50} per dose is more commonly preferred. In some cases, vaccine of high potency will prevent the development of local tongue lesions at the site of challenge. In South American countries a variation of the potency test is performed, the PGP test (percentage of protection against generalised foot infection). A group of 16 bovines of 18–

24 months of age, with the same characteristics described for the PD_{50} test, are vaccinated with a full vaccine dose by the route recommended by the manufacturer. These animals and a control group of two nonvaccinated animals are challenged 4 weeks after vaccination with a suspension of bovine virus that is fully virulent and appropriate to the virus types in the vaccine under test by inoculating a total of 10,000 BID_{50} (50% bovine infectious dose), intradermally into two sites on the upper surface of the tongue. Unprotected animals show lesions at sites other than the tongue. Control animals must develop lesions on at least three feet; for routine prophylactic use, the vaccine should protect at least 12 animals out of 16 vaccinated.

Potency tests in other target species, such as sheep, goats or buffalo are not common, as a successful test in cattle is considered to be sufficient to endorse its use in other species. Under circumstances where a vaccine is produced for use primarily in one particular species, it may be more appropriate to potency test the vaccine in that same species. However, in respect to the limited data for African buffalo or Asiatic buffalo (*Bubalus bubalis*) and sheep, and the often inapparent nature of the disease in these species, potency results from a cattle test should be a good indicator of the vaccines applicability in these other species.

A similar protocol to the cattle test can be adopted for potency testing FMD vaccines in pigs. Using three groups of five pigs, one group is vaccinated with the full pig dose recommended by the manufacturer, one group receives a 1/4 dose, and a third group receives a 1/16 dose of vaccine. Traditionally, the response to oil vaccine is allowed longer to develop, and not until day 28 after vaccination are the three groups, plus two unvaccinated control pigs challenged. Challenge is by intradermal injection into the heel bulbs of one foot with 10,000 $TCID_{50}$ (0.2 ml), as calculated by growth in a suitable pig cell culture, of a virulent challenge virus homologous to a strain used in the vaccine. The animals are observed daily for 10 days after challenge for clinical signs of FMD, but animals are removed as soon as they develop generalised FMD to avoid excessive challenge to those remaining. Both control animals should develop clinical signs on more than one foot. From the number of animals protected in each group, the PD_{50} content of the vaccine is calculated. There are a variety of methods for calculating PD_{50} (22), but procedures based on Kärber are generally preferred. The vaccine should contain at least 3 PD_{50} per dose for pigs. Likewise, a similar protocol to the PGP test in cattle can be adopted for pigs using a group of 16 animals vaccinated with a full vaccine dose and two nonvaccinated control animals. Challenge is by intradermal injection into the heel bulbs of one foot with 10,000 BID_{50} (0.2 ml) of a virulent challenge virus homologous to the strain used in the vaccine.

Other tests, including measurement following vaccination of virus neutralising antibodies in cell culture, or ELISA antibodies, or serum-protecting antibodies in suckling mice, may be used to assess the potency of a vaccine provided that a statistical evaluation has established a satisfactory correlation between the results obtained by the test on the relevant vaccine serotype and the potency test in cattle (42). For example, the expected percentage of protection is used to analyse the sera of a group of at least 16 vaccinated cattle and to express the probability of an animal being protected by measuring neutralising, ELISA or protecting antibodies. In a single group of animals given a full dose of vaccine, the mean individual expected percentage protection should be equal to or greater than 75% when 16 animals are used or 70% when 30 animals are used in the experimental group.

The presence of more than one serotype in a vaccine does not interfere with the induction of antibodies against another serotype or the correlation of antibody titre with protection.

c) Purity

The OIE *Terrestrial Animal Health Code* stipulates that a criterion for regaining FMD free status following an outbreak, if vaccine is used, is to test the vaccinated animals for antibody against NSP. Likewise, countries wishing to be recognised as FMD free with vaccination must demonstrate the absence of virus circulation by showing that vaccinated animals are free from antibody to NSPs arising as a result of infection. Consequently, FMD antigens used to formulate vaccines that may be used in these circumstances, should be purified to reduce the NSP content.. A test method that can be used to evaluate the purity of the vaccine is to vaccinate three calves three times over 3–6 months, preferably with at least a double dose of a trial blend of the vaccine, and then test them for the presence of antibody against NSP using the tests described in Section B.2.d. of this chapter. If antibody is detected against NSP, the antigen may be further purified before the final vaccine is formulated. An alternative method is to vaccinate the calves used in the safety test two more times over 3–6 months and then test them for the presence of antibody against NSP.

d) Duration of immunity

In order to establish a satisfactory level of immunity it is usual to give a primary course of two inoculations, 2–4 weeks apart, followed by revaccination every 4–12 months. The frequency of revaccination will depend on the epidemiological situation and the type and quality of vaccine used. Where access to the animals is

difficult, it is preferable to use oil adjuvanted vaccine at 4 months and 1 year of age, followed by annual revaccination.

For calves born of vaccinated dams, the first vaccination should be delayed as long as possible to allow decline of maternal antibody, but not beyond 4 months, as at that time a high proportion can be expected to respond effectively to vaccination. For calves born of nonvaccinated dams, the first vaccination may be at 1 week of age (3).

e) Stability

The shelf life of conventional FMD vaccines is usually 1–2 years at 4°C, but they are temperature labile and should neither be frozen nor stored above 4°C.

f) Preservatives

The most commonly used preservatives are chloroform and merthiolate. The latter is used at a final concentration of 1/30,000 (w/v).

g) Precautions (hazards)

Current FMD vaccines are innocuous and present no toxic hazard to the user. Care must be taken to avoid self-injection with oil-emulsion vaccines.

4. Batch control

a) Sterility

The bulk inactivated antigen, the adjuvants, the dilution buffers and the final formulated product should all undergo sterility testing. This may be carried out directly with components of the vaccine and the final product, but the preferred method is to collect any contaminating microorganisms by membrane filtration of the material to be examined and to detect them by incubation of the membranes with culture media. The latter procedure allows the removal of preservatives, etc., which may inhibit the detection of microorganisms. Guidelines on techniques and culture media, which allow the detection of a wide range of organisms, are described in the European Pharmacopoeia 2002 (ref. 19; also refer to Chapter I.1.5.).

b) Innocuity

Following inactivation, a sample of each batch of inactivated antigen representing at least 200 doses should be tested for freedom from infectious virus by inoculation of sensitive monolayer cell cultures, preferably of the same origin as those used for the production of antigen. It may be preferable to concentrate the antigen to do this, in which case it must be shown that the concentrated material does not interfere with the sensitivity or reading of the assay. The cell sheets are examined daily over a period of 3 days, after which the spent medium is transferred to fresh monolayers and the original monolayers are replenished with fresh medium. Using this method, traces of live virus can be amplified by the passage procedure and detected on the basis of CPE observed. Two to three passages of the original virus preparation are commonly used. A variant on this method is to freeze–thaw the old monolayers to release intracellular virus, which can be detected by further passage.

c) Safety

This test may also confirm innocuity but is not as sensitive as the *in vitro* tests described above. For the purposes of batch release, each of at least two healthy seronegative cattle is inoculated by the recommended route of administration with double the recommmeded dose of vaccine. The animals are observed for local and systemic reactions to vaccination for no fewer than 14 days. Should any of the animals develop clinical signs of FMD, the vaccine will fail the safety test. Equally, any undue toxicity attributable to the vaccine should be assessed and may prevent acceptance of the batch. Ideally, vaccines prepared for species other than cattle should also be safety tested in the species for which they are intended, administering a double dose of vaccine according to the manufacturer's recommended route and dose volume. The animals should be examined daily for a minimum of 14 days for evidence of toxicity or signs of FMD.

c) Potency

Potency is only examined on the final formulated product (see Section C.5.b.). Antigen load can be used as an indirect indicator of potency, provided a correlation has previously been established between antigen load, serological response and protection against challenge.

6. Storage and monitoring of antigen concentrates

The process of storing concentrated antigens at ultra-low temperature for later formulation into FMD vaccine is becoming an increasingly popular option for vaccine manufacture. It not only forms the basis for the storage of antigens in a strategic reserve for emergency purposes (see Chapter 'Guidelines for International Standards for Vaccine Banks'), but allows the manufacturer immediate access to many different antigen strains which can be

rapidly formulated and dispatched to the customer. Such stockpiling minimises delays subsequent to an order, particularly where a multivalent vaccine is requested. Another advantage of this procedure is that much of the quality testing can be completed well in advance of shipment.

a) Pre-storage criteria

It is necessary to state that antigens have to be controlled using standards indicated in Sections C1–4.

Special attention should be paid to the following:

- freedom from extraneous agents;

  antigens should be proven pure and free from all extraneous agents listed by the appropriate licensing authorities.

- sensitivity of the cell line used to detect residual virus;

  Cells used to test for absence of residual live virus are not suitable if use of an amount of virus corresponding to 1 µg of 146S antigen gives a titre of less than 10^6 CC ID_{50}.

- emergency procedures for provisional acceptance of new Master Seed Virus (MSV), and subsequent release of formulated vaccines.

In the case of incursion in a region of a new strain that is antigenically distinct from existing vaccine strains, it may be necessary to develop a new vaccine strain from a representative field isolate. Before the new MSV can be accepted, full compliance should be demonstrated with the relevant guidelines to demonstrate freedom from all extraneous agents listed by the appropriate licensing authorities using both general and specific tests, and to establish homology to the original candidate isolates. The time taken to raise the specific antisera necessary to neutralise the new strain for use in the general tests for detection of extraneous agents and to conduct other specific tests that require specialised techniques may be lengthy. Therefore, in emergency situations where there is insufficient time to complete full testing of the MSV, provisional acceptance of the new strain should be based on a risk analysis of the possibility of contamination of the antigen produced from the new MSV with extraneous agents. This risk assessment should take into account that a validated procedure to inactivate enveloped viruses must be used when establishing the MSV and that the virus is inactivated using a chemical inactivant with first order kinetics.

In order to accelerate the release of batches of vaccine formulated to contain new vaccine strains, it may be acceptable for batch potency testing to be carried out using a vaccine formulated using an intermediate antigen lot pending production of all of the batches of antigen that are intended to constitute the final antigen lot. This will allow the potency of antigen derived from a new MSV to be determined whilst the manufacturer continues to build up stocks of this new antigen.

a) Storage criteria

- **Facilities**

It is important that the area of storage chosen to hold antigen concentrates is suitable in the context of the required national or internationally accepted standards of Good Manufacturing Principles.

- **Containment of stored antigens**

The dose numbers or volumes stored are an important consideration, particularly where a reserve is shared between Member Countries and there is variation in number of doses perceived to be needed by each member in an emergency. It may be advisable to store antigen concentrates in user-friendly units to allow better usage of storage space and capability in producing smaller vaccine batches. One to two litre sized containers can accommodate about 20,000–25,000 bovine doses. Where the requirement is for a large stockpile of a particular vaccine strain that can only be produced from several separate production runs, Vaccine Bank managers must consider the need to either formulate each lot into a representative final blend for testing purposes or mixing the individual batches, at some convenient point, for ease of formulating and/or testing.

The type of container used to hold antigen concentrate is important. Under ultra-low temperature conditions it is important to use containers made from materials that do not become brittle and fragile, a good example being fluoropolymer based moulded bottles. Polyfluoro-alkoxy (PFA) based bottles, for example, have a temperature resistance range of between –270°C and +250°C.

- **Labelling of stored antigens**

Although there are national and international guidelines on the required labelling of veterinary medical products, there are no such guidelines currently for emergency stored materials such as the antigen component of a vaccine. Under ultra-low temperature conditions, the method of labelling must be of a durable nature. From experience, wire tagging bottles is the most preferred option using a metal tag sizeable enough to allow the necessary detail. Such detail should include the antigen/vaccine strain, batch number, date received and should also include an individual container or stock number. This information should be clear to read and marked on the tag using an indelible marker pen. Aluminium metal tags have been used for such purpose and these can be obtained with different colour coatings to allow better identification and accessibility, particularly when different antigen strains are housed in the same container. Metal tags also allow information to be permanently engraved.

- **Monitoring**

It is vitally important that antigen concentrates are optimally maintained and routinely monitored in order to have some assurance that they will be efficacious when needed. Therefore arrangements should be made to monitor these antigen concentrates on a routine basis and to include where necessary, and at appropriate time intervals, a testing regime to ensure integrity of the antigen component or acceptable potency of the final product. For example, 24 hour storage temperature monitoring is normally undertaken and recorded in FMD vaccine banks, as well as periodic inspection of the bottles containing the antigen for cracks or leakage. Depending on type, volume and how they are stored there may also be value in weighing antigen deposits annually to ensure they have not lyophilised. Some FMD vaccine banks have incorporated physico-chemical tests like SDS Page or sucrose density gradient analyses to monitor virus integrity and hence stability and some have also carried out in-vivo tests. However, since it has been shown that the shelf-lives of FMD antigen concentrates are likely to be well in excess of 15 years when stored at ultra-low temperature a physico-chemical approach would appear sufficient.

The following timetable of tests is proposed as suitable for validation and re-validation of stored antigens.

Time	Test
On receipt (year 0) and every 5 years thereafter	146S quantification* Potency test in cattle which, at the discretion of the bank holder, may be a 'truncated' test** to demonstrate that the minimum potency of the vaccine remains greater than the minimum requirement or may rely on serological techniques where potency has been adequately correlated with immunogenicity for the antigen concerned (see section on Potency for detail)
Years 2 and 4, and immediately before formulation if the need arises	146S quantification
Every 5 years	Evaluation of all data for the preceding 5 years to assess need to replace antigen

* Other physiochemical tests such as SDS-PAGE have been used to evaluate integrity of VP1 but are not sufficiently validated for routine use.

** In a truncated test all animals in the next lower volume group are assumed to have not been protected. The test therefore gives an artificially low PD_{50} value but reduces the number of animals required.

To support this testing depositories of antigen concentrates should include a number of small samples that are representative of the larger stock. Small aliquots/stocks of FMD antigen have usually consisted of a volume representing approximately one milligram of antigen.

REFERENCES

1. ADAMOWICZ PH., LEGRAND B., GUERCHE J. & PRUNET P. (1974). Un nouveau procedé de concentration et de purification du virus. Application du virus de la fièvre aphteuse produit sur cellules BHK21 pour l'obtention des vaccins hautement purifiés. *Bull. OIE*, **81**, 1125–1150.

2. AMAREL-DOEL C.M.F., OWEN N.E., FERRIS N.P., KITCHING R.P. & DOEL T.R. (1993). Detection of foot-and-mouth disease viral sequences in clinical specimens and ethyleneimine-inactivated preparations by the polymerase chain reaction. *Vaccine*, **11**, 415–421.

3. AUGE DE MELLO P., GOMES I. & BAHNEMANN H.G. (1989). The vaccination of young cattle with an oil adjuvant foot-and-mouth disease vaccine. *Bol. Centr. Panam. Fiebre. Aftosa*, **55**, 3–14.

4. BAHNEMANN H.G. (1975). Binary ethyleneimine as an inactivant for foot-and-mouth disease virus and its application for vaccine production. *Arch. Virol*., **47**, 47–56.

5. BAHNEMANN H.G. (1990). Inactivation of viral antigens for vaccine preparation with particular reference to the application of binary ethylenimine. *Vaccine,* **8**, 299–303.

6. BARNETT P.V., PULLEN L., WILLIAMS L. & DOEL T.R. (1996). International bank for foot-and-mouth disease vaccine: assessment of Montanide ISA 25 and ISA 206, two commercially available oil adjuvants. *Vaccine*, **14**, 1187–1198.

7. BARTELING S.Z. & VREESWIJK Z. (1991). Developments in foot-and-mouth disease vaccines. *Vaccine*, **9**, 75–88.

8. BASTOS A.D.S. (1998). Detection and characterization of foot-and-mouth disease virus in sub-Saharan Africa. *Onderstepoort J. Vet. Res.,* **65**, 37–47.

9. BERGMANN I.E., MALIRAT V., NEITZERT E., PANIZUTTI N., SANCHEZ C. & FALCZUK A. (2000). Improvement of serodiagnostic strategy for foot and mouth disease virus surveillance in cattle under systematic vaccination: a combined system of an indirectELISA-3ABC with an enzyme-linked immunoelectrotransfer blot. *Arch. Virol.,* **145**, 473–489.

10. CLARKE J.B. & SPIER R.E. (1980). Variation in the susceptibility of BHK populations and cloned cell lines to three strains of foot-and-mouth disease virus. *Arch. Virol.,* **63**, 1–9.

11. DE DIEGO M., BROCCHI E., MACKAY D. & DE SIMONE F. (1997). The use of the non-structural polyprotein 3ABC of FMD virus as a diagnostic antigen in ELISA to differentiate infected from vaccinated cattle. *Arch. Virol.,* **142**, 2021–2033.

12. DOEL T.R. & BACCARINI P.J. (1981). Thermal stability of FMDV. *Arch. Virol.,* **70**, 21–32.

13. DOEL T.R. & COLLEN T. (1982). Qualitative assessment of 146S particles of FMDV in preparations destined for vaccines. *J. Biol. Stand*., **10**, 69–81.

14. DOEL T.R., FLETTON B. & STAPLE R.F. (1982). Further developments in the quantification of small RNA viruses by UV photometry of sucrose density gradients. *Dev. Biol. Stand*., **50**, 209–219.

15. DOEL T.R. & PULLEN L. (1990). International bank for foot-and-mouth disease vaccines: stability studies with virus concentrates and vaccines prepared from them. *Vaccine*, **8**, 473–478.

16. DOEL T.R. & STAPLE R.F. (1982). The elution of FMDV from vaccines adjuvanted with aluminium hydroxide and with saponin. *J. Biol. Stand*., **10**, 185–195.

17. DOEL T.R., WILLIAMS L. & BARNETT P.V. (1994). Emergency vaccination against foot-and-mouth disease. The rate of development of immunity and its implications for the carrier state. *Vaccine*, **12**, 592–600.

18. EUROPEAN PHARMACOPOEIA (1993). Second Edition. Monograph No. 63. Editions of the Council of Europe, Strasbourg, France.

19. EUROPEAN PHARMACOPOEIA (2002). Fourth Edition. Section 2.6.1 Editions of the Council of Europe, Strasbourg, France.

20. FERRIS N.P. & DAWSON M. (1988). Routine application of enzyme-linked immunosorbent assay in comparison with complement fixation for the diagnosis of foot-and-mouth and swine vesicular disease. *Vet. Microbiol*., **16**, 201–209.

21. FOOD AND AGRICULTURAL ORGANIZATION OF THE UNITED NATIONS (FAO) (1984). Emerging Diseases of Livestock. Vol. 1. The Diseases and their Diagnosis, Geering W.A., ed. FAO, Rome, Italy, 43–51.

22. FOOD AND AGRICULTURAL ORGANIZATION OF THE UNITED NATIONS (FAO) (1997). Potency assessment of inactivated viral vaccines. *In:* FAO Animal Production and Health Series No 35. Vaccine Manual. The Production and Quality Control of Veterinary Vaccines for use in Developing Countries, Mowat N. & Rweyemamu M., eds. FAO, Rome, Italy, 395–409.

23. GOLDING S.M., HEDGER R.S., TALBOT P. & WATSON J. (1976). Radial immunodiffusions and serum neutralisation techniques for the assay of antibodies to swine vesicular disease. *Res. Vet. Sci.*, **20**, 142–147.

24. HAMBLIN C., BARNETT I.T.R. & HEDGER R.S. (1986). A new enzyme-linked immunosorbent assay (ELISA) for the detection of antibodies against foot-and-mouth disease virus. I. Development and method of ELISA. *J. Immunol. Methods*, **93**, 115–121.

25. HAMBLIN C., KITCHING R.P., DONALDSON A.I., CROWTHER J.R. & BARNETT I.T.R. (1987). Enzyme-linked immunosorbent assay (ELISA) for the detection of antibodies against foot-and-mouth disease virus. 3. Evaluation of antibodies after infection and vaccination. *Epidemiol. Infect.*, **99**, 733–744

26. HERBERT W.J. (1965). Multiple emulsions. A new form of mineral-oil antigen adjuvant. *Lancet*, **II**, 771.

27. KITCHING R.P. & DONALDSON A.I. (1987). Collection and transportation of specimens for vesicular virus investigation. *Rev. sci. tech. Off. int. Epiz.*, **6**, 263–272.

28. MACKAY D.K. (1998). Differentiating infection from vaccination in foot-and-mouth disease. *Vet. Q.*, **20** (Suppl. 2), 2–5.

29. MACKAY D.K., BULUT A.N., RENDLE T., DAVIDSON F. & FERRIS N.P. (2001). A solid-phase competition ELISA for measuring antibody to foot-and-mouth disease virus. *J. Virol. Methods*, **97** (1–2), 33–48.

30. MACKAY D.K.J, FORSYTH M.A., DAVIES P.R., BERLINZANI, A., BELSHAM G.J., FLINT M. & RYAN M.D. (1997). Differentiating infection from vaccination in foot-and-mouth disease using a panel of recombinant, non-structural proteins in ELISA. *Vaccine*, **16**, 446–459.

31. MCVICAR J.W. & SUTMOLLER P. (1970). Foot-and-mouth disease: the agar gel immunodiffusion precipitin test for antibody to virus-infection-associated (VIA) antigen as a tool for epizootiologic surveys. *Am. J. Epidemiol.,* **92**, 273–278.

32. MINISTRY OF AGRICULTURE, FISHERIES AND FOOD (1986). Foot-and-mouth disease. Ageing of lesions. Her Majesty's Stationery Office, London, UK.

33. NEITZERT E., BECK E., AUGE DE MELLO P., GOMES I. & BERGMANN I.E. (1991). Expression of the aphthovirus RNA polymerase gene in *Escherichia coli* and its use together with other bioengineered non-structural antigens in detection of late persistent infections. *Virology*, **184**, 799–804.

34. OFFICE INTERNATIONAL DES EPIZOOTIES (2002). OIE Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases. Office International des Epizooties (OIE), 12 rue de Prony, 75017 Paris, France.

35. PAIBA G.A., ANDERSON J., PATON D.J., SOLDAN A.W., ALEXANDERSEN S., CORTEYN M., WILSDEN G., HAMBLIN P., MACKAY D.K.J. & DONALDSON A.I. (2004). Validation of a foot-and-mouth disease antibody screening solid-phase competition ELISA (SPCE). *J. Virol. Methods,* **115**, 145–158.

36. ROEDER P.L. & LE BLANC SMITH P.M. (1987). The detection and typing of foot-and-mouth disease virus by enzyme-linked immunosorbent assay: a sensitive, rapid and reliable technique for primary diagnosis. *Res. Vet. Sci.,* **43**, 225–232.

37. SAMUEL A.R., OULDRIDGE E.J., ARROWSMITH A.E.M., KITCHING R.P. & KNOWLES N.J. (1990). Serological analysis of type O isolates of FMD from the Middle East 1981–88. *Vaccine*, **8**, 390–395.

38. SKINNER H.H. (1960). Some techniques for producing and studying attenuated strains of the virus of foot and mouth disease. *Bull. OIE*, **53**, 634–650.

39. SORENSEN K.J., MADSEN K.G., MADSEN E.S., SALT J.S., NQUINDI J. & MACKAY D.K.J. (1998). Differentiation of infection from vaccination in foot-and-mouth disease by the detection of antibodies to the non-structural proteins 3D, 3AB and 3ABC in ELISA using antigens expressed in baculovirus. *Arch. Virol.*, **143**, 1461–1476.

40. STREBEL K., BECK E., STROHMAIER D. & SCHALLER H. (1986). Characterisation of foot-and-mouth disease virus gene products with antisera against bacterially synthesised fusion proteins. *J. Virol.*, **57**, 983–991.

41. VAN MAANEN C. (1990). A complex-trapping-blocking (CTB) ELISA, using monoclonal antibodies and detecting specifically antibodies directed against foot and mouth disease types A, O and C. 1. Method and characteristics. *Vet. Microbiol.*, **24**, 171–178.

42. VIANNA FILHO Y.L., ASTUDILLO V., GOMES I., FERNANDEZ G., ROZAS C.E.E., RAVISON J.A. & ALONSO A. (1993). Potency control of foot-and-mouth disease vaccine in cattle. Comparison of the 50% protective dose and protection against generalisation. *Vaccine*, **11–14**, 1424–1428.

43. WAGNER G.G., CARD J.L. & COWAN K.M. (1970). Immunochemical studies of foot-and-mouth disease virus. VII. Characterization of foot-and-mouth disease virus concentrated by polyethylene glycol precipitation. *Arch. Ges. Virusforsch.*, **30**, 343–352.

44. WOODBURY E.L., ILOTT M.C., BROWN C.C. & SALT J.S. (1995). Optimization of an *in situ* hybridization technique for the detection of foot-and-mouth disease virus in bovine tissues using the digoxigenin system. *J. Virol. Methods*, **51**, 89–94.

*
* *

NB: There are OIE Reference Laboratories for Foot and mouth disease (see Table in Part 3 of this *Terrestrial Manual* or consult the OIE Web site for the most up-to-date list: www.oie.int).

ADVICE FOR MEMBER COUNTRY COMMENTS

Chapter Number and Title: 2.7.12. Highly pathogenic avian influenza*

* As you may be aware, the OIE Terrestrial Animal Health Standards Commission is proposing an updated chapter on avian influenza for inclusion in the *Terrestrial Animal Health Code*. Should this updated chapter be adopted in May 2005, the OIE Biological Standards Commission will propose chapter 2.7.12 Avian influenza (next chapter in this batch) for inclusion in the *Terrestrial Manual*. If the *Terrestrial Code* chapter is not adopted, the OIE Biological Standards Commission will propose chapter 2.7.12 Highly pathogenic avian influenza (this chapter) for inclusion in the *Terrestrial Manual*.

Country making the comments: Community

Date: 8-4-05

General Comments

NONE

Specific Comments (add continuation sheets if required)

NONE

line:

ADVICE FOR MEMBER COUNTRY COMMENTS

Chapter Number and Title: 2.7.12. Avian influenza*

* As you may be aware, the OIE Terrestrial Animal Health Standards Commission is proposing an updated chapter on avian influenza for inclusion in the *Terrestrial Animal Health Code*. Should this updated chapter be adopted in May 2005, the OIE Biological Standards Commission will propose chapter 2.7.12 Avian influenza (this chapter) for inclusion in the *Terrestrial Manual*. If the *Terrestrial Code* chapter is not adopted, the OIE Biological Standards Commission will propose chapter 2.7.12 Highly pathogenic avian influenza (previous chapter in this batch) for inclusion in the *Terrestrial Manual*.

Country making the comments: Community

Date: 8-4-05

General Comments

The collection of truely tracheal swabs from alive birds is difficult for the unexperienced. Therefore, most swabs will be sampled from oro-pharyngeal sites if the bird is alive on sampling. Tracheal swabs are less difficult to obtain from dead birds. Due to the – usually –
extremely narrow nasal cavity in most bird species, oro-nasal sampling is impossible and should not be mentioned in the manual. The specific comments refer to this Statement.

Specific Comments (add continuation sheets if required)

line 91: oropharyngeal or tracheal swabs
line 94: oropharyngeal
line 332: oropharyngeal or tracheal swabs from clinically affected or dead birds
line 341: oropbaryngeal

ADVICE FOR MEMBER COUNTRY COMMENTS

Chapter Number and Title: 2.5.1. **Contagious equine metritis**

Country making the comments : Community

Date : April, 1st 2005

General comments

No technical error has been detected and the main diagnostic methods are presented.

However, could it be possible to specify if during the screening for contagious equine metritis (caused by *Taylorella equigenitalis*), the presence of *Taylorella asinigenitalis* must be considered as a negative or a positive result?

Specific Comments (add continuation sheets if required)

Line 147 : In France, swabs should arrive at the laboratory no later than 24 hours.

Line 171 : The second part of the sentence is unclear. The culture media prepared should be tested by inoculation of small numbers of *T. equigenitalis* before their use on suspect samples.

Line 188 : In France, results of culture are certified 6 days after the plate inoculation and incubation.

Foot note 2 page 4 : a typing error has been found « Montpelier". The correct word is "Montpellier".

ADVICE FOR MEMBER COUNTRY COMMENTS

Chapter Number and Title: 2.3.12. Haemorrhagic septicaemia

Country making the comments: Community

Date: 8-4-05

General Comments

NONE

Specific Comments (add continuation sheets if required)

NONE

line:

ANNEX II

ADDITIONAL TSE TESTS

The Community proposes extending the current list of five rapid tests listed for the detection of the disease-specific forms of PrP with the new approved tests listed hereafter:

1. Name: Enfer TSE Kit version 2.0, automated sample preparation

   Company: Distributor: Abbott Diagnostics, Abbott Labs, 100 Abbott Park Road, Abbott Park, Il 60034-3500, USA.
   Supplier: Enfer Scientific Ltd., Newbridge Industrial Estate, Newbridge,
   Co. Kildare. Ireland.Description: Manual or Automated, qualitative microplate-based chemiluminescent immunoassay for the detection of resistant prion protein (PrP^{res}). PrP^{res} in extracted samples is bound to prepared wells in microtitre plates and detected with an anti-PrP polyclonal primary antibody, a horseradish peroxidase-conjugated secondary antibody and a chemiluminescent substrate. Measured by chemiluminometry.

2. Name: CediTect BSE test

   Company: Cedi Diagnostics BV, Postbus 2271, 803 AG Lelystad, the Netherlands

   Description: Qualitative chemiluminescent filter ELISA which uses a proteinase K digested homogenate in the immunodetection procedure. 2 samples of the sample homogenate are used, one treated with chaotrophic agent and the other is not. The chaotrophic agent aids breakdown of quaternary structures, making residual epitopes fully accessible to detecting antibody. Measured by chemiluminometry

3. Name: IDEXX HerdChek BSE Antigen Test Kit, EIA

   Company: IDEXX Laboratories, One IDEXX Drive, Westbrook, ME 04092, USA

   Description: Antigen-capture enzyme linked immunoassay using a chemical polymer for selective PrP^{Sc} capture and a horse radish peroxidase conjugated monoclonal detection antibody. Colour development relates to the amount of PrP^{Sc} captured by the ligand immobilised on the plate. The reaction is measured by reading absorbance of the colour reaction.

4. Name: Institut Pourquier Speed'it BSE

   Company : Institut Pourquier, 326 rue de la Galera – 34097 MONTPELIER Cedex 5 France

   Description : Plate-based sandwich immunoassay using horseradish peroxidase-conjugated monoclonal antibody directed against unfolded PrP^{Sc} to detect proteinase K resistant PrP fractions from the digest that are captured by a different plate-bound monoclonal antibody. Measured by chemiluminometry.

5. Name : Prionics-Check PrioSTRIP

   Company : Prionics AG, Wagistrasse 27a, CH-8952 Schlieren, Switzerland

   Description: Immunochromatogenic assay which uses two different monoclonal antibodies to detect Proteinase K resistant PrP fractions. Proteinase K treated

homogenate is incubated with a monoclonal antibody conjugate. Strips are applied to sample conjugate. Read visually or automatically.

6. Name: Roboscreen Beta Prion BSE EIA Test Kit

   Company: Roboscreen GmbH, Delitzersche Strasse 135, Laborgebäude, D- 04129 Leipzig

   Description: Sandwich immunoassay using two different monoclonal antibodies directed against two epitopes presented in a highly unfolded state of bovine PrP^{Sc}. Homogenisation is carried out, which includes Proteinase K digestion and a stringent unfolding step of PK resistant PrP. Measured by colorimetry.

7. Name: Roche Applied Science PrionScreen

   Company: Roche Diagnostics GmbH, Werk Penzberg, Nonnenwald 2, 82372 Penzberg

   Description: Plate-based sandwich immunoassay which uses horseradishperoxidase-conjugated monoclonal antibody directed against unforlded PrP^{Sc} to detect proteinase K resistant PrP fractions from the digest that are captured by a different, biotin –conjugated antibody which is bound to the plate well. The colour reaction is measured by optical density.

WELFARE

Appendix XXII

Community position:
Concerning the development of these animal welfare guidelines the Community is very pleased at the excellent progress being made in this important new area of work for the OIE. The ad hoc groups are to be commended on the preparation of these important guidelines within such a short timeframe since the OIE has assumed its new animal welfare mandate. The Community wishes to emphasise the need for such animal welfare guidelines to have a solid scientific basis and looks forward to the OIE extending its work in the animal welfare area to cover over issues included within the OIE animal welfare mandate (e.g. farmed fish, animals used for experimental purposes etc.). Some drafting comments are included in the text below. As a general comment since the guidelines share many general principles and themes (e.g. land and sea transport) care should be taken to ensure consistency in the common terminology used across the guidelines and to avoid discrepancies in the general principles which are shared by separate guidelines. Clarification is also needed on the scope of these guidelines and in particular the animal species to which they will be applicable. The proposed definition of the term "animal" and species to which the guidelines will be applicable should also be clarified.

GUIDELINES FOR THE SLAUGHTER OF ANIMALS FOR HUMAN CONSUMPTION

The ad hoc *group approached its work by assessing the animal welfare concerns associated with every procedure during the pre-slaughter and slaughter processes, reviewing them on the basis of the available scientific data, independent of any religious or cultural context. Once those animal welfare concerns were qualified, the ad hoc group considered the specific issues associated with slaughter without stunning, such as the necessary restraint, the pain likely to be associated with the cut (for which it noted that there were no definitive data) and distress prior to unconsciousness (using available data to estimate the length of this period).*

The ad hoc *group acknowledged the significance of religious requirements, cultural and ethnic factors associated with some forms of slaughter. The* ad hoc *group felt it important that these should not be treated as exempt from these guidelines, which are intended to provide a framework within which variations to certain steps in the process may be practised to improve animal welfare.*

The ad hoc *group believed that methods of lairaging, and the moving and restraining of animals prior to and during religious slaughter are separate issues from religious slaughter requirements; with regard to restraint, there is a wide variation in methods, ranging from those with acceptable animal welfare to some which are totally unacceptable under any slaughter method. The* ad hoc *group also contended that some distressful and painful methods applied to conscious animals such as shackling and hoisting by the hind leg(s) or dragging by the leg(s) are not part of any religious requirements, are unacceptable in all circumstances, and should be phased out.*

Article 1

General principles for slaughter

These guidelines address the need to ensure the welfare of food animals during pre-slaughter and slaughter processes, until they are dead.

Community position:

It should be clarified whether these guidelines also apply to animals killed outside slaughterhouses. In the next sentence a reference to "camelids" should be inserted after the word "ratites" since camelids are frequently referred to in these guidelines.

These guidelines apply to those domestic animals commonly slaughtered in slaughterhouses, that is: cattle, buffalo, sheep, goats, deer, horses, pigs, ratites and poultry. Other animals, wherever they have been reared, should be managed to ensure that their transport, lairaging, restraint and slaughter is carried out without causing undue stress to the animals; the principles underpinning these guidelines apply also to these animals.

Personnel

Community position:
It is important to state that personnel should be properly trained, including with regard to animal welfare aspects. The Community suggests the following insertion (italicised) "be patient, considerate, competent, ***demonstrate a positive attitude to animal welfare*** and be familiar with the guidelines in this document and their application within the national context"

Persons engaged in the unloading, moving, lairaging, care, restraining, stunning, slaughter and bleeding of animals play an important role in the welfare of those animals. For this reason, there should be a sufficient number of personnel, who should be patient, considerate, competent and familiar with the guidelines in this document and their application within the national context

Community position:
For clarity the word "good" should be inserted before "animal welfare".

The management of the slaughterhouse and the *Veterinary Services* should ensure that slaughterhouse staff carry out their tasks in accordance with the principles of animal welfare.

Animal behaviour

Animal handlers should be experienced and competent in handling and moving farm livestock, and understand the behaviour patterns of animals and the underlying principles necessary to carry out their tasks.

The behaviour of individual animals or groups of animals will vary, depending on their breed, sex, temperament and age and the way in which they have been reared and handled. Despite these differences, the following behaviour patterns which are always present to some degree in domestic animals, should be taken into consideration in handling and moving the animals.

Appendix XXII (contd)

Most domestic livestock are kept in herds and follow a leader by instinct.

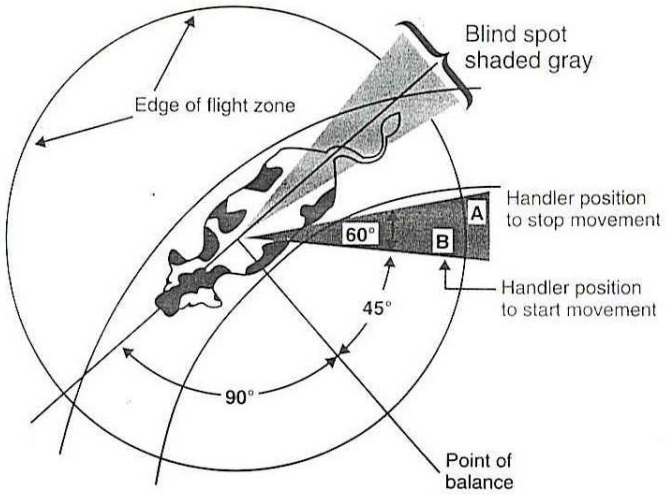
Community position:
For additional clarity the following sentence should be added to the end of the next sentence: "As an example horned and non-horned animals should not be mixed in the same areas of a slaughterhouse (pens and races)."

Animals which are likely to be hostile to each other in a group situation should not be mixed at slaughterhouses.

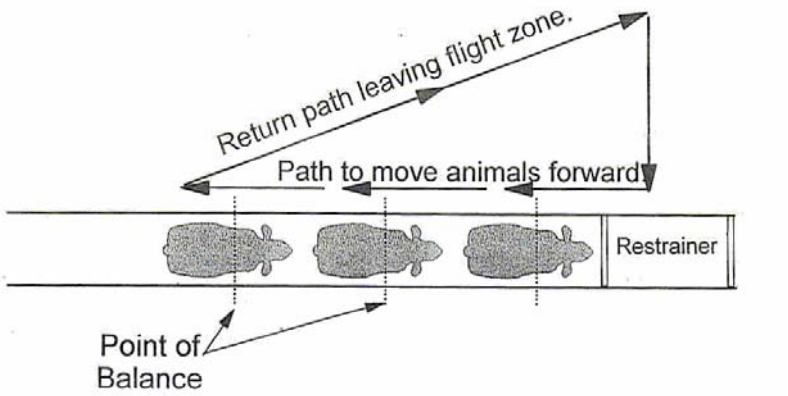
The desire of some animals to control their personal space should be taken into account in designing facilities.

Domestic animals will try to escape if an animal handler approaches closer than a certain distance. This critical distance, which defines the flight zone, varies among species and individuals of the same species, and depends upon previous contact with humans. Animals reared in close proximity to humans i.e. tame have no flight zone, whereas those kept in free range or extensive systems may have flight zones which may vary from one metre to many metres. Animal handlers should avoid sudden penetration of the flight zone which may cause a panic reaction which could lead to aggression or attempted escape.

An example of a flight zone (cattle)



Handler movement pattern to move cattle forward



Animal handlers should use the point of balance at an animal's shoulder to move animals, adopting a position behind the point of balance to move an animal forward and in front of the point of balance to move it backward.

Domestic animals have wide-angle vision but only have limited forward binocular vision and poor perception of depth. This means that they can detect objects and movements beside and behind them, but can only judge distances directly ahead.

Although all domestic animals have a highly sensitive sense of smell, they react in different ways to the smells of slaughterhouses. Smells which cause fear or other negative responses should be taken into consideration when managing animals.

Appendix XXII (contd)

Community position:
The following sentence should be added to the end of the next paragraph: "Sensitivity to such noises should also be taken into account when handling animals".

Domestic animals can hear over a greater range of frequencies than humans and are more sensitive to higher frequencies. They tend to be alarmed by constant loud noise and by sudden noises, which may cause them to panic.

Distractions and their removal

Distractions that may cause approaching animals to stop, baulk or turn back should be designed out from new facilities or removed from existing ones. Below are examples of common distractions and methods for eliminating them:

- Reflections on shiny metal or wet floors - move a lamp or change lighting.
- Dark entrances to chutes, races, stun boxes or conveyor restrainers - illuminate with indirect lighting which does not shine directly into the eyes of approaching animals.
- Animals seeing moving people or equipment up ahead - install solid sides on chutes and races or install shields.
- Chains or other loose objects hanging in chutes or on fences - remove them.
- Uneven floors or a sudden drop in floor levels at the entrance to conveyor restrainers – avoid uneven floor surfaces or install a solid false floor under the restrainer to provide an illusion of a solid and continuous walking surface.

Community position:
The following text should be added to the end of the next bullet point to provide extra clarity: "or vent high pressure to the external environment using flexible hosing".

- Sounds of air hissing from pneumatic equipment - install silencers or use hydraulic equipment.
- Clanging and banging of metal objects - install rubber stops on gates and other devices to reduce metal to metal contact.
- Air currents from fans or air curtains blowing into the face of animals - redirect or reposition equipment.

Article 2

Moving and handling animals

The following principles should apply to unloading animals, moving them into lairage pens, out of the lairage pens and up to the slaughter point:

Community position:
The words "and health" should be inserted after the words "animal welfare" in the next bullet point.

- The conditions of the animals should be assessed upon their arrival for any animal welfare problems.
- Injured or sick animals, requiring immediate slaughter, should be killed humanely at the site where they are found.
- The use of force on animals that have little or no room to move should not occur.

Community position:
The following text should be added after the first sentence of the next bullet point to ensure correct interpretation and proper application of this provision: "Their use should be minimal and only permitted when an animal has a clear path ahead to move."

- The use of instruments which administer electric shocks (e.g. goads and prods) and their power output should be restricted to that necessary to assist movement of the animals. If such use is necessary, it should be limited to the hindquarters of pigs and large ruminants, and never on sensitive areas such as the eyes, mouth, ears, anogenital region or belly. Such instruments should not be used on horses, sheep and goats of any age, or on calves or piglets, nor on animals that have little or no room to move.

Community position:
The first sentence of the next bullet point should be deleted since it is vague and would be difficult to apply. The following text should be added to the end of the bullet point "When the regular slipping or falling of animals at a point in the slaughterhouse occurs it should be investigated for faults in flooring, raceway design, lighting or handling which should be rectified to enable free movement of the animals without the need to use such instruments".

- Performance standards should be established in which numerical scoring is used to evaluate the use of such instruments and to measure the percentage of animals moved with an electric instrument. In properly designed and constructed facilities with competent animal handlers, it should be possible to move 75% or more of the animals without the use of electric instruments.

Community position:
The wording of the next bullet point is unclear and should be replaced with this revised text : "Aids for moving animals such as panels, flags, plastic paddles, flappers (a length of cane with a short strap of leather or canvas attached), plastic bags and metallic rattles should be used in a manner sufficient to encourage and direct movement of the animals but without physical contact with them**."**

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

- Shouting or yelling at animals to encourage them to move should not occur as such actions may make the animals agitated, leading to crowding or falling.

- Implements which cause pain and suffering such as large sticks, sticks with sharp ends, metal piping, fencing wire or heavy leather belts should not be used to move animals.

- Animals should be grasped or lifted in a manner which avoids pain or suffering and physical damage (e.g. bruising, fractures, dislocations). In the case of quadrupeds, manual lifting by a person should only be used in young animals or small species, and in a manner appropriate to the species; grasping or lifting such animals only by their wool, hair, feet, neck, ears or tails causing pain or suffering should not be permitted, except in an emergency where animal welfare or human safety may otherwise be compromised.

- Conscious animals should not be thrown or dragged.

- Animals should not be forced to move at a speed greater than their normal walking pace, in order to minimise injury through falling or slipping. Performance standards should be established where numerical scoring of the prevalence of animals slipping or falling is used to evaluate whether animal moving practices and/or facilities should be improved. In properly designed and constructed facilities with competent animal handlers, it should be possible to move 99% of animals without their falling.

Community position:
The following bullet point should be re-worded as "Animals should not be forced to walk over the top of other animals".

-

- Animal handlers should not force an animal to walk over the top of other animals.

Community position:
The second sentence of the next bullet point should be re-worded as "Animal handlers should never apply an injurious object or irritant substance to animals and especially not to sensitive areas such as eyes, mouth, ears, anogenital region or belly.**"**

- Under no circumstances should animal handlers resort to violent acts to move animals, such as crushing or breaking animals' tails, grasping animals' eyes or pulling them by their ears.

Requirements for animals delivered in containers

Community position:
To provide more clear instructions to the readers of these guidelines in safeguarding animal welfare the following sentence should be added to the end of the next bullet point: "Such containers should carry labels to indicate the presence of live animals and also indicating the top surface of the container."

- Containers in which animals are transported should be handled with care, and should not be thrown, dropped or knocked over. Where possible, they should be loaded and unloaded horizontally and mechanically.

- Animals delivered in containers with perforated or flexible bottoms should be unloaded with particular care in order to avoid injury. Where appropriate, animals should be unloaded from the containers individually.

- Animals which have been transported in containers should be slaughtered as soon as possible; mammals and ratites which are not taken directly upon arrival to the place of slaughter should have drinking water available to them from appropriate facilities at all times. Delivery of poultry for slaughter should be scheduled such that they are not deprived of water at the premises for longer than 12 hours. Animals which have not been slaughtered within 12 hours of their arrival should be fed, and should subsequently be given moderate amounts of food at appropriate intervals.

Appendix XXII (contd)

Community position:
In the title the plural form "Provisions" should be used.

Provision relevant to restraining and containing animals

Provisions relevant to restraining animals for stunning or slaughter without stunning, to help maintain animal welfare include:

Community position:
The following two bullet points should be added to the end of this list to facilitate clearer application of these guidelines:

The means of restraint and the position that the animal is held in should assist in achieving an effective stun.
The means of restraint should be suitable or adaptable for all species and sizes of animals for which its use is intended.

- Provision of a non-slip floor
- Avoidance of excessive pressure applied by restraining equipment that causes struggling or vocalisation in animals
- Equipment engineered to reduce noise of air hissing and clanging metal
- Absence of sharp edges in restraining equipment that would harm animals
- Avoidance of jerking or sudden movement of restraining device

Methods of restraint causing avoidable suffering, such as the following, should not be used in conscious animals because they cause severe pain and stress:

- suspending or hoisting animals (other than poultry) by the feet or legs
- indiscriminate and inappropriate use of stunning equipment
- mechanical clamping of an animal's legs or feet (other than shackles used in poultry and ostriches) as the sole method of restraint
- breaking legs, cutting leg tendons or blinding animals in order to immobilise them
- severing the spinal cord, for example using a puntilla or dagger, to immobilise animals
- using electric currents to immobilise animals, except for proper stunning.

Article 3

Lairage design and construction

The lairage should be designed and constructed to hold an appropriate number of animals in relation to the throughput rate of the slaughterhouse without compromising the welfare of the animals.

In order to permit operations to be conducted as smoothly and efficiently as possible without injury or undue stress to the animals, the lairage areas should be designed and constructed so as to allow the animals to move freely in the required direction, using their behavioural characteristics and without undue penetration of their flight zone.

The following guidelines may help to achieve this.

Design

Community position:
The word "number" should be inserted after the word "minimum".

- The lairage should be designed to allow a one-way flow of animals from unloading to the point of slaughter, with a minimum of abrupt corners to negotiate.

Community position:
In order to ensure proper safeguards for animal health and welfare the text "in the form of an isolation pen with suitable equipment and facilities" should be added after the word "provided".

- In red meat slaughterhouses, pens, passageways and races should be arranged in such a way as to permit inspection of animals at any time, and to permit the removal of sick or injured animals when considered to be appropriate, for which separate appropriate accommodation should be provided.

Community position:
Suggested minor grammatical re-wording of the end of the last sentence of the first bullet point: "without introducing a risk of bruising and injury in the animals, and should not hinder the movement of the animals."

- Each animal should have room to stand up and lie down and, when confined in a pen, to turn around. The lairage should have sufficient accommodation for the number of animals intended to be held. Drinking water should always be available to the animals, and the method of delivery should be appropriate to the type of animal held. Troughs should be designed and installed in such a way as to minimise the risk of fouling by faeces, without introducing risk of bruising and injury in animals, and should not hinder the movement of animals.

- Holding pens should be rectangular rather than square, to allow as many animals as possible to stand or lie down against a wall. Where feed troughs are provided, they should be sufficient in number and feeding space to allow adequate access of all animals to feed. The feed trough should not hinder the movement of animals.

Community position:
For improved clarity the wording of the next bullet point should be replaced with this revised text : "Where tethers, ties or individual stalls are used, these should be designed so as not to cause injury or distress to the animals and should also allow the animals to stand, lie down and access any food or water that may need to be provided**."**

- Where tethers, ties or individual stalls are used, these should be designed so as not to cause injury or distress especially when the animals are lying down, standing up, drinking and feeding.

- Passageways and races should be either straight or slightly curved, as appropriate to the animal species. Passageways and races should have solid sides, but when there is a double race the shared partition should allow adjacent animals to see each other. For pigs and sheep, passageways should be wide enough to enable two or more animals to walk side by side for as long as possible. At the point where passageways are reduced in width, this should be done by a means which prevents excessive bunching of the animals.

- Animal handlers should be positioned alongside races and passageways on the inside radius of any curve, to take advantage of the natural tendency of animals to circle an intruder. Where one-way gates are used, they should be of a design which avoids bruising. Races should be horizontal but where there is a slope, they should be constructed to allow the free movement of animals without injury.

- There should be a waiting pen, with a level floor and solid sides, between the holding pens and the race leading to the point of stunning or slaughter, to ensure a steady supply of animals for stunning or slaughter and to avoid having animal handlers trying to rush animals from the holding pens. The waiting pen should preferably be circular, but in any case, so designed that animals cannot be trapped or trampled.

- Ramps or lifts should be used for loading and unloading of animals where there is a difference in height or a gap between the floor of the vehicle and the unloading area. The ramp should be well drained, non-slippery and adjustable to facilitate easy movement of animals without causing distress or injury.

Community position:
To ensure proper animal welfare safeguards an additional bullet point should be added as follows :
"Unloading ramps should be designed and constructed so as to permit animals to be unloaded from vehicles on the level or at the minimum gradient achievable. Lateral side protection should be available to prevent animals escaping or falling."

-

Construction

- Lairages should be constructed and maintained so as to provide protection from unfavourable climatic conditions, using strong and resistant materials such as concrete and metal which has been treated to prevent corrosion. Surfaces should be easy to clean. There should be no sharp edges or protuberances which may injure the animals.

- Floors should be well drained and not slippery; they should not cause injury to the animals' feet. Where necessary floors should be insulated or provided with appropriate bedding. Drainage grids should be placed at the sides of pens and passageways and not where animals would have to cross them. Discontinuities or changes in floor patterns or texture which could cause baulking in the movement of animals should be avoided.

Appendix XXII (contd)

- Lairages should be provided with adequate lighting, but care should be taken to avoid harsh lights and shadows, which frighten the animals or affect their movement. The fact that animals will move more readily from a darker area into a well-lit area might be exploited by providing for lighting that can be regulated accordingly.

Community position:
For improved clarity the next bullet point should be replaced with the following text:
"*Lairages should be adequately ventilated to ensure that waste gases, e.g. ammonia are not allowed to build up and that draughts do not exist at animal height. Ventilation should be variable and able to cope with the range of expected climatic conditions and the number of animals the lairage will be expected to hold.***"**

-

- Lairages should be well ventilated, and the air flow should be arranged so that odours and draughts do not adversely affect the health and welfare of the anima1s.

- Care should be taken to protect the animals from excessively or potentially disturbing noises, for example by avoiding the use of noisy hydraulic or pneumatic equipment, and muffling noisy metal equipment by the use of suitable padding, or by minimising the transmission of such noise to the areas where animals are held and slaughtered.

- Where animals are kept in outdoor lairages without natural shelter or shade, they should be protected from the effects of adverse weather conditions.

Article 4

Care in lairages

Animals in lairages should be cared for in accordance with the following guidelines:

- As far as possible established groups of animals should be kept together. Each animal should have enough space to stand up, lie down and turn around. Animals hostile to each other should be separated.

- Where tethers, ties or individual stalls are used they should allow animals to stand up and lie down without causing injury or distress.

Community position:
For clarity the words "amounts of bedding" should be inserted after the word "sufficient".

- Where bedding is provided, it should be maintained in a condition that minimises risks to the health and safety of the animals, and sufficient should be used so that animals do not become soiled with manure.

- Animals should be kept securely in the lairage and care should be taken to prevent them from escaping and from predators.

- Suitable drinking water should be available to the animals on their arrival and at all times to animals in lairages unless they are to be slaughtered without delay.

- If animals are not to be slaughtered as soon as possible, suitable feed should be available to the animals on arrival and at intervals appropriate to the species. Unweaned animals should be slaughtered as soon as possible.

Community position:
For improved clarity and to facilitate proper application the next bullet point should be replaced with the following text: "Animals should arrive in the lairage clean and dry. In order to prevent heat stress, animals subjected to high temperatures, particularly pigs and poultry, should be cooled by the use of water sprays, fans or other suitable means However the potential for water sprays to reduce the ability of animals to thermoregulate (especially poultry) by reducing their capability to lose heat by evaporative cooling must be considered in any decision to use water sprays".

- In order to prevent heat stress, animals subjected to high temperatures, particularly pigs and poultry, should be cooled by the use of water sprays, fans or other suitable means.

Community position:
In the next bullet point the first word "That" should be replaced with the word "The". For clarity the following text should be added to the end of the bullet point : "Lighting should also be adequate to permit inspection of all animals. Subdued lighting, and for example, blue light may be useful in poultry lairages in helping to calm birds."

- That lairage area should be well lit in order to enable the animals to see clearly without being dazzled. During the night, the lights should be dimmed.

Community position:
The words "separated and" should be inserted before the word "treated" in the last sentence of the next bullet point. The word "humanely" should be inserted before the word "killed".

- The condition and state of health of the animals in a lairage should be inspected at least every morning and evening by a veterinarian or, under the latter's responsibility, by another competent person. Animals which are sick, weak, injured or showing visible signs of distress should be treated or killed immediately.

- Lactating dairy animals should be slaughtered as soon as possible. Dairy animals with obvious udder distension should be milked to minimise udder discomfort.

Community position:
The word "giving" should be replaced by "which have given". To ensure proper animal welfare safeguards an additional sentence should be added: "Under normal circumstances animals which are expected to give birth during a journey should not be transported".

- Pregnant animals giving birth during the journey or in the lairage should be slaughtered as soon as possible or provided with conditions which are appropriate for suckling and the welfare of the newborn.

Community position:
For clarity the next bullet point should be replaced with the following text: "Horned or tusked animals should be kept in familiar groups and not mixed with unhorned/untusked animals."

- Animals with horns or tusks capable of injuring other animals, if aggressive, should be penned separately.

Recommendations for specific species are described in detail in Articles 6-9.

Article 5

Management of foetuses during slaughter of pregnant animals

Community position:
The Community believes that due to the limited amount of scientific data currently available on this issue of the management of foetuses during the slaughter of pregnant animals, this text should be retained as being "under study".

Relevant scientific articles which should be reviewed include the following:

MELLOR D L & GREGORY N G 2003 New Zealand Veterinary Journal 51 2-13 Responsiveness, behavioural Arousal and awareness in fetal and newborn lambs: experimental, practical and therapeutic implications.

VAN DER VALK, J., MELLOR, D., BRANDS, R., FISCHER, R., GRUBER, F., GSTRAUNTHALER, G., HELLEBREKERS, L., HYLLNER, J., JONKER, H., PRIETO, P., THALEN, M. AND BAUMANS, V. (2004). The humane collection of fetal bovine serum and possibilities for serum-free cell and tissue culture. Toxicology In Vitro 18, 1-12.

MELLOR, D.J., DIESCH, T.J., GUNN, A.J. AND BENNET, L. (2005). The importance of 'awareness' for understanding fetal pain. Brain Research Reviews (in press).

(DEBARGE ,V.H., A. DELELIS, S. JAILLARD, B. LARRUE, P. DERUELLE, A.S. DUCLOY, F. PUECH u. L. STORME (2005): Effects of nociceptive stimuli on the pulmonary circulation in the ovine fetus. Am. J. Physiol. Regul. Integr. Comp. Physiol. 288 (2), S. 547-553). Other relevant scientific references are listed below.

AMERIOUN, E. u. M. WESTGREN (1998): Insufficient knowledge about pain in the unborn child. Lakartidningen 95 (25), S. 2959 – 2961.

GOODMAN, N.W. (1997): Changing tactics in the abortion afgument: does a fetus feel pain? Br. J. Hosp. Med. 58 (11), S. 550.

HUANG, W., J. DEPREST, C. MISSANT u. M. VAN DE VELDE (2004): Management of fetal pain during invasive fetal procedures. A review. Acta Anestiol. Belg. 55 (29, S. 119 – 123

MATHIEU-CAPUTO, D., M. DOMMERGUES, F. MULLER u. Y. DUMEZ (2000): Fetal pain. Presse Med. 29 (12), S. 663 – 669

MELLOR, D.J. u. K.J. STAFFORD (2004): Animal welfare implications of neonatal mortality in farm animals. Vet. Journal 168 (2), S. 118 – 133

SMITH, R.P., R. GITAU, V. GLOVER u. N.M. FISK (2000): Pain and distress in the human fetus. Eur. J. Obstet. Gynaecol. Reprod. Biol. 92 (1), S. 161 – 165

STRUMPER, D., M.E. DURIEUX, W. GOGARTEN, H. VAN AKEN, K. HARTLEB u. M.A. MARCUS (2003): Fetal plasma concentrations after amniotic sufentalnil in chronically instrumented pregnant sheep. Anaestesiology 98 (6), S. 1400 – 1406, Discussion 5A-6A

The welfare of foetuses during slaughter of pregnant animals needs to be safeguarded.

- Foetuses should not be removed from the uterus sooner than five minutes after the maternal neck or chest cut, to ensure absence of consciousness. A foetal heartbeat will usually still be present and foetal movements may occur at this stage, but these are only a cause for concern if the exposed foetus successfully breathes air.

- If a live mature foetus is removed from the uterus, it should be prevented from inflating its lungs and breathing air (e.g. by clamping the trachea).

- When uterine, placental or foetal tissues, including foetal blood, are not to be collected as part of the post-slaughter processing of pregnant animals, all foetuses should be left inside the unopened uterus until they are dead. When uterine, placental or foetal tissues are to be collected, where practical, foetuses should not be removed from the uterus until at least 15-20 minutes after the maternal neck or chest cut.

- If there is any doubt about consciousness, the foetus should be killed with a captive bolt or a blow to the head with a suitable blunt instrument.

The above guidelines do not refer to foetal rescue. Foetal rescue, the practice of attempting to revive foetuses found alive at evisceration of the dam, should not be attempted during normal commercial slaughter as it may lead to serious welfare complications in the newborn animal. These include impaired brain function resulting from oxygen shortage before rescue is completed, compromised breathing and body heat production because of foetal immaturity, and an increased incidence of infections due to a lack of colostrum.

Appendix XXII (contd)

Article 6

Community position:
The word "acceptable" should be deleted since this is open to a wide range of possible interpretations or mis-interpretations.

Summary of acceptable handling and restraining methods, and the associated animal welfare issues

Community position:
The importance of properly functioning equipment and operator competence should be emphasised as key AW requirements. Some methods such as gas and electrical methods can result in stunning and killing (gas stun/kill depending on exposure times etc.). The wording should be clarified accordingly. Some textual suggestions have been introduced directly into the table. Regarding the issue of the Weinberg pen the very serious animal welfare concerns associated with this system should be emphasised and the fact that it should not be used since alternative and more animal-friendly methods are available.

	Presentation of animals	Specific procedure	Specific purpose	AW concerns/implications	Key AW requirements highlight need for properly functioning equipment and operator competence	Applicable species
No restraint	Animals are grouped	Group container	Gas stunning (consider issue of gas stunning/killing)	Specific procedure is suitable only for gas stunning	Competent animal handlers in lairage; facilities; stocking density	Pigs, poultry
		In the field	Free bullet	Shooting distance, ~~calibre and ballistics~~ *Selection of appropriate firearm and ammunition, location of shot and achieving outright kill with first shot*	Operator competence	Deer
		Group stunning pen	Head-only electrical stunning Captive bolt	Uncontrolled movement of animals impedes use of hand operated electrical and	Competent animal handlers in lairage and at stunning point	Pigs, sheep, goats, calves

				mechanical stunning methods		
	Individual animal confinement	Stunning pen/box	Electrical and mechanical stunning methods	Loading of animal; accuracy of stunning method, slippery floor and animal falling down, *means of restricting head movement*	Competent animal handlers	Cattle, buffalo, sheep, goats, horses, pigs, deer, camelids, ratites
Restraining methods	Head restraint, upright	Halter/ head collar/bridle	Captive bolt Free bullet	Suitable for halter-trained animals; stress in untrained animals	Competent animal handlers	Cattle, buffalo, horses, camelids
	Head restraint, upright	Neck yoke	Captive bolt Electrical-head-only Free bullet Slaughter without stunning	Stress of loading and neck capture; stress of prolonged restraint, horn configuration; unsuitable for fast line speeds, animals struggling and falling due to slippery floor, excessive pressure	Equipment; competent animal handlers, prompt stunning or slaughter	Cattle
	Leg restraint	Single leg tied in flexion (animal standing on 3 legs)	Captive bolt Free bullet	Ineffective control of animal movement, misdirected shots, *potential for injury*	Competent animal handler	Breeding pigs (boars and sows)

Appendix XXII (contd)

	Presentation of animals	Specific procedure	Specific purpose	AW concerns/implications	Key AW requirements	Applicable species
Restraining methods	Upright restraint	Beak holding	Captive bolt Electrical-head-only	Stress of capture	Sufficient competent animal handlers	Ostriches
		Head restraint in electrical stunning box	Electrical-head-only	Stress of capture and positioning	Competent animal handler	Ostriches
	Holding body upright- manual	Manual restraint	Captive bolt Electrical-head-only Slaughter without stunning	Stress of capture and restraint; accuracy of stunning/slaughter	Competent animal handlers	Sheep, goats, calves, ratites, small camelids, poultry
	Holding body upright mechanical	Mechanical clamp / crush / squeeze/ V-restrainer (static)	Captive bolt Electrical methods Slaughter without stunning	Loading of animal and overriding; excessive pressure	Proper design and operation of equipment	Cattle, buffalo, sheep, goats, deer, pigs, ostriches
	Lateral restraint – manual or mechanical	Restrainer/cradle /cratch	Slaughter without stunning	Stress of restraint	Competent animal handlers	Sheep, goats, calves, camelids, cattle
	Upright restraint mechanical	Mechanical straddle (static)	Slaughter without stunning Electrical methods Captive bolt	Loading of animal and overriding	Competent animal handlers	Cattle, sheep, goats, pigs
	Upright restraint – manual or mechanical	Wing shackling	Electrical	Excessive tension applied prior to stunning	Competent animal handlers	Ostriches

Appendix XXII (contd)

	Presentation of animals	Specific procedure	Specific purpose	AW concerns/implications	Key AW requirements	Applicable species
Restraining and /or conveying methods	Mechanical - upright	V-restrainer	Electrical methods Captive bolt Slaughter without stunning	Loading of animal and overriding; excessive pressure, size mismatch between restrainer and animal	Proper design and operation of equipment	Cattle, calves, sheep, goats, pigs
	Mechanical- upright	Mechanical straddle – band restrainer (moving)	Electrical methods Captive bolt Slaughter without stunning	Loading of animal and overriding, size mismatch between restrainer and animal	Competent animal handlers, proper design and layout of restraint	Cattle, calves, sheep, goats, pigs
	Mechanical - upright	Flat bed/deck Tipped out of containers on to conveyors	Presentation of birds for shackling prior to electrical stunning Gas stunning	Stress and injury due to tipping in dump-module systems height of tipping conscious poultry broken bones and dislocations	Proper design and operation of equipment	Poultry
	Suspension and/or inversion	Poultry shackle	Electrical stunning Slaughter without stunning	Inversion stress; pain from compression on leg bones	Competent animal handlers; proper design and operation of equipment	Poultry
	Suspension and/or inversion	Cone (this term may need to be explained)	Electrical – head-only; Captive bolt Slaughter without stunning	Inversion stress	Competent animal handlers; proper design and operation of equipment	Poultry
	Upright restraint	Mechanical leg clamping	Electrical – head-only	Stress of resisting restraint in ostriches	Competent animal handlers; proper equipment design and operation	Ostriches

Community position:
The very serious animal welfare concerns associated with the Restraining by inversion method should be emphasised to a much greater degree. Alternative more animal welfare-friendly methods are available and should be used.

Appendix XXII (contd)

	Presentation of animals	Specific procedure	Specific purpose	AW concerns/implications	Key AW requirements	Applicable species
Restraining by inversion	Rotating box	Fixed side(s) (e.g. Weinberg)	Slaughter without stunning	*Very serious animal welfare concerns*, Inversion stress; stress of resisting restraint, prolonged restraint. Keep restraint as brief as possible	Proper design and operation of equipment. *Alternative more animal welfare friendly methods should be used.*	Cattle
Restraining by inversion		Compressible side(s)	Slaughter without stunning	Inversion stress, stress of resisting restraint, prolonged restraint. Preferable to rotating box with fixed sides; Keep restraint as brief as possible	Proper design and operation of equipment	Cattle
Body restraint	Casting/ hobbling	Manual	Mechanical stunning methods Slaughter without stunning	Stress of resisting restraint; animal temperament; bruising. Keep restraint as short as possible	Competent animal handlers	Sheep, goats, calves, small camelids, pigs
Leg restraints		Rope casting	Mechanical stunning methods Slaughter without stunning	Stress of resisting restraint; prolonged restraint, animal temperament; bruising. Keep restraint as short as possible	Competent animal handlers	Cattle, camelids
		Tying of 3 or 4 legs	Mechanical stunning methods Slaughter without stunning	Stress of resisting restraint; prolonged restraint, animal temperament; bruising. Keep restraint as short as possible	Competent animal handlers	Sheep, goats, small camelids, pigs

Appendix XXII (contd)

Article 7

Stunning methods

Stunning

The competence of the operators, and the appropriateness and effectiveness of the method used for stunning are the responsibility of the management of the slaughterhouse, and should be checked regularly by a competent authority.

Persons carrying out stunning should be properly trained and competent, and should ensure that:

Community position:
The digit "1" should be deleted.

- the animal is adequately restrained,1
- animals in restraint are stunned as soon as possible;
- the equipment used for stunning is maintained and operated properly in accordance with the manufacturer's recommendations, in particular with regard to the species and size of the animal;
- the instrument is applied correctly;
- stunned animals are bled out (slaughtered) as soon as possible,
- do not stun animals when slaughter is likely to be delayed.

Community position:
For clarity an additional bullet point should be added as follows

"Backup stunning devices should be available for immediate use if the primary method of stunning fails".

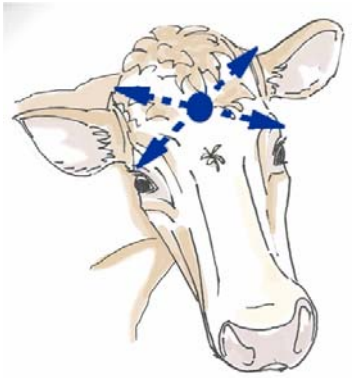
-

In addition, such persons should be able to recognise when an animal is not correctly stunned and should take appropriate action.

Mechanical stunning

A mechanical device should be applied usually to the front of the head and perpendicular to the bone surface. The following diagrams illustrate the proper application of the device for certain species.

Cattle



The optimum position for cattle is at the intersection of two imaginary lines drawn from the rear of the eyes to the opposite horn buds.

Community position:
A frontal view image of the optimal point of application for the pig would be clearer and preferable.

Pigs

Community position:
The letter "h" should be deleted from the word "chord".

The optimum position for pigs is just above the eyes and directing the shot down the line of the spinal chord.

Sheep

Community position:
The letter "h" should be deleted from the word "chord".

The optimum position for hornless sheep and goats is on the midline, just above the eyes and directing the shot down the line of the spinal chord.

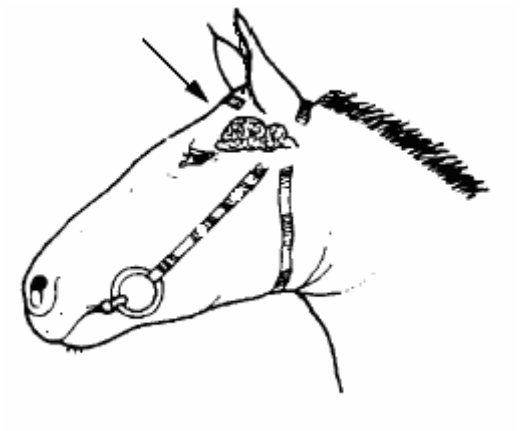
Goats

The optimum position for heavily horned sheep and horned goats is behind the poll, aiming towards the angle of the jaw.

Appendix XXII (contd)

Community position:
A frontal view image of the optimal point of application for the horse would be clearer and preferable.

Horses



Place the muzzle at right angles to the frontal surface well above the point where imaginary lines from eye to ear cross.

Signs of correct stunning using a mechanical instrument:

i) the animal collapses immediately and does not attempt to stand up;

ii) the body and muscles of the animal become tonic (rigid) immediately after the shot;

iii) normal rhythmic breathing stops; and

iv) the eyelid is open with the eyeball facing straight ahead and is not rotated.

Electrical stunning

a) General

An electrical device should be applied to the animal in accordance with the following guidelines.

Community position:
For clarity the words "effectively stunned already" should replace the word "stunned" in the next paragraph.

Electrodes should be designed, constructed, maintained and cleaned regularly to ensure that the flow of current is optimal and in accordance to manufacturing specification. They should be placed so that they span the brain. The application of electrical currents which bypass the brain are unacceptable unless the animal has been stunned. The use of a single current leg-to-leg is unacceptable as a stunning method.

If, in addition, it is intended to cause cardiac arrest, the electrodes should either span the brain and immediately thereafter the heart, on the condition that it has been ascertained that the animal is adequately stunned, or span brain and heart simultaneously.

Community position:
The word "shall" needs to be replaced by the word "should".

Electrical stunning equipment should not applied on animals as a means of guidance, movement, restraint or immobilisation, and shall not deliver any shock to the animal before the actual stunning or killing.

Community position:
For clarity the words "As part of routine maintenance" should be added to the start of the next paragraph.

Electrical stunning apparatus should be tested prior to application on animals using appropriate resistors or dummy loads to ensure the power output is adequate to stun animals.

The apparatus should incorporate a device which monitors and displays stunning current delivered to the animals

Community position:
The word "can" needs to be replaced by "should".

Appropriate measures, such as removing excess wool or wetting the skin only at the point of contact can be taken to minimise impedance of the skin and facilitate effective stunning.

Community position:
The word "indicate" should be replaced by "indicated".

The stunning apparatus requires for electrical stunning should be provided with adequate power to achieve continuously the minimum current level recommended for stunning as indicate in the table below:

Community position:
For sheep and goats under field conditions 1.0 amps is required as a minimum current level. 0.5 amps is only suitable under laboratory conditions as a minimum current level. For a clear scientific basis for this remark see page 77/78 the report of the European Food Safety Authority available via the website http://www.efsa.eu.int/science/ahaw/ahaw_opinions/495_en.html
Therefore in the table for sheep and goats 0.5 amps should be replaced by 1.0 amps

Species	*Minimum current levels*
Cattle	***1.5 amps***
Calves	***1.0 amps***
Pigs	***1.25 amps***
Sheep & Goats	***0.5 amps***
Ostriches	***0.4 amps***

Community position:
The words "not more than" should be inserted before the words "one second".

In all cases, the correct current level shall be attained within one second of the initiation of stun and maintained at least for between one and three seconds and in accordance with the manufacturer's instructions.

b) Electrical stunning of birds using a waterbath

In the case of birds suspended on a moving line, measures should be taken to ensure that the birds are not wing flapping at the entrance of the stunner. The birds should be secure in their shackle, but there should not be undue pressure on their shanks.

Waterbaths for poultry should be adequate in size and depth for the type of bird being slaughtered, and their height should be adjustable to allow for the head of each bird to be immersed. The electrode immersed in the bath should extend the full length of the waterbath. Birds should be immersed in the bath up to the base of their wings.

The waterbath should be designed and maintained in such a way that when the shackles pass over the water they are in continuous contact with the earthed rubbing bar.

The control box for the waterbath stunner should incorporate an ammeter which displays the total current flowing through the birds.

Community position:
To facilitate improved application of these guidelines the following text should be added to the end of the next paragraph: "Additional salt should be added regularly as a solution to maintain suitable constant concentrations in the waterbath."

The shackle-to-leg contact should be wetted preferably before the birds are inserted in the shackles. In order to improve electrical conductivity of the water it is recommended that salt be added in the waterbath as necessary.

Birds should receive the current for at least 4 seconds.

Using waterbaths, birds are stunned in groups and different birds will have different impedances. The voltage should be adjusted so that the total current is the required current per bird as shown in the table hereafter, multiplied by the number of birds in the waterbath at the same time.

Community position:
To ensure proper application the following text should be added: "Any water overflowing from a waterbath should be appropriately channelled away from the birds and workers to prevent pre-stun shocks."

Appendix XXII (contd)

Community position:
Water bath stunners for poultry often use frequencies of up to and over 500 Hz. Therefore minimum acceptable currents for these systems should also be elaborated.

The following values have been found to be satisfactory when employing a 50 Hertz sinusoidal alternating current.

Species	*Current (milliamperes per bird)*
Broilers	***120***
Layers (spent hens)	***120***
Turkeys	***150***
Ducks and Geese	***130***

While a lower current may also be satisfactory, the current shall in any case be such as to ensure that unconsciousness occurs immediately and lasts until the bird has been killed by cardiac arrest or by bleeding. When higher electrical frequencies are used, higher currents may be required.

Every effort shall be made to ensure that no conscious or live birds enter the scalding tank.

In the case of automatic systems, until fail-safe systems of stunning and bleeding have been introduced, a manual back-up system should be in place to ensure that any birds which have missed the waterbath stunner and/or the automatic neck-cutter are immediately stunned and/or humanely killed, and they are dead before entering scald tank.

Community position:
The word "slaughter" should be inserted before the word "line".

To lessen the number of unstunned birds, reaching neck cutters, steps should be taken to ensure that small birds do not go on the line amongst bigger birds and that these small birds are stunned separately.

Gas stunning

a) Stunning of pigs by exposure to carbon dioxide (CO_2)

Community position:
The word "there" should be inserted after the word "kept". "Occur" should be replaced by "occurs". The words "as rapidly as possible" should be added after the words "maximum concentration of the gas".

The concentration of CO_2 for stunning should be preferably 90% by volume but in any case no less than 80% by volume. After entering the stunning chamber the animals should be conveyed to the point of maximum concentration of the gas and be kept until they are dead or brought into a state of insensibility which lasts until death occur due to bleeding. Ideally, pigs should be exposed to this concentration of CO_2 for three minutes.

In any case, the concentration of the gas should be such that it minimises as far as possible all stress of the animal prior to loss of consciousness.

The chamber in which animals are exposed to CO_2 and the equipment used for conveying them through it shall be designed, constructed and maintained in such a way as to avoid injury or unnecessary stress to the

animals. The animal density within the chamber should be such to avoid stacking animals on top of each others.

Community position:
The following sentence should be added: "Sticking should occur as soon as possible after exit from the gas chamber."

The conveyor and the chamber shall be adequately lit to allow the animals to see their surroundings and if possible, each other.

It should be possible to inspect the CO_2 chamber whilst it is in use, and to have access to the animals in emergency cases.

Community position:
The word "a" should be inserted before the word "register", "of" should be inserted after the word "stunning".

The chamber shall be equipped to continuously measure and display register at the point of stunning the CO_2 concentration and the time of exposure, and to give a clearly visible and audible warning if the concentration of CO_2 falls below the required level.

b) Inert gas mixtures for stunning pigs (under development)

Inhalation of high concentration of carbon dioxide is aversive and can be distressing to animals. Therefore, the use of non-aversive gas mixtures is being developed.

Community position:
For clarity the heading should be amended to read as "Such gas mixtures include:".

Gas mixtures:

i) a maximum of 2% by volume of oxygen in argon, nitrogen or other inert gases, or

Community position:
The word "to" should be deleted.

ii) to a maximum of 30% by volume of carbon dioxide and a maximum of 2% by volume of oxygen in mixtures with carbon dioxide and argon, nitrogen or other inert gases.

Exposure time to the gas mixtures should be sufficient to ensure that no pigs regain consciousness before death supervenes through bleeding or cardiac arrest is induced.

c) Gas stunning of poultry

The main objective of gas stunning is to avoid the pain and suffering associated with shackling conscious poultry under water bath stunning and killing systems. Therefore, gas stunning should be limited to birds contained in crates or on conveyors only. The gas mixture should be non-aversive to poultry.

Gas stunning of poultry in their transport containers will eliminate the need for live bird handling at the processing plant and all the problems associated with the electrical stunning.

Gas stunning poultry on a conveyor eliminates the problems associated with the electrical water bath stunning.

Live poultry shall be conveyed into the gas mixtures either in transport crates or on conveyor belts.

Community position:

For clarity the heading should be amended to read as "Gas mixtures used for stunning poultry include:". The word "a" should be inserted before each method. A consistent notation of "min" or minutes" should be chosen.

i) Gas mixtures used for stunning poultry

- Minimum of 2 min exposure to 40% carbon dioxide, 30% oxygen and 30% nitrogen, followed by a minimum of 1 min exposure to 80% carbon dioxide in air; or

- Minimum of 2 min exposure to any mixture of argon, nitrogen or other inert gases with atmospheric air and carbon dioxide, provided that the carbon dioxide concentration does not exceed 30% by volume and the residual oxygen concentration does not exceed 2% by volume; or
- Minimum of 2 min exposure to argon, nitrogen, other inert gases or any mixture of these gases in atmospheric air with a maximum of 2% residual oxygen by volume; or
- Minimum of 2 minutes exposure to a minimum of 55% carbon dioxide in air.

ii) Requirements for effective use:

Community position:
For improved clarity the words "and should be at room temperature to prevent any thermal shock" should be added to the first bullet point. The first two bullet points should be combined by using the word "and"

- Compressed gases should be vaporised prior to administration into the chamber.
- Under no circumstances, should solid gases with freezing temperatures enter the chamber.
- Gas mixtures should be humidified.
- Appropriate gas concentrations should be monitored and displayed continuously at the level of the birds inside the chamber.

Appendix XXII (contd)

Under no circumstances should birds exposed to gas mixtures be allowed to regain consciousness. If necessary, the exposure time should be extended.

Bleeding

From the point of view of animal welfare, animals which are stunned with a reversible method should be bled without delay and in any case within the following time limits:

Community position:
The CO2 concentration should be clarified. It should be clarified whether the table refers to pigs and poultry. The word "captive" should be inserted before the word "bolt".

Stunning method	*Maximum delay for bleeding to be started*
Electrical methods and non penetrating bolt	***20 seconds***
CO_2	***60 seconds (after leaving the chamber)***

Community position:
The words "view of" should be inserted before the words "animal welfare".

All animals should be bled by incising both carotid arteries, or the vessels from which they arise (e.g. chest stick). However, when the stunning method used causes cardiac arrest, the incision of all of these vessels is not necessary from the point of animal welfare.

It should be possible for staff to observe, inspect and access the animals throughout the bleeding period. Any animal showing signs of recovering consciousness should be restunned.

After incision of the blood vessels, no scalding carcass treatment or dressing procedures should be performed on the animals for at least thirty seconds, or in any case until all brain-stem reflexes have ceased.

Article 8

Community position:
As previously indicated the word "acceptable" should be deleted from the table title.

Summary of acceptable stunning methods and the associated animal welfare issues

Community position:
The column heading "comment" could be replaced by a title such as "Other considerations". Some minor comments are indicated directly in the text.

Method	Specific method	AW concerns/implications	Key AW requirements applicable	Species	Comment
Mechanical	Free bullet	Inaccurate targeting and inappropriate ballistics	Accuracy; head shots only ~~correct ballistics~~, *Selection of appropriate firearm and ammunition, achieving outright kill with first shot*	Cattle, calves, buffalo, deer, horses, pigs (boars and sows)	Personnel safety
	Captive bolt - penetrating	Inaccurate targeting, velocity and diameter of bolt	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, buffalo, sheep, goats, deer, horses, pigs, camelids, ratites	Unsuitable for specimen collection from TSE suspects. A back-up gun should be available in the event of an ineffective shot
	Captive bolt - non-penetrating	Inaccurate targeting, velocity of bolt, potentially higher failure rate than penetrating captive bolt	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, sheep, goats, deer, pigs, camelids, ratites	Presently available devices are not recommended for young bulls and animals with a thick skull. *This device should not be used in young calves with inadequately ossified skulls*
	Manual percussive blow	Inaccurate targeting; insufficient power; size of instrument	Competent animal handlers; restraint;	Young and small mammals,	Mechanical devices potentially more reliable. Where manual percussive blow

			accuracy. Not recommended for general use	ostriches and poultry	is used, unconsciousness should be achieved with single sharp blow delivered to central skull bones
Electrical	Split application: 1. across head then head to chest; 2. across head then across chest	Accidental pre-stun electric shocks; electrode positioning; application of a current to the body while animal conscious; inadequate current and voltage	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, sheep, goats and pigs, ratites and poultry	Systems involving repeated application of head-only or head-to-leg with short current durations (<1 second) in the first application should not be used. Where cardiac arrest occurs, the carcass may not be suitable for Halal

Appendix XXII (contd)

Method	Specific method	AW concerns/implications	Key AW requirements applicable	Species	Comment
Electrical	Single application: 1. head only; 2. head to body; 3. head to leg	Accidental pre-stun electric shocks; inadequate current and voltage; wrong electrode positioning; recovery of consciousness	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, sheep, goats, pigs, ratites, poultry	Where cardiac arrest occurs, the carcass may not be suitable for Halal
	Waterbath	Restraint, accidental pre-stun electric shocks; inadequate current and voltage; recovery of consciousness	Competent operation and maintenance of equipment	Poultry only	Where cardiac arrest occurs, the carcass may not be suitable for Halal
Gaseous	CO_2 air/O_2 mixture; CO_2 inert gas mixture	Aversiveness of high CO_2; respiratory distress; inadequate exposure	Concentration; duration of exposure; design, maintenance and operation of equipment; stocking density management	Pigs, poultry	Gaseous methods may not be suitable for Halal
	Inert gases	Recovery of consciousness	Concentration; duration of exposure; design, maintenance and operation of equipment; stocking density management	Pigs, poultry	Gaseous methods may not be suitable for Halal

Article 9
Summary of acceptable slaughter methods, and the associated animal welfare issues

Community position:
Competent operators should be emphasised as a key requirement.

Slaughter methods	Specific method	AW concerns / implications	Key requirements	Species	Comments
Bleeding out by severance of blood vessels in the neck without stunning	Full frontal cutting across the throat	Failure to cut both common carotid arteries; occlusion of cut arteries	A very sharp blade or knife, of sufficient length so that the point of the knife remains outside the incision during the cut; the point of the knife should not be used to make the incision. An incision which does not close over the knife during the throat cut.	Cattle, buffalo, horses, camelids, sheep, goats, poultry, ratites	This method is applicable to Halal and Kosher for relevant species
Bleeding with prior stunning	Neck stab followed by forward cut	Ineffective stunning; failure to cut both common carotid arteries; impaired blood flow; delay in cutting after reversible stunning	Prompt and accurate cutting;	Camelids, sheep, goats, poultry, ratites	
	Neck stab alone	Ineffective stunning; failure to cut both common carotid arteries; impaired blood flow; delay in cutting after reversible stunning	Prompt and accurate cutting	Camelids, sheep, goats, poultry, ratites	
	Chest stick into major arteries or hollow-tube knife into heart	Ineffective stunning; Inadequate size of stick wound inadequate length of sticking knife; delay in sticking after reversible stunning	Prompt and accurate sticking;	Cattle, sheep, goats, pigs	
	Neck skin cut	Ineffective stunning; Inadequate	Prompt and accurate cutting of vessels	Cattle	

	followed by severance of vessels in the neck	size of stick wound; Inadequate length of sticking knife; delay in sticking after reversible stunning			

Appendix XXII (contd)

Slaughter methods	Specific method	AW concerns / implications	Key requirements	Species	Comments
Bleeding with prior stunning	Automated mechanical cutting	Ineffective stunning; failure to cut and misplaced cuts. Recovery of consciousness following reversible stunning systems	Design, maintenance and operation of equipment; accuracy of cut; manual back-up	Poultry only	
	Manual neck cut on one side	Ineffective stunning; recovery of consciousness following reversible stunning systems	Prior non-reversible stunning	Poultry only	N.B. slow induction of unconsciousness under slaughter without stunning
	Oral cut	Ineffective stunning; recovery of consciousness following reversible stunning systems	Prior non-reversible stunning	Poultry only	N.B. slow induction of unconsciousness in non-stun systems. *Major blood vessels to the head (carotids) may not be severed by an oral cut*
Other methods without stunning	Decapitation with a sharp knife	Pain due to loss of consciousness not being immediate		Sheep, goats, poultry	This method is only applicable to Jhatka
	Manual neck dislocation and decapitation	Pain due to loss of consciousness not being immediate; difficult to achieve in large birds	Neck dislocation should be performed in one stretch to sever the spinal cord	Poultry only	Slaughter by neck dislocation should be performed in one stretch to sever the spinal cord
Cardiac arrest in a waterbath electric stunner	Bleeding by evisceration		Induction of cardiac arrest	Quail	
	Bleeding by neck cutting			Poultry	

Article 10

Methods, procedures or practices unacceptable on animal welfare grounds

Community position:
The term "puntilla" may not be easily understood by many readers and should be clearly explained using a few words. It should be emphasised that electroimmobilisation should not be used as a restraining method in unstunned animals. The reference to fish does not seem appropriate in the Terrestrial Animals Code.

- The restraining methods through immobilisation by injury like 'puntilla', breaking legs and 'leg tendon cutting', cause severe pain and stress in animals. Those methods are not acceptable in any species.

- The use of electrical stunning method with single application leg to leg is ineffective and unacceptable in any species. The electrocution in this way is likely to be painful. The animal welfare concerns are:

    - accidental pre-stun electric shocks;
    - inadequate current and voltage;
    - wrong electrode positioning;
    - recovery of consciousness.

- The slaughter method of brain stem severance by piercing through the eye socket or skull bone is not acceptable in any species except fish.

Appendix XXII (contd)

GUIDELINES FOR THE LAND TRANSPORT OF ANIMALS

Article 1

Responsibilities

The welfare of animals during their *transport* is the joint responsibility of all people involved.

The roles of each of those responsible are defined below:

- Owners and managers of animals are responsible for the general health of the animals and their fitness for the *journey*, and their welfare during the *journey*, regardless of whether duties are subcontracted to other parties during *transport*. They are also responsible for ensuring compliance with any required veterinary or other certification, and for the presence during the *journey* of at least one *animal handler* competent for the species being transported, with the authority to take prompt action. They are also responsible for ensuring that equipment and veterinary assistance are provided as appropriate for the species and *journey*.

Community position:
For clarity the words "including any stops at resting points during the journey" should be added before the words "and for emergencies".

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

Community position:
For clarity the words "when such a journey log is required" should be added to the end of the first sentence.

- *Animal handlers* are responsible for the humane handling and care of the animals, especially during *loading* and *unloading*, and for maintaining a journey log. In the absence of a separate animal handler, the driver is the animal handler.

- Transport companies, *vehicle* owners and drivers are responsible for planning the *journey* to ensure the care of the animals:

  - transport companies and vehicle owners are responsible for choosing appropriate *vehicles* and ensuring that properly trained staff are available for *loading* and caring for animals,

  - transport companies and vehicle owners are responsible for developing and keeping up to date contingency plans to address emergencies and minimise stress during *transport*,

Community position:
The next bullet point should be re-worded as follows: "transport companies and vehicle owners are responsible for producing a journey plan when such a plan is required. This should include details of a loading plan, journey duration and location of resting places."

  -

- transport companies and vehicle owners are responsible for producing a journey plan which includes a loading plan, journey duration and location of resting places,
- drivers are responsible for *loading* only those animals which are fit to travel, for their correct *loading* into the *vehicle* and their inspection during the *journey*, and for appropriate responses to problems arising.

Community position:
An extra bullet point should be added: "transporters are also responsible for the welfare of the animals during the actual transport".

-

- Managers of facilities at the start and at the end of the *journey*, and at *resting points* are responsible for:
  - providing suitable premises for *loading*, *unloading* and securely holding the animals, with water and feed when required, until further *transport*, sale or other use (including rearing or slaughter),
  - providing competent animal handlers to load, unload, drive and hold animals in a manner that causes minimum stress and injury,
  - minimising the opportunities for disease transmission,
  - providing appropriate facilities, with water and feed when required,

- providing appropriate facilities for emergencies,
- providing facilities for washing and disinfecting *vehicles* after *unloading*,
- providing facilities and competent staff to allow the humane killing of animals when required,
- ensuring proper rest times and minimal delay during stops. See Article XXX

Community position:
The responsibilities of the Competent Authorities should include giving priority to animal consignments at frontiers in order to allow them to pass without undue delay. This should be recognised in the text.

- The responsibilities of *Competent Authorities* include:
  - establishing minimum standards for animal welfare, including requirements for inspection of animals before, during and after their *travel*, and appropriate certification and record keeping,
  - approving facilities, *containers* and *vehicles* for the *transport* of animals,
  - setting standards for the competence of drivers, *animal handlers* and managers,
  - ensuring appropriate awareness and training of drivers, *animal handlers* and managers,
  - implementation of the standards, including through accreditation of / interaction with other organisations,
  - monitoring and evaluating the effectiveness of standards of health and other aspects of welfare,
  - monitoring and evaluating the use of veterinary medications.
- All individuals, including veterinarians, involved in transporting animals and the associated handling procedures should receive appropriate training and be competent to meet their responsibilities.

Article 2

Competence

- All people handling animals, or who are otherwise responsible for animals during *journeys*, should be competent according to their responsibilities listed in Article 1. Competence may be gained through formal training or practical experience. Competence in areas other than animal welfare would need to be addressed separately.
- The competence of *animal handlers* should be demonstrated through a current certificate from an independent body, accredited by the *Competent Authority*. The certificate should be in one of the OIE official languages if the international *transport* of animals is involved.
- The assessment of the competence of *animal handlers* should at a minimum address knowledge, and ability to apply that knowledge, in the following areas:
  - planning a *journey*, including appropriate *space allowance*, and feed, water and ventilation requirements,

- responsibilities for animals during the *journey*, including *loading* and *unloading*,

Appendix XXII (contd)

- sources of advice and assistance,
- animal behaviour, general signs of disease, and indicators of poor animal welfare such as stress, pain and fatigue, and their alleviation,
- relevant authorities and applicable transport regulations, and associated documentation requirements,

Community position:
The words "and disinfection" should be added after the word "cleaning" in the next bullet point.

-
- general disease prevention procedures, including cleaning,
- appropriate methods of driving,
- methods of inspecting animals, managing situations frequently encountered during *transport* such as adverse weather conditions, and dealing with emergencies,
- species-specific aspects of animal handling and care, including feeding, watering and inspection,
- maintaining a journey log and other records.

Article 3

Planning the journey

Community position:
Planning should also incorporate forecasting expected transfer time when changing mode of transport (e.g. from vehicle to aeroplane or to roll-on roll-off vessel Expected waiting time at frontiers/ inspection points should also be taken into account.

General

- Adequate planning is a key factor affecting the welfare of animals during a *journey*.
- Before the journey starts, plans should be made in relation to:
  - preparation of animals for the *journey*,
  - choice of road or rail,
  - nature and duration of the *journey*,
  - *vehicle* / *container* design and maintenance, including roll-on roll-off vessels,
  - required documentation,
  - *space allowance*,
  - rest, water and feed,
  - observation of animals en route,
  - control of disease, and
  - emergency response procedures.

- Regulations concerning drivers (for example maximum driving periods) should be harmonised with maximum transport journey intervals appropriate for the species.

Preparation of animals for the journey

- When animals are to be provided with a novel diet or method of water provision during *transport*, an adequate period of adaptation should be planned.

- Animals should be exposed to appropriate contact with humans and handling conditions (including methods of restraint) prior to *transport* to reduce their fearfulness and improve their approachability (see Article 5).

- Behaviour-modifying compounds (such as tranquillisers) should not be used routinely during *transport*. Such compounds should only be administered when a problem exists in an individual animal, and should be administered by a veterinarian or other person who has been instructed in their use by a veterinarian.

Nature and duration of the journey

- The maximum duration of a *journey* should be determined according to:
    - the ability of the animals to cope with the stress of *transport* (such as very young, old, lactating or pregnant animals),
    - the animals' previous transport experience,
    - the onset of fatigue,
    - the need for special attention,
    - the need for feed and water,
    - the increased susceptibility to injury and disease,
    - *space allowance*, vehicle design, road conditions, driving quality,
    - weather conditions.

Vehicle and container design and maintenance

- *Vehicles* and *containers* used for the *transport* of animals should be designed, constructed and fitted as appropriate to the species, size and weight of the animals to be transported; special attention should be paid to the avoidance of injury to animals through the use of secure smooth fittings free from sharp protrusions. The avoidance of injury to drivers and *animal handlers* while carrying out their responsibilities should be emphasised.

- *Vehicles* and *containers* should be designed with the structures necessary to provide protection from adverse weather conditions and to minimise the opportunity for animals to escape.

- In order to minimise the likelihood of the spread of pathogenic agents during transport, *vehicles* and *containers* should be designed to permit thorough cleaning and disinfection, and the containment of faeces and urine during a *journey*.

- *Vehicles* and *containers* should be maintained in good mechanical and structural condition.

Community position:
The word "is" before "stationary" should be amended to "are".

- *Vehicles* and *containers* should *have* adequate ventilation to meet variations in climate and the thermo-regulatory needs of the animal species being transported; the ventilation system should be capable of operating when the *vehicles* is stationary and the air flow should be adjustable.

- *Vehicles* should be designed so that the faeces or urine from animals on upper levels do not soil animals on lower levels, nor their feed and water.

- When *vehicles* are carried on board ferries, facilities for adequately securing them should be available.

Appendix XXII (contd)

- If feeding or watering while the *vehicle* is moving is required, adequate facilities on the *vehicle* should be available.

Community position:
The words "or equivalent material" should be inserted after the word "bedding".

-

- Suitable bedding should be added to vehicle floors to assist absorption of urine and faeces, to minimise slipping by animals, and protect animals (especially young animals) from hard flooring surfaces and adverse weather conditions.

Special provisions for transport in vehicles (road and rail) on roll-on/roll-off vessels or for containers

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

- *Vehicles* and *containers* should be secured to the ship before the start of the sea journey to prevent them being displaced by the motion of the vessel.

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

Space allowance

- The number of animals which should be transported on a *vehicle* or in a *container* and their allocation to different compartments should be determined before the *vehicle* or *container* is loaded.

- The space required on a *vehicle* or in a *container* depends upon whether or not the animals need to lie down (for example pigs, camels and poultry), or to stand (horses). Animals which will need to lie down often stand when first loaded or when the *vehicle* is driven with too much lateral movement or sudden braking.

- When animals lie down, they should all be able to adopt a comfortable, normal lying posture which allows necessary thermoregulation.

Community position:
The words "without body contact with other animals" should be deleted.

-

- When animals are standing, they should have sufficient space to adopt a balanced position without body contact with other animals.

Community position:
The words "and there should be sufficient headroom to allow adequate airflow over the animals" should be added to the end of the next bullet point.

- The amount of headroom necessary depends on the species of animal. Each animal should be able to assume its natural position for *transport* (including during *loading* and *unloading*) without coming into contact with the roof or upper deck of the *vehicle*.

-

Community position:

The last sentence of the next bullet point should be re-phrased as follows: "The size of pens on the vehicle should be varied to where possible accommodate already established groups of animals avoiding group sizes which are too large."

- Calculations according to the *space allowance* permitted for each animal should be carried out, using the figures given in these guidelines (see Appendix XXX) or, in their absence, in a relevant national or international document. The size of already established groups will affect the number and size of the pens, and the distribution of animals in pens on the *vehicle*.

- Other factors which may influence *space allowance* include:
  - *vehicle* / *container* design
  - length of journey
  - need to provide feed and water on the *vehicle*
  - quality of roads
  - expected weather conditions.

Rest, water and feed

- There should be planning for the availability of suitable water and feed during the *journey*. Feed should be of appropriate quality and composition for the species, age, condition of the animals, climatic conditions, etc.

- Animals should be rested at *resting points* at appropriate intervals during the *journey*. The type of transport and species being transported should determine the frequency of rest stops and whether the animals are unloaded. There should be planning for water and feed availability during rest stops.

Community position:
For improved clarity the title of the next section should be changed to "Ability to observe animals during transport".

Ability to observe animals en route in relation to journey duration

Community position:
The next bullet point should be re-worded as follows: "Vehicle design and the placing of animals in pens should be such that each animal can be observed during the transport".

- Animals should be positioned to enable each animal to be observed regularly during the *journey* to ensure their safety and good welfare.

- If the animals are in crates or on multi-tiered vehicles which do not allow free access for observation, for example where the roof of the tier is too low (i.e. less than 1.3 m), animals cannot be inspected adequately, and serious injury or disease could go undetected. In these circumstances, a shorter journey duration should be allowed, and the maximum duration will vary according to the rate at which problems arise in the species and under the conditions of transport.

Control of disease

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

  - mixing of animals from different sources in a single consignment should be minimised,

  - contact at *resting points* between animals from different sources should be avoided,

  - when possible, animals should be vaccinated against diseases to which they are likely to be exposed at their destination,

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

Emergency response procedures

- Appropriate contingency plans to address emergencies should be prepared in advance (see Article 7).

Other considerations

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

- In some circumstances, transportation during the night may reduce thermal stress or the adverse effects of other external stimuli.

Appendix XXII (contd)

Article 4

Documentation

- Animals should not be loaded until the required documentation is complete.
- The documentation accompanying the consignment should include:

Community position:
It should be clarified what a journey travel plan consists of. A contingency plan for emergencies should also be added as part of the required documentation for such journeys.

-
  - journey travel plan,
  - date, time, and place of *loading* and *unloading*,
  - veterinary certification, when required,
  - driver's competencies,
  - identities of the animals transported to allow traceback of individual animals to the premises of departure, and where possible to the premises of origin,
  - details of any animals considered 'at risk' (Article 5),
  - documentation of the period of rest, and access to feed and water, prior to the *journey*,
  - *stocking density* estimate for each load in the consignment,
  - the journey log - daily record of inspection and important events, including records of morbidity and mortality, climatic conditions, rest stops, travel time and distance, feed and water offered and estimates of consumption, medication provided, and mechanical defects.
- When veterinary certification is required to accompany consignments of animals, it should include:
  - appropriate animal identification (description, number, etc.),
  - health status including test, treatment and vaccination status
  - when required, details of disinfection carried out.

  At the time of certification, the veterinarian should notify the animal handler of any factors affecting the animals' fitness to travel for a particular journey.

Article 5

Pre-journey period

General

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

- Feed and water should be provided pre-journey if the journey duration is greater than the normal inter-feeding and drinking interval for the animal. Recommendations for specific species are described in detail in Article XXX.

- When animals will be provided with a novel diet or method of water provision during or after *transport*, an adequate period of pre-exposure is necessary.

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

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

Selection of compatible groups

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

  o animals reared together should be maintained as a group; animals with a strong social bond should be transported together,

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

Community position:
The word "should" needs to be deleted after the word "offspring".

  o young or small animals should be separated from older or larger animals, with the exception that dam and offspring should be transported together,

Community position:
The words "unless judged to be compatible" should be added to the end of the next bullet point.

  o

  o animals with horns or antlers should not be mixed with animals lacking horns or antlers,

  o animals of different species should not be mixed unless they are judged to be compatible.

Shelter in the assembly/holding area

- Assembly/holding areas should be designed to:

  - securely hold the animals,

  - maintain a safe environment from hazards, including predators and disease,

  - protect animals from exposure to severe weather conditions,

- allow for maintenance of social groups, and
- allow for rest, and appropriate water and feed.

Effect of travel experience, long and short term

Community position:
The words "if known" should be added after the word "conditioning".

- Consideration should be given to an animal's previous transport experience, training and conditioning as these may reduce fear and stress in animals. Animals that are carefully and regularly transported may show less adverse responses to transport.

Appendix XXII (contd)

- Exposure to familiar personnel should reduce the fearfulness of animals and improve their approachability during transport procedures.

Community position:
The "Fitness to travel" section is an example where important differences are apparent between the guidelines for land and sea transport. Wherever possible such inconsistencies should be eliminated. Therefore under the heading fitness to travel two extra bullet points should be added
"- newborn with an unhealed navel
- pregnant animals which would be in the final 10% of their expected gestation period"

-

Fitness to travel

- Each animal should be inspected by a veterinarian or an *animal handler* to assess fitness to travel. Animals found unfit to travel should not be loaded onto a *vehicle*, except for transport to receive veterinary treatment.
- Humane and effective arrangements should be made by the owner or agent for the handling and care of any animal rejected as unfit to travel.
- Animals that are unfit to travel include:
  - those that are sick, injured, weak, disabled or fatigued,
  - those that are unable to stand unaided and bear weight on each leg,
  - those that are blind in both eyes,
  - those that cannot be moved without causing them additional suffering,
  - pregnant animals which are likely to give birth during the *journey*,
  - those whose body condition would result in poor welfare because of the expected climatic conditions.
- Risks during *transport* can be reduced by selecting animals best suited to the conditions of travel and those that are acclimatised to expected weather conditions.
- Animals 'at risk' which require special conditions (such as in the design of facilities and vehicles, and the length of the journey) and additional attention during *transport*, may include:
  - large or obese individuals,
  - very young or old animals,
  - excitable or aggressive animals,
  - animals which have had little contact with humans,
  - animal subject to motion sickness,
  - females in late pregnancy or heavy lactation; dam and offspring,

- those with a history of exposure to stressors or pathogenic agents prior to *transport*.

Specific species requirements

Transport procedures should be able to take account of variations in the behaviour of the species. Flight zones, social interactions and other behaviour vary significantly among species and even within species. Facilities and handling procedures that are successful with one species are often ineffective or dangerous with another.

- Recommendations for specific species are described in detail in Article XXX.

Article 6

Loading

Experienced supervision

- Since *loading* has been shown to be the procedure most likely to be the cause of poor welfare in transported animals, the methods to be used should be carefully planned.
- *Loading* should be supervised by *animal handlers*. These *animal handlers* should ensure that animals are loaded quietly and without unnecessary noise, harassment or force, and that untrained assistants or spectators do not impede the process.
- When *containers* are loaded onto a *vehicle*, this should be carried out in such a way to avoid poor animal welfare.

Facilities

- The facilities for *loading* including the collecting area, races and loading ramps should be designed and constructed to take into account the needs and abilities of the animals with regard to dimensions, slopes, surfaces, absence of sharp projections, flooring, etc.
- Loading facilities should be properly illuminated to allow the animals to be observed by the *animal handler(s)*, and to allow the animals' ease of movement at all times. Facilities should provide uniform lighting directly over approaches to sorting pens, chutes, loading ramps, with brighter lighting inside *vehicles* / *containers*, in order to minimise baulking. Dim lighting may be advantageous for the catching of poultry and some other animals.
- Ventilation during *loading* and the *journey* should provide for fresh air, the removal of excessive heat, humidity and noxious fumes (such as ammonia and carbon monoxide), and the prevention of accumulations of ammonia and carbon dioxide. Under warm and hot conditions, ventilation should allow for the adequate convective cooling of each animal. In some instances, adequate ventilation can be achieved by increasing the *space allowance* for animals.

Goads and other aids

- The following principles should apply:
    - Animals which have little or no room to move should not be subjected to physical force or goads and other aids which compel movement.
    - Useful and permitted aids include panels, flags, plastic paddles, flappers (a length of cane with a short strap of leather or canvas attached), plastic bags and metallic rattles; they should be used in a manner sufficient to encourage and direct movement of the animals but without physical contact with them.
    - Painful procedures (including whipping, tail twisting, use of nose twitches, pressure on eyes, ears or external genitalia), or the use of unsuitable goads or other aids (including sticks with sharp ends, lengths of metal piping, fencing wire or heavy leather belts), should not be used to move animals.

Appendix XXII (contd)

- The use of goads which administer electric shocks should be discouraged, and restricted to that necessary to assist movement of the animal. Such use should be limited to battery-powered goads on the hindquarters of adult pigs and cattle, and never on sensitive areas such as the eyes, mouth, ears, anogenital region or belly. Such instruments should not be used on other animals.

Community position:
The sea transport guidelines do not require dogs to be muzzled. An appropriate common wording could be "muzzled where necessary".

-

- The use of muzzled, well trained dogs to help with the *loading* of some species may be acceptable.

- The throwing or dropping of animals, or their lifting or dragging by their tail, head, horns, ears, limbs, wool, hair or feathers should not be permitted. The manual lifting of small animals is permissible.

Article 7

Travel

- Drivers and *animal handlers* should check the load immediately before departure to ensure that the animals have been properly loaded. Each load should be checked again early in the trip and adjustments made as appropriate. Periodic checks should be made throughout the trip.

- Drivers should utilise smooth, defensive driving techniques, without sudden turns or stops, to minimise uncontrolled movements of the animals.

Methods of restraining or containing animals

- Methods of restraining animals should be appropriate to the species involved and the training of the individual animal.

- Recommendations for specific species are described in detail in Article XXX.

Regulating the environment within vehicles or containers

- Animals should be protected against harm from hot or cold conditions during *travel*. Effective ventilation procedures for maintaining the animals' environment within *vehicles* or *containers* will vary according to whether conditions are cold, hot and dry or hot and humid, but in all conditions a build-up of noxious gases should be prevented. Specific temperature and humidity parameters are described in detail in Appendix XXX.

Community position:
In the next bullet point the words "maximal ventilation" should be replaced with the words "adequate and appropriate ventilation".

- The animals' environment in hot weather can be regulated by the flow of air produced by the movement of the *vehicle*. In warm and hot weather, the duration of journey stops should be minimised and *vehicles* should be parked under shade, with maximal ventilation.

- To minimise slipping and soiling, and maintain a healthy environment, urine and faeces should be removed from floors when necessary and disposed of in such a way as to prevent the transmission of disease and in compliance with all relevant health and environmental legislation.

Sick, injured and dead animals

- A driver or *animal handler* finding sick, injured or dead animals should act according to a predetermined emergency response plan (see Appendix XXX).
- If possible, sick or injured animals should be segregated.
- Ferries (roll-on roll-off) should have procedures to treat sick or injured animals during the *journey*.

- In order to reduce the likelihood that animal transport will increase the spread of infectious disease, contact between transported animals, or the products of the transported animals, and other farm animals should be minimised.

- During the *journey*, when disposal of a dead animal becomes necessary, this should be carried out in such a way as to prevent the transmission of disease and in compliance with all relevant health and environmental legislation.

- When euthanasia is necessary, the driver or *animal handler* should ensure that it is carried out humanely, and results in immediate death. When necessary, assistance should be sought from a veterinarian or other person(s) competent in euthanasia procedures. Recommendations for specific species are described in the Chapter on humane killing of animals for disease control purposes.

Water and feed requirements

- If journey duration is such that feeding or watering is required or if the species requires feed or water throughout, access to suitable feed and water for all the animals carried in the *vehicle* should be provided. There should be adequate space for all animals to move to the feed and water sources and due account taken of likely competition for feed.

- Recommendations for specific species are described in detail in Article XXX.

Rest periods and conditions including hygiene

- Animals that are being transported should be rested at appropriate intervals during the *journey* and offered feed and water, either on the *vehicle* or, if necessary, unloaded into suitable facilities.

- Suitable facilities should be used en route, when resting requires the *unloading* of the animals. These facilities should meet the needs of the particular animal species and should allow access of all animals to feed and water.

In-transit observations

Community position:
No clear basis is given for the figure of "with a maximum interval of 5 hours" and this should be deleted. "Is commenced" should be replaced by "has commenced".

- Animals being transported by road should be observed soon after a *journey* is commenced and whenever the driver has a rest stop (with a maximum interval of 5 hours). After meal breaks and refuelling stops, the animals should be observed immediately prior to departure.

- Animals being transported by rail should be observed at each scheduled stop nearest to 5 hours since the last observation. The responsible rail transporter should monitor the progress of trains carrying animals and take all appropriate action to minimise delays.

- During stops, it should be ensured that the animals continue to be properly confined, have appropriate feed and water, and their physical condition is satisfactory.

Article 8

Unloading and post-journey handling

General

- The required facilities and the principles of animal handling detailed in Article 6 (Loading) apply equally to *unloading*, but consideration should be given to the likelihood that the animals will be fatigued.

Appendix XXII (contd)

- *Unloading* should be supervised by an *animal handler* with knowledge and experience of the behavioural and physical characteristics of the species being unloaded. Animals should be unloaded from the *vehicle* into appropriate facilities as soon as possible after arrival at the destination but sufficient time should be allowed for unloading to proceed quietly and without unnecessary noise, harassment or force.

- Facilities should provide all animals with appropriate care and comfort, adequate space and ventilation, access to feed (if appropriate) and water, and shelter from extreme weather conditions.

- For details regarding the *unloading* of animals at a slaughterhouse, see Chapter on Slaughter of animals for human consumption.

Sick and injured animals

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

- At the destination, the *animal handler* during transit should ensure that responsibility for the welfare of sick, injured or disabled animals is transferred to a suitable person.

- There should be appropriate facilities and equipment for the humane unloading of animals that are non-ambulatory due to fatigue, injury or sickness. These animals should be unloaded in a manner that causes the least amount of suffering. After *unloading*, separate pens and other appropriate facilities should be available for sick or injured animals.

- Feed, if appropriate, and water should be available for each sick or injured animal.

Addressing disease risks

- The following should be taken into account in addressing the greater risk of disease due to animal transport and the possible need for segregation of transported animals at the destination:

    - increased contact among animals, including those from different sources and with different disease histories,

    - increased shedding of pathogens and increased susceptibility to infection related to stress and impaired defences against disease, including immunosuppression,

    - exposure of animals to pathogens which may contaminate *vehicles*, *resting points*, markets etc.

Cleaning and disinfection

- *Vehicles*, crates, *containers*, etc. used to carry the animals should be cleaned before re-use through the physical removal of manure and bedding by scraping, washing and flushing *vehicles* and *containers* with water and detergent. This should be followed by *disinfection* when there are concerns about disease transmission.

Community position:

- **The next two bullet points could be combined to avoid unnecessary repetition. For example a suggested combined wording is "Manure, litter, bedding and the bodies of any animals which die during the journey should be disposed of in such a way as**

to prevent the transmission of disease and in compliance with all relevant health and environmental legislation."

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

- When disposal of a dead animal becomes necessary, this should be carried out in such a way as to prevent the transmission of disease and in compliance with all relevant health and environmental legislation.

- Establishments like livestock markets, slaughterhouses, resting sites, railway stations, etc. where animals are unloaded should be provided with appropriate areas for the cleaning and *disinfection* of *vehicles*.

Community position:
It should be clarified why and under what circumstances disinfestation would be necessary and how it should be performed, by whom etc.

-

- Where *disinfestation* is necessary, it should be carried out with the minimum stress to the animals.

Article 9

Actions in the event of a refusal to allow the completion of the journey

- The welfare of the animals should be the first consideration in the event of a refusal to allow the completion of the *journey***.**
- When the animals have been refused import, the *Competent Authority* of that country should make available suitable isolation facilities to allow the *unloading* of animals from a *vehicle* and their secure holding, without posing a risk to the health of national herd or flock, pending resolution of the situation. In this situation, the priorities should be:
    - the *Competent Authority* of the importing country should provide urgently in writing the reasons for the refusal,
    - in the event of a refusal for animal health reasons, the *Competent Authority* of the importing country should provide urgent access to a veterinarian, where possible an OIE veterinarian(s) appointed by the Director General, to assess the animals' health status with regard to the importing country's concerns, and the necessary facilities and approvals to expedite the required diagnostic testing,
    - the *Competent Authority* of the importing country should provide access to allow continued assessment of the health and other aspects of the welfare of the animals,
    - if the matter cannot be promptly resolved, the *Competent Authorities* of the exporting and importing countries should call on the OIE to mediate.
- In the event that a *Competent Authority* requires the animals to remain on the *vehicle*, the priorities should be:

Community position:
The words "and take steps to ensure that ventilation is adequate" should be added after the word "necessary". The spelling of "reprovisioning" should be corrected.

-
    - the *Competent Authority* should allow reprovisionsing of the *vehicle* with water and feed as necessary,
    - the *Competent Authority* should provide urgently in writing the reasons for the refusal,
    - in the event of a refusal for animal health reasons, the *Competent Authority* should provide urgent access to an independent veterinarian(s) to assess the animals' health status, and the necessary facilities and approvals to expedite the required diagnostic testing,

- the *Competent Authority* should provide access to allow continued assessment of the health and other aspects of the welfare of the animals.

Community position:
The following bullet point should be added: "The Competent Authority should also be authorised to promptly deal with and any animal health or welfare issues which arise, including the emergency slaughter of animals where necessary."

- The OIE should utilise its dispute settlement mechanism to identify a mutually agreed solution which will address animal health and any other welfare issues in a timely manner.

Appendix XXII (contd)

Article XXX

Species specific issues

Community position:
The text on species specific issues included in the sea transport guidelines should be replicated here.

(To be developed)

Appendix XXII (contd)

GUIDELINES FOR THE TRANSPORT OF ANIMALS BY SEA

Article 1

Responsibilities

Once the decision to transport animals by sea has been made, the welfare of animals during their transport is paramount and is the joint responsibility of all people involved. These guidelines may also be applied to the transport of animals by water within a country.

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

The roles of each of those responsible are defined below:

- *Exporters*, owners of animals and managers of facilities are jointly responsible for the general health of the animals and their fitness for the *journey*.

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

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

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

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

    - choosing appropriate *vessels* and ensuring that competent *animal handlers* are available for *loading* and caring for animals throughout the *journey*,

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

    - correct *loading* of the ship, regular inspections during the *journey* and for appropriate responses to problems arising

Community position: For clarity after the word "law" the following text should be added: "and in compliance with all relevant health and environmental legislation."

    -

- disposal of carcases according to international law.

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

Appendix XXII (contd)

- Managers of facilities during *loading* of the animals are responsible for:
  - providing suitable premises for *loading* the animals,
  - providing competent *animal handlers* to load the animals in a manner that causes minimum stress and injury,
  - providing appropriate facilities for emergencies,

Community position:
The initial letter "a" of the word "animal" should also be italicised.

  - providing facilities and veterinarians or competent a*nimal handlers* capable of killing animals humanely when required.

- Managers of facilities at the end of the *journey* are responsible for:
  - providing suitable facilities for *unloading* the animals onto transport vehicles for immediate movement or securely holding the animals in lairage, with shelter, water and feed, when required, for transit,
  - providing competent *animal handlers* to unload the animals with minimum stress and injury,
  - minimising the opportunities for disease transmission while the animals are in the facilities,
  - providing appropriate facilities for emergencies,
  - providing facilities and veterinarians or competent *animal handlers* capable of killing animals humanely when required.

- The responsibilities of the *Competent Authority* of the exporting country include:
  - establishing minimum standards for animal welfare, including requirements for inspection of animals before and during their travel, and for certification and record keeping,
  - approving facilities, *containers*, *vehicles/vessels* for the holding and transport of animals,
  - setting competence standards for *animal handlers* and managers,
  - ensuring that the *vessel* transporting animals meets the required standards, including those of the importing country,
  - implementation of the standards, including through accreditation of / interaction with other organisations and competent authorities,
  - monitoring and evaluating health and welfare performance, including the use of any veterinary medications.

- The responsibilities of the *Competent Authority* of the importing country include:
  - establishing minimum standards for animal welfare, including requirements for inspection of animals after their travel, and for certification and record keeping,
  - approving facilities, *containers* and vehicles for the *unloading*, holding and transport of animals,

- setting competence standards for *animal handlers* and managers,

- implementation of the standards, including through accreditation of / interaction with other organisations and competent authorities,
- ensuring that the exporting country is aware of the required standards for the *vessel* transporting the animals,
- monitoring and evaluating health and welfare performance, including the use of any veterinary medications.

Community position:
The words "when travelling on vessels" should be added after the word "veterinarians".

-

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

Article 2

Competence

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

- This competence should be demonstrated through a current certificate in one of the OIE official languages from an independent body accredited by a *Competent Authority*.

Community position:
This is another area where consistency with the land transport guidelines in terms of terminology and provisions specified should be ensured.

- Assessment of competence for *animal handlers* should at a minimum address knowledge, and ability to apply that knowledge, in the following areas:
  - responsibilities for animals during the *journey*,
  - sources of advice and assistance,
  - animal behaviour, general signs of disease, and indicators of poor animal welfare such as stress, pain and fatigue, and their alleviation,
  - relevant authorities and applicable transport regulations, and associated documentation requirements,

Community position:
The words "and disinfection" should be added after the word "cleaning".

-

  - general disease prevention procedures, including cleaning,

- appropriate methods of animal handling during transport and associated activities such as assembling, *loading*, and *unloading*,
- methods of inspecting animals, managing situations frequently encountered during transport such as adverse weather conditions, and dealing with emergencies,
- species-specific aspects of animal handling and care, including feeding, watering and inspection,
- appropriate record keeping and journey log.

- Assessment of competence for *exporters* should at a minimum address knowledge, and ability to apply that knowledge, in the following areas:
  - planning a *journey*, including appropriate *space allowances*, and feed, water and ventilation requirements,
  - relevant authorities and applicable transport regulations, and associated documentation requirements,

Appendix XXII (contd)

- appropriate methods of animal handling during transport and associated activities such as cleaning and disinfection, assembling, *loading*, and *unloading*,
- species-specific aspects of animal handling and care, including appropriate equipment and medication,
- sources of advice and assistance,
- appropriate record keeping and journey log.
- managing situations frequently encountered during transport such as adverse weather conditions, and dealing with emergencies

Article 3

Documentation

- Animals should not be loaded until the documentation required to that point is complete.

Community position:
The contents of the journey travel plan should be clarified. A contingency plan in case of emergencies should also be required documentation.

- The documentation accompanying the consignment should include:
  - journey travel plan,
  - time, date and place of *loading*,
  - the journey log – a daily record of inspection and important events which includes records of morbidity and mortality, climatic conditions, food and water consumed, medication provided, mechanical defects,

Community position:
The word "expected" should be added before the word "time".

  -
  - time, date and place of arrival and *unloading*,
  - veterinary certification, when required,
  - animal identification to allow traceback of individual animals to the premises of departure, and where possible to the premises of origin,
  - details of animals at risk,
  - number of *animal handlers* on board, and their competencies,
  - stocking density estimate for each load in the consignment.

Community position:
In order to ensure consistency with the previous bullet point on veterinary certification, the next bullet point could be re-phrased as follows "In cases where veterinary certification is required this should accompany…".

  -

- Veterinary certification should accompany consignments of animals and address:

Community position:
The words "when required" should be added after the word "vessel".

-
  - cleaning and disinfection of the *vessel*,
  - fitness of the animals to travel,
  - animal identification (description, number, etc.),
  - health status including tests, treatment and vaccinations carried out, if required.

Article 4

Planning the journey

General

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

- Before the journey starts, plans should be made in relation to:
    - type of transport *vessel* required,
    - route, taking into account distance, expected weather and sea conditions,
    - nature and duration of *journey*,
    - daily care and management of the animals,
    - avoiding the mixing of animals from different sources in a single pen group.
    - provision of appropriate equipment and medication for the numbers and species carried
    - emergency response procedures
- Preconditioning may be required, e.g. for dry food, and unfamiliar methods of supply of feed and water.
- Potential for spread of infectious disease
    - when requested by the *Veterinary Authority* of the importing country, animals should be vaccinated against diseases to which they are likely to be exposed at their destination.
- There should be planning for water and feed availability during the *journey*. Feed should be of appropriate quality and composition for the species, age, condition of the animals, etc.
- Extreme weather conditions are hazards for animals undergoing transport and require appropriate vessel design to minimise risks. Special precautions should be taken for animals that have not been acclimatised or which are unsuited to either hot or cold conditions. In some extreme conditions of heat or cold, animals should not be transported at all.
- Behaviour-modifying or other medication should not be used routinely during transport. Such medicines should only be administered when a problem exists in an individual animal, and should be administered by a veterinarian or other person who has been instructed in their use by a veterinarian. Treated animals should be placed in a dedicated area.
- There should be an emergency management plan that identifies the important adverse events that may be encountered during the *journey*, the procedures for managing each event and the action to be taken in an emergency. For each important event, the plan should document the actions to be undertaken and the responsibilities of all parties involved, including communications and record keeping.

Vessel and container design and maintenance

- *Vessels* used for the sea transport of animals should be designed, constructed and fitted as appropriate to the species, size and weight of the animals to be transported; special attention should be paid to the avoidance of injury to animals through the use of secure smooth fittings free from sharp protrusions and the provision of non-slip flooring. The avoidance of injury to animal handlers while carrying out their responsibilities should be emphasised.
- *Vessels* should be designed to permit thorough cleaning and disinfection, and the management of faeces and urine.

Appendix XXII (contd)

Community position:
The words "and fittings therein" should be inserted after the word "vessels" in the next bullet point.

- *Vessels* should be maintained in good mechanical and structural condition.

Community position:
To improve application the sentence "An emergency power supply should be available to maintain ventilation in the case of primary machinery breakdown" should be added to the end of the next bullet point.

-

- *Vessels* should have adequate ventilation to meet variations in climate and the thermo-regulatory needs of the animal species being transported; the ventilation system should be capable of operating when the *vessel* is stationary and the air flow should be adjustable.

Community position:
The need for lighting to facilitate inspection of the animals needs to be mentioned.

-

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

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

- Stowage of feed and bedding should be carried out in such a way to ensure protection from the elements and sea water

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

- The above principles apply also to *containers* used for the transport of animals.

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

Community position:
A fourth bullet point should be inserted under this heading with the following text : "Road vehicles and containers should be fitted with an appropriate ventilation system which permits a sufficient flow of air through its livestock compartment to maintain a suitable environment for the animals. Due to the risk of limited airflow on certain vessels' decks, the road vehicle or container may require a forced ventilation system of greater capacity than that provided by natural ventilation."

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

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

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

Space allowance

Community position:
The word "different" should be deleted from the next bullet point.

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

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

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

- The same principles apply when animals are transported in *containers*.

Ability to observe animals en route

Community position:
There is considerable duplication between the next 2 bullet points and they should be replaced with the following combined text: "Animals should be positioned to enable them to be observed regularly and clearly by the *animal handler* or other responsible person during the *journey* to ensure their safety and good welfare".

- Animals should be positioned to enable them to be observed regularly during the *journey* to ensure their safety and good welfare.

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

Emergency response procedures

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

Article 5

Pre-journey period

General

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

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

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

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

- Pre-journey holding areas should be designed to:

    - securely contain the animals,

    - maintain an environment safe from hazards, including predators and disease,

    - protect animals from exposure to adverse weather conditions, and

    - allow for rest, watering and feeding.

Selection of compatible groups

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

    - animals of different species should not be mixed unless they are judged to be compatible,

Community position:
It would be useful to add some further examples of possible incompatible groups, for example mixing male and female animals, animals in oestrus etc.

    -

    - animals of the same species can be mixed unless there is a significant likelihood of aggression; aggressive individuals should be segregated,

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

- animals with horns or antlers should not be mixed with animals lacking horns or antlers,

Appendix XXII (contd)

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

Fitness to travel

Community position:
Consistency with the land transport guidelines should be ensured e.g. newborn with an unhealed navel being included here but not in the land transport guidelines.

- Animals should be inspected before travel and those found unfit to travel by farm staff, *animal handlers* or veterinarians should not be loaded onto a *vessel*.
- Humane and effective arrangements should be made by the owner or agent for the handling and care of any animal rejected as unfit to travel.
- Animals that are unfit to travel include:
  - those that are sick, injured, weak, disabled or fatigued,
  - those that are unable to stand unaided and bear weight on each leg,
  - those that are blind in both eyes,
  - those that cannot be moved without causing them additional suffering,
  - newborn with an unhealed navel,
  - females travelling without young which have given birth within the previous 48 hours,
  - pregnant animals which would be in the final 10% of their gestation period at the planned time of unloading.
- Risks during transport can be reduced by selecting animals best suited to the conditions of travel and those that are acclimatised to expected weather conditions.
- Animals at risk, and requiring better conditions and additional attention during transport include:
  - very large or obese individuals,
  - very young or old animals,
  - excitable or aggressive animals,
  - animals which have had little contact with humans,
  - females in the last third of pregnancy or in heavy lactation.
- Hair or wool length needs consideration in relation to the weather conditions expected.

Article 6

Loading

Experienced supervision

- *Loading* should be carefully planned as it has the potential to be the cause of poor welfare in transported animals.
- *Loading* should be supervised by the *Competent Authority* and managed by an *animal handler(s)*. *Animal handlers* should ensure that animals are loaded quietly and without unnecessary noise, harassment or force, and that untrained assistants or spectators do not impede the process.

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

Facilities

- The facilities for *loading* including the collecting area at the wharf, races and loading ramps should be designed and constructed to take into account of the needs and abilities of the animals with regard to dimensions, slopes, surfaces, absence of sharp projections, flooring, sides etc.
- All loading facilities should be properly illuminated to allow the animals to be easily inspected by the *animal handler(s)*, and to allow the animals' ease of movement at all times.

Goads and other aids

- The following principles should apply:
    - Goads (aids for encouraging animals to move) should not be used on animals that have little or no room to move.
    - Useful and permitted goads include panels, flags, plastic paddles, flappers (a length of cane with a short strap of leather or canvas attached), plastic bags and metallic rattles; they should be used in a manner sufficient to encourage and direct movement of the animals but without physical contact with them.
    - Unsuitable goads such as large wooden sticks, sticks with sharp ends, lengths of metal piping, fencing wire or heavy leather belts should not be used to strike animals.
    - The use of goads which administer electric shocks should be discouraged, and restricted to that necessary to assist movement of the animal. If such use is necessary, it should be limited to the hindquarters of pigs and large ruminants, and never on sensitive areas such as the eyes, mouth, ears, anogenital region or belly. Such instruments should not be used on horses, sheep and goats of any age, or on calves or piglets.

Community position:
Consistency with the land transport guidelines should be ensured with regard to the possible need to muzzle dogs. If dogs are well-trained they should not need to be muzzled. The words "muzzled where necessary" could be used.

-
    - The use of well trained dogs to help with the *loading* of some species may be acceptable.
    - Manual lifting is permissible for young animals that may have difficulty negotiating ramps, but the lifting of animals by their tail, head, horns, ears, limbs, wool or hair should not be permitted.

Article 7

Travel

Inspections

Community position:
In the first bullet point the figure "24" should be changed to "12" since every 24 hours is not sufficiently frequent to identify and address any health or welfare problems which may develop. For a clear scientific basis see the SCAHAW report http://europa.eu.int/comm/food/fs/sc/scah/out71_en.pdf
And the EFSA report http://www.efsa.eu.int/science/ahaw/ahaw_opinions/424_en.html

- Competent *animal handler(s)* should check the consignment immediately before departure to ensure that the animals have been loaded according to the load plan. Each consignment should be checked again within 24 hours.

Community position:
The words "if necessary" should be added after the word "adjustments" in the next bullet point. The figure "48" should be changed to "24". For a clear scientific basis see the SCAHAW report http://europa.eu.int/comm/food/fs/sc/scah/out71_en.pdf
And the EFSA report http://www.efsa.eu.int/science/ahaw/ahaw_opinions/424_en.html

-
- Adjustments should be made to the stocking density within 48 hours of departure and as appropriate during the *journey*.

Appendix XXII (contd)

- Each pen of animals should be observed on a daily basis for normal behaviour, health and welfare, and the correct operation of ventilation, watering and feeding systems. There should also be a night patrol. Any necessary corrective action should be undertaken promptly.
- Adequate access to suitable feed and water should be ensured for all animals in each pen.

Sick and injured animals

- Sick or injured animals should be segregated/isolated.
- Sick or injured animals should be treated promptly and appropriately, and veterinary advice should be sought if necessary. All drugs and products should be used in accordance with the manufacturer's recommendations.
- A record of treatments carried out and their outcomes should be kept.
- When euthanasia is necessary, the person responsible for the animals must ensure that it is carried out humanely, and results in immediate death. When necessary, assistance should be sought from a veterinarian or other person(s) competent in euthanasia procedures. Recommendations for specific species are described in Chapter on humane killing of animals for disease control purposes.

Cleaning and disinfection

- *Vessels* and *containers*, used to carry the animals should be cleaned before re-use through the physical removal of manure and bedding by scraping, washing and flushing *vessels* and *containers* with water. This should be followed by *disinfection* when there are concerns about disease transmission.
- Manure, litter and bedding should be disposed of in such a way as to prevent the transmission of disease and in compliance with all relevant health and environmental legislation.

Community position:
It should be clarified when disinfestation would be required and how this should be performed.

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

Article 8

Unloading and post-journey handling

General

- The required facilities and the principles of animal handling detailed in Article 6 (Loading) apply equally to *unloading*, but consideration should be given to the likelihood that the animals will be fatigued.
- *Unloading* should be carefully planned as it has the potential to be the cause of poor welfare in transported animals.
- A livestock *vessel* should have priority attention when arriving in port and have priority access to a berth with suitable unloading facilities. As soon as possible after the ship's arrival at the port and

acceptance of the consignment by the *Competent Authority*, animals should be unloaded into appropriate facilities.

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

- *Unloading* should be supervised by the *Competent Authority* and managed by a competent *animal handler(s)*. The *animal handlers* should ensure that animals are unloaded quietly and without unnecessary noise, harassment or force, and that untrained assistants or spectators do not impede the process.

Facilities

- The facilities for *unloading* including the collecting area at the wharf, races and unloading ramps should be designed and constructed to take into account of the needs and abilities of the animals with regard to dimensions, slopes, surfaces, absence of sharp projections, flooring, sides etc.
- All unloading facilities should be properly illuminated to allow the animals to be easily inspected by the *animal handler(s)*, and to allow the animals' ease of movement at all times.
- In case of emergencies, port facilities should provide animals with appropriate care and comfort, adequate space, access to quality feed and clean drinking water, and shelter from extreme weather conditions.

Sick and injured animals

- In some cases, where animals are non-ambulatory due to fatigue, injury or sickness, it may be in the best welfare interests of the animal to be treated or euthanased aboard the *vessel*.
- If *unloading* is in the best welfare interests of animals that are fatigued, injured or sick, there should be appropriate facilities and equipment for the humane unloading of such animals. These animals should be unloaded in a manner that causes the least amount of suffering. After *unloading*, appropriate facilities and treatments should be provided for sick or injured animals.

Article 9

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

- The welfare of the animals should be the first consideration in the event of a refusal to import.
- When a shipment has been refused import, the *Competent Authority* of that country should make available suitable isolation facilities to allow the *unloading* of animals from a *vessel* and their secure holding, without posing a risk to the health of the national herd, pending resolution of the situation. In this situation, the priorities should be:
    - the *Competent Authority* of the importing country should provide urgently in writing the reasons for the refusal,
    - in the event of a refusal for animal health reasons, the *Competent Authority* of the importing country should provide urgent access to an OIE-appointed veterinarian(s) to assess the animals' health status with regard to the importing country's concerns, and the necessary facilities and approvals to expedite the required diagnostic testing
    - the *Competent Authority* of the importing country should provide access to allow continued assessment of the ongoing health and welfare situation,
    - if the matter cannot be promptly resolved, the *Competent Authority* of the exporting and importing countries should call on the OIE to mediate.
- In the event that the animals are required to remain on the *vessel*, the priorities should be:
    - the *Competent Authority* of the importing country should allow reprovision of the *vessel* with water and feed as necessary,

Appendix XXII (contd)

- the *Competent Authority* of the importing country should provide urgently in writing the reasons for the refusal,

- in the event of a refusal for animal health reasons, the *Competent Authority* of the importing country should provide urgent access to an OIE-appointed veterinarian(s) to assess the animals' health status with regard to the importing country's concerns, and the necessary facilities and approvals to expedite the required diagnostic testing,

- the *Competent Authority* of the importing country should provide access to allow continued assessment of the ongoing health and welfare situation,

- if the matter cannot be urgently resolved, the *Competent Authorities* of the exporting and importing countries should call on the OIE to mediate.

Community position:
The following bullet point should be added: "The Competent Authority should also be authorised to promptly deal with and any animal health or welfare issues which arise, including the emergency slaughter of animals where necessary."

- The OIE should utilise its dispute settlement mechanism to identify a mutually agreed solution which will address the animal health and welfare issues in a timely manner.

Article 10

Species specific issues

Community position:
It would be very useful to replicate this text in the land transport guidelines.

Cattle are sociable animals and may become agitated if they are singled out. Social order is usually established at about two years of age. When groups are mixed, social order has to be re-established and aggression may occur until a new order is established. Crowding of cattle may also increase aggression as the animals try to maintain personal space. Social behaviour varies with age, breed and sex; *Bos indicus* and *Bos indicus*-cross animals are usually more temperamental than European breeds. Young bulls, when moved in groups, show a degree of playfulness (pushing and shoving) but become more aggressive and territorial with age. Adult bulls have a minimum personal space of six square metres. Cows with young calves can be very protective, and handling calves in the presence of their mothers can be dangerous.

Goats should be handled calmly and are more easily led or driven than if they are excited. When goats are moved, their gregarious tendencies should be exploited. Activities which frighten, injure or cause agitation to animals should be avoided. Bullying is particularly serious in goats. Housing strange goats together could result in fatalities, either through physical violence, or subordinate goats being refused access to food and water.

Sheep are sociable animals with good eyesight and tend to "flock together", especially when they are agitated. They should be handled calmly and their tendency to follow each other should be exploited when they are being moved. Sheep may become agitated if they are singled out for attention and will strive to rejoin the group. Activities which frighten, injure or cause agitation to sheep should be avoided. They can negotiate steep ramps.

Pigs have poor eyesight, and may move reluctantly in strange surroundings. They benefit from well lit loading bays. Since they negotiate ramps with difficulty, these should be as level as possible. Ideally a hydraulic lift should be used for greater heights. Pigs also negotiate steps with difficulty. A good 'rule-of-thumb' is that no step should be higher than the pig's front knee.

Appendix XXII (contd)

Horses in this context include all solipeds, donkeys, mules, hinnies and zebra. They have good eyesight and a very wide angle of vision. They may have a history of loading resulting in good or bad experiences. Good training should result in easier loading, but some horses can prove difficult, especially if they are inexperienced or have associated loading with poor transport conditions. In these circumstances two experienced handlers can load an animal by linking arms or using a strop below its rump. Blindfolding may even be considered. Ramps should be as shallow as possible. Steps are not usually a problem when horses mount a ramp, but they tend to jump a step when descending, so steps should be as low as possible. Horses benefit from being individually stalled, but may be transported in compatible groups. When horses are to travel in groups, their shoes should be removed.

Camelids in this context comprise llamas, alpacas, guanaco and vicuna. They have good eyesight and, like sheep, can negotiate steep slopes, though ramps should be as shallow as possible. They load most easily in a bunch as a single animal will strive to rejoin the others. Whilst they are usually docile, they have an unnerving habit of spitting in self-defence. During transport they usually lie down. They frequently extend their front legs forward when lying, so gaps below partitions should be high enough so that their legs are not trapped when the animals rise.

———————

Appendix XXII (contd)

GUIDELINES FOR THE HUMANE KILLING OF ANIMALS FOR DISEASE CONTROL PURPOSES

Article 1

General principles

This chapter is based on the premise that a decision to kill the animals has been made.

- All personnel involved in the humane killing of animals should have the relevant skills and competencies.
- As necessary, operational procedures should be adapted to the specific circumstances operating on the premises and should address, apart from animal welfare, operator safety, biosecurity and environmental aspects.
- Following the decision to kill the animals, killing should be carried out as quickly as possible and normal husbandry should be maintained until the animals are killed.
- The handling and movement of animals should be minimised and when done, it should be done in accordance with the guidelines described below.
- Animal restraint should be sufficient to facilitate effective killing, and in accordance with animal welfare and operator safety requirements; when restraint is required, killing should follow with minimal delay.
- When animals are killed for disease control purposes, methods used should result in immediate death or immediate loss of consciousness lasting until death; when loss of consciousness is not immediate, induction of unconsciousness should be non-aversive and should not cause anxiety, pain, distress or suffering in the animals.
- For animal welfare considerations, young animals should be killed before older animals; for biosecurity considerations, infected animals should be killed first, followed by in-contact animals, and then the remaining animals.
- There should be continuous monitoring of the procedures to ensure they are consistently effective with regard to animal welfare, operator safety and biosecurity.
- When the operational procedures are concluded, there should be a written report describing the practices adopted and their effect on animal welfare, operator safety and biosecurity.

Community position:
In other guidelines the spelling "carcass" is used. A consistent notation would be preferable.

- To the extent possible to minimise public distress, killing of animals and carcase disposal should be carried out away from public view.
- These general principles should also apply when animals need to be killed for other purposes such as after natural disasters.

Article 2

Organisational structure

Community position:

It should be clarified whether it is the structure of the competent authority which is being described. A new paragraph should also be added "National contingency plans should be understood at and applicable to local levels. Local level plans should be based on national plans and be informed by local knowledge".

Disease control contingency plans should be in place at a national level and should contain details of management structure, disease control strategies and operational procedures; animal welfare considerations should be addressed within these disease control contingency plans. The plans should also include a strategy to ensure that an adequate number of personnel trained in the humane killing of animals is available.

Disease control contingency plans should address the animal welfare issues that may result from animal movement controls.

Community position:
After the word "involved" the word "has" could be replaced by the word "have".

The operational activities should be led by an *official veterinarian* who has the authority to appoint the personnel in the specialist teams and ensure that they adhere to the required animal welfare and biosecurity standards. When appointing the personnel, he/she should ensure that the personnel involved has the required competencies.

The *official veterinarian* should be responsible for all activities across one or more affected premises and should be supported by coordinators for planning (including communications), operations and logistics to facilitate efficient operations.

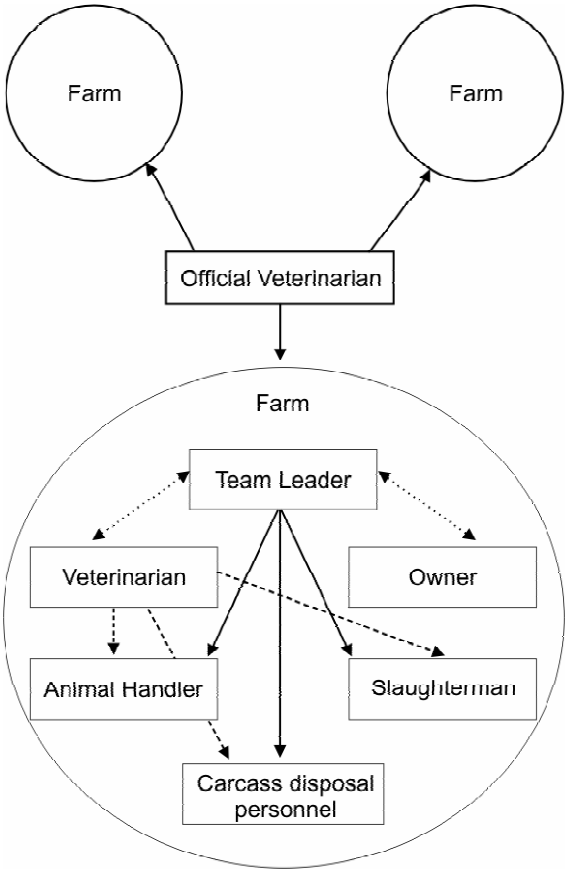
The *official veterinarian* should provide overall guidance to personnel and logistic support for operations on all affected premises to ensure consistency in adherence to the OIE animal welfare and animal health guidelines.

A specialist team, led by a team leader answerable to the *official veterinarian*, should be deployed to work on each affected premises. The team should consist of personnel with the competencies to conduct all required operations; in some situations, personnel may be required to fulfil more than one function. Each team should contain a veterinarian.

Community position:
The term "slaughterers" is used subsequently in the text rather than the word "slaughterman" which appears in the figure. A consistent approach to the use of terminology is needed.

In considering the animal welfare issues associated with killing animals, the key personnel, their responsibilities and competencies required are described in Article 3.

Community position:
In the figure which follows the owner and veterinarian should also be linked by a dotted line.


Farm
Farm
Official Veterinarian
Farm
Team Leader
Veterinarian
Owner
Animal Handler
Slaughterman
Carcass disposal personnel

Appendix XXII (contd)

Article 3

Responsibilities and competencies of the specialist team

Team leader

- Responsibilities
  - plan overall operations on an affected premises
  - determine and address requirements for animal welfare, operator safety and biosecurity
  - organise, brief and manage team of people to facilitate humane killing of the relevant animals on the premises in accordance with national regulations and these guidelines
  - determine logistics required
  - monitor operations to ensure animal welfare, operator safety and biosecurity requirements are met
  - report upwards on progress and problems

Community position:
It should be clarified whether the written report should also consider operator safety and biosecurity as mentioned in the third last bullet point of article 1.

  - provide a written report at the conclusion of the killing, describing the practices adopted and their effect on animal welfare

- Competencies
  - appreciation of animal welfare and the underpinning behavioural, anatomical and physiological processes involved in the killing process

Community position:
The word "the" could be added before the word "premises".

  - skills to manage all activities on premises and deliver outcomes on time

Community position:
The words "of the procedures" could be added after the word "effects".

  - awareness of psychological effects on farmer, team members and general public
  - effective communication skills

Veterinarian

- Responsibilities
  - determine and implement the most appropriate killing method to ensure that animals are killed without avoidable pain and distress

Community position:
The words "of the animals" could be added after the word "killing".

-
  - determine and implement the additional requirements for animal welfare, including the order of killing

Community position:
A new bullet point should be added "ensure that final checks for death after killing are carried out by competent persons at appropriate times after the killing procedure".

-
  - minimise the risk of disease spread within and from the premises through the supervision of biosecurity procedures
  - continuously monitor animal welfare and biosecurity procedures

Community position:
The words "and biosecurity" could be added after the word "welfare".

-
  - in cooperation with the leader, prepare a written report at the conclusion of the killing, describing the practices adopted and their effect on animal welfare

- Competencies
  - ability to assess animal welfare, especially the effectiveness of stunning and killing and to correct any deficiencies

Community position:
A new bullet point should be added "expert knowledge in humane handling, restraint and killing techniques".

-
  - ability to assess biosecurity risks

Animal handlers

- Responsibilities
    - review on-site facilities in terms of their appropriateness
    - design and construct temporary animal handling facilities, when required

Community position:
The words "in a calm and controlled manner" should be added after the word animals in the next bullet point.

    -
    - move and restrain animals
- Competencies
    - experience of animal handling in emergency situations and in close confinement

Slaughterers

- Responsibilities
    - ensure humane killing of animals through effective stunning and killing
- Competencies
    - when required by regulations, licensed to use necessary equipment or licensed to be slaughterers
    - competent to use and maintain relevant equipment
    - competent to use techniques for the species involved
    - competent to assess effective stunning and killing

Carcase disposal personnel

- Responsibilities
    - ensure efficient carcase disposal (to ensure killing operations are not hindered)
- Competencies
    - competent to use and maintain available equipment and apply techniques for the species involved

Farmer / owner / manager

- Responsibilities
    - assist when requested
- Competencies
    - specific knowledge of his/her animals and their environment

Article 4

Operational guidelines

Planning the humane killing of animals

Many activities will need to be conducted on affected premises, including the humane killing of animals. The team leader should develop a plan for humanely killing animals on the premises which should include consideration of:

Appendix XXII (contd)

- Minimising handling and movement of animals
- Killing the animals on the affected premises; however, there may be circumstances where the animals may need to be moved to another location for killing; when the killing is conducted at an abattoir, the guidelines in the Chapter on slaughter of animal for human consumption should be followed.
- The species, number, age and size of animals to be killed, and the order of killing them

Community position:
The words "aspects such as animal welfare, biosecurity considerations" should be added after the word "animals".

- Methods of killing the animals, and their cost

Community position:
A new bullet point should be added "competence and skills of those who will carry out the killing procedures". It is important that sufficient attention is given to the issue of proper staff training and competence.

- Housing and location of the animals
- The availability and effectiveness of equipment needed for killing of the animals
- The facilities available on the premises that will assist with the killing
- Biosecurity and environmental issues
- The health and safety of personnel conducting the killing
- Any legal issues that may be involved, for example where restricted veterinary drugs or poisons may be used, or where the process may impact on the environment, and
- The presence of other nearby premises holding animals.

In designing a killing plan, it is essential that the method chosen be consistently reliable to ensure that all animals are humanely and quickly killed.

Article 5

Table summarising killing methods described in Articles 6-17*

Species	Age range	Procedure	Restraint necessary	Animal welfare concerns with inappropriate application	Article reference
Cattle	All	free bullet	no	non-lethal wounding	
	all except neonates	captive bolt - penetrating, followed by pithing or bleeding	yes	ineffective stunning	

	adults only	captive bolt - non-penetrating, followed by bleeding	yes	ineffective stunning, regaining of consciousness before killing	
	calves only	electrical, two stage application	yes	pain associated with cardiac arrest after ineffective stunning	
	calves only	electrical, single application (method 1)	yes	ineffective stunning	
	All	injection with barbiturates and others	yes	non-lethal dose, pain associated with injection site	

Appendix XXII (contd)

Species	Age range	Procedure	Restraint necessary	Animal welfare concerns with inappropriate application	Article reference
Sheep and goats	all	free bullet	no	non-lethal wounding	
	all except neonates	captive bolt - penetrating, followed by pithing or bleeding	yes	ineffective stunning, regaining of consciousness before killing	
	all except neonates	captive bolt - non-penetrating, followed by bleeding	yes	ineffective stunning, regaining of consciousness before killing	
	neonates	captive bolt - non-penetrating	yes	non-lethal wounding	
	all	electrical, two stage application	yes	pain associated with cardiac arrest after ineffective stunning	
	all	electrical, single application (Method 1)	yes	ineffective stunning	
	neonates only	CO_2 air mixture	yes	slow induction of unconsciousness, aversiveness of induction	
	neonates only	nitrogen/inert gas mixed with CO_2	yes	slow induction of unconsciousness, aversiveness of induction	
	neonates only	Nitrogen/inert gases	yes	slow induction of unconsciousness,	
	all	injection of barbiturates and others	yes	non-lethal dose, pain associated with injection site	
pigs	all	free bullet	no	non-lethal wounding	
	all except neonates	captive bolt - penetrating, followed by pithing or bleeding	yes	ineffective stunning,	
	neonates only	captive bolt - non-penetrating	yes	non-lethal wounding	
	All §	electrical, two stage application	yes	pain associated with cardiac arrest after ineffective stunning	

Appendix XXII (contd)

Species	Age range	Procedure	Restraint necessary	Animal welfare concerns with inappropriate application	Article reference
	All	electrical, single application (Method 1)	yes	ineffective stunning	
	neonates only	CO_2 air mixture	yes	slow induction of unconsciousness, aversiveness of induction	
	neonates only	nitrogen/inert gas mixed with CO_2	yes	slow induction of unconsciousness, aversiveness of induction	
	neonates only	Nitrogen/inert gases	yes	slow induction of unconsciousness,	
	All	injection with barbiturates and others	yes	non-lethal dose, pain associated with injection site	
poultry	adults only	captive bolt - non-penetrating	yes	ineffective stunning	
Community position: **The word "embryonated" should be added before the word "eggs".**					
	day-olds and eggs only	maceration	no	non-lethal wounding, non- immediacy;	
	adults only	electrical single application (Method 2)	yes	ineffective stunning	
	adults only	electrical single application, followed by killing (Method 3)	yes	ineffective stunning; regaining of consciousness before killing	
	All	CO_2 air mixture Method 1 Method 2	yes no	slow induction of unconsciousness, aversiveness of induction	
	All	nitrogen/inert gas mixed with CO_2	yes	slow induction of unconsciousness, aversiveness of induction	
	All	Nitrogen/inert gases	yes	slow induction of unconsciousness	

	All	injection of barbiturates and others	yes	non-lethal dose, pain associated with injection site	

Species	Age range	Procedure	Restraint necessary	Animal welfare concerns with inappropriate application	Article reference
	adults only	addition of anaesthetics to feed or water, followed by an appropriate killing method	no	ineffective or slow induction of unconsciousness	

* the methods are described in the order of mechanical, electrical and gaseous, not in an order of desirability from an animal welfare viewpoint

§ the only preclusion against the use of this method for neonates is the design of the stunning tongs that may not facilitate their application across such a small-sized head/body.

Article 6

Free bullet

Introduction

A free bullet is a projectile fired from a shotgun, rifle, handgun or purpose-made humane killer.

The most commonly used firearms for close range use are:

- humane killers (specially manufactured/adapted single-shot weapons)
- shotguns (12, 16, 20, 28 bore and .410)
- rifles (.22 rimfire)
- handguns (various calibres from .32 to .45)

The most commonly used firearms for long range use are:

- rifles (.22, .243, .270 and .308)

A free bullet used from long range should be aimed to penetrate the skull or soft tissue at the top of the neck of the animal, to cause irreversible concussion and death and should only be used by properly trained and competent marksmen.

Community position:
A new sentence should be added "A heart shot may also achieve a rapid, effective and humane kill and in terms of shot accuracy may be an easier alternative to a head or neck shot".

Requirements for effective use

- The marksman should take account of human safety in the area in which he/she is operating

- The marksman should ensure that the animal is not moving and in the correct position to enable accurate targeting and the range should be as short as possible (5 –50 cm for a shotgun) but the barrel should not be in contact with the animal's head

Community position:
The words "without exiting the animal's body" should be inserted after the word "cranium".

-

- The correct cartridge, calibre and type of bullet for the different species age and size should be used. Ideally the ammunition should expand upon impact and dissipate its energy within the cranium

- Shot animals should be checked to ensure the absence of brain stem reflexes.

Appendix XXII (contd)

Figure 1. The optimum shooting position for cattle is at the intersection of two imaginary lines drawn from the rear of the eyes to the opposite horn buds.

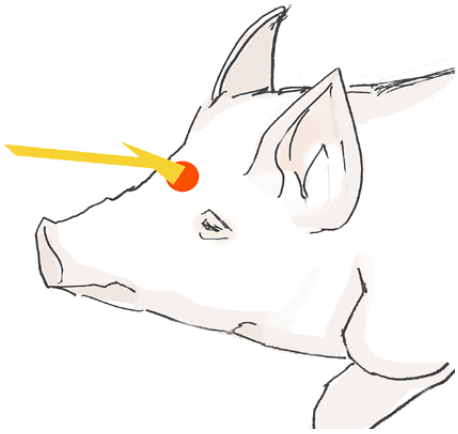
Community position:
The letter "h" should be deleted from the word "chord".

Figure 2. The optimum shooting position for hornless sheep and goats is on the midline, just above the eyes and directing the shot down the line of the spinal chord.

Figure 3. The optimum shooting position for heavily horned sheep and horned goats is behind the poll.

Community position:
The letter "h" should be deleted from the word "chord". A frontal view of the optimum shooting position would be clearer.

Figure 4. The optimum shooting position for pigs is just above the eyes and directing the shot down the line of the spinal chord.



Advantages

- Used properly, it provides a quick and effective method for killing
- It requires minimal or no restraint and can be use to kill from a distance

Community position:
After the word "spaces" the words "and which would respond poorly to any form of handling or restraint" should be added.

-
- It is suitable for killing agitated animals in open spaces

Disadvantages

- Potentially dangerous to humans and other animals in the area
- Potential for non-lethal wounding
- Destruction of brain tissue may preclude diagnosis of some diseases
- Leakage of bodily fluids may present a biosecurity risk
- Legal requirements may preclude or restrict use

- Limited availability of competent personnel

Conclusions

- A suitable method for cattle, sheep, goats and pigs, including large animals in open spaces.

Appendix XXII (contd)

Article 7

Penetrating captive bolt

Introduction

A penetrating captive bolt is fired from a gun powered by either compressed air or a blank cartridge. There is no free projectile.

The captive bolt should be aimed on the skull in a position to penetrate the cortex and mid-brain of the animal. The impact of the bolt on the skull produces unconsciousness. Physical damage to the brain caused by penetration of the bolt may result in death, however pithing or bleeding should be performed as soon as possible after the shot to ensure the death of the animal.

Requirements for effective use

Community position:
After the word "length" the words "and diameter" should be added.

- For cartridge powered and compressed air guns, the bolt velocity and the length of the bolt should be appropriate to the species and type of animal, in accordance with the manufacturer's recommendations
- Captive bolt guns should be frequently cleaned and maintained in good working condition
- More than one gun may be necessary to avoid overheating and a back-up gun should be available in the event of an ineffective shot
- Animals should be restrained; at a minimum they should be penned for cartridge powered guns and in a race for compressed air guns
- The operator should ensure that the animal's head is accessible

Community position:
The word "hornless" should be replaced by the word "horned".

-
- The operator should fire the captive bolt at right angles to the skull in the optimal position (see figures 1, 3 & 4. The optimum shooting position for hornless sheep is on the highest point of the head, on the midline and aim towards the angle of the jaw)
- To ensure the death of the animal, pithing or bleeding should be performed as soon as possible after stunning
- Animals should be monitored continuously after stunning until death to ensure the absence of brain stem reflexes

Advantages

- Mobility of cartridge powered equipment reduces the need to move animals

- Immediate onset of a sustained period of unconsciousness

Disadvantages

- Poor gun maintenance and misfiring, and inaccurate gun positioning and orientation may result in poor animal welfare
- Post stun convulsions may make pithing difficult and hazardous
- Difficult to apply in agitated animals
- Repeated use of a cartridge powered gun may result in over-heating

- Leakage of bodily fluids may present a biosecurity risk
- Destruction of brain tissue may preclude diagnosis of some diseases

Conclusion

A suitable method for cattle, sheep, goats and pigs (except neonates), when followed by pithing.

Article 8

Captive bolt - non-penetrating

Introduction

A non-penetrating captive bolt is fired from a gun powered by either compressed air or a blank cartridge. There is no free projectile.

The gun should be placed on the front of the skull to deliver a percussive blow which produces unconsciousness in cattle (adults only), sheep, goats and pigs, and death in poultry and neonate sheep, goats and pigs. In mammals, bleeding should be performed as soon as possible after the blow to ensure the death of the animal.

Requirements for effective use

- For cartridge powered and compressed air guns, the bolt velocity should be appropriate to the species and type of animal, in accordance with the manufacturer's recommendations
- Captive bolt guns should be frequently cleaned and maintained in good working condition
- More than one gun may be necessary to avoid overheating and a back-up gun should be available in the event of an ineffective shot

Community position:
The term "cones" should be more clearly explained or a suitable figure inserted to illustrate. For clarity the following sentence should also be added "Larger birds such as adult turkeys may be penned allowing sufficient room for a slaughterman to move around the pen applying the captive bolt to the heads of individual birds".

- Animals should be restrained; at a minimum mammals should be penned for cartridge powered guns and in a race for compressed air guns; birds should be restrained in cones, shackles, crushes or by hand.
- The operator should ensure that the animal's head is accessible

Community position:
The position/format of figure 5 should be clarified.

- The operator should fire the captive bolt at right

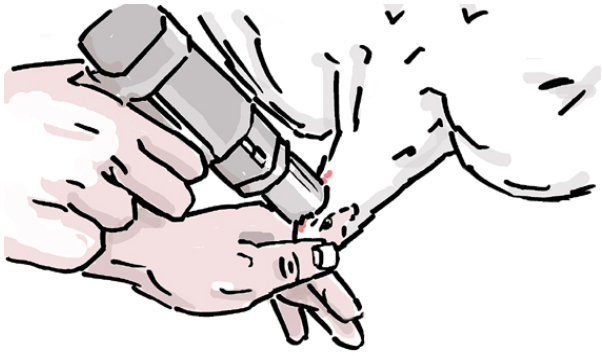


Figure 5 The optimum shooting position for

angles to the skull in the optimal position (figures 1-5)

- To ensure death in non-neonate mammals, bleeding should be performed as soon as possible after stunning
- Animals should be monitored continuously after stunning until death to ensure the absence of brain stem reflexes

Advantages

Community position:
The words "neonatal sheep, goats and pigs" should replace the word "neonates".

- Immediate onset of unconsciousness, and death in birds and neonates
- Mobility of equipment reduces the need to move animals

Disadvantages

- As consciousness can be regained quickly in non-neonate mammals, they should be bled as soon as possible after stunning
- Laying hens in cages have to be removed from their cages and most birds have to be restrained
- Poor gun maintenance and misfiring, and inaccurate gun positioning and orientation may result in poor animal welfare
- Post stun convulsions may make bleeding difficult and hazardous
- Difficult to apply in agitated animals; such animals may be sedated in advance of the killing procedure
- Repeated use of a cartridge powered gun may result in over-heating
- Bleeding may present a biosecurity risk

Conclusions

- A suitable method for poultry, and neonate sheep, goats and pigs.
- If bleeding does not present a biosecurity issue, this is a suitable method for cattle (adults only), and non-neonate sheep, goats and pigs.

Article 9

Maceration

Introduction

Maceration, utilising a mechanical apparatus with rotating blades or projections, causes immediate fragmentation and death in day-old poultry and embryonated eggs

Requirements

- Maceration requires specialised equipment which should be kept in excellent working order
- The rate of introducing the birds should not allow the equipment to jam, birds to rebound from the blades or the birds to suffocate before they are macerated

Advantages

- Procedure results in immediate death
- Large numbers can be killed quickly

Disadvantages

- Specialised equipment is required
- Macerated tissues may present a biosecurity issue

Conclusion

A suitable method for killing day-old poultry and embryonated eggs.

Article 10

Electrical – two stage application

Introduction

A two stage application of electric current comprises firstly an application of current to the head by scissor-type tongs, immediately followed by an application of the tongs across the chest in a position that spans the heart.

The application of sufficient electric current to the head will induce 'tonic/clonic' epilepsy and unconsciousness. Once the animal is unconscious, the second stage will induce ventricular fibrillation (cardiac arrest) resulting in death. The second stage (the application of low frequency current across the chest) should only be applied to unconscious animals to prevent unacceptable levels of pain.

Figure 6. Scissor-type stunning

Requirements for effective use

- The stunner control device should generate a low frequency (30 – 60 Hz) current with a minimum voltage of 250 volts true RMS under load.
- Appropriate protective clothing (including rubber gloves and boots) should be worn.
- Animals should be restrained, at a minimum free-standing in a pen, close to an electrical supply.
- Two team members are required, the first to apply the electrodes and the second to manipulate the position of the animal to allow the second application to be made.
- A stunning current should be applied via scissor-type stunning tongs in a position that spans the brain for a minimum of 3 seconds; immediately following the application to the head, the electrodes should be transferred to a position that spans the heart and the electrodes applied for a minimum of 3 seconds.
- Electrodes should be cleaned regularly and after use, to enable optimum electrical contact to be maintained.
- Animals should be monitored continuously after stunning until death to ensure the absence of brain stem reflexes.

Advantages

- The application of the second stage minimises post-stun convulsions and therefore the method is particularly effective with pigs.
- Non-invasive technique minimises biosecurity risk.

Disadvantages

- Requires a reliable supply of electricity.
- The electrodes must be applied and maintained in the correct positions to produce an effective stun and kill.

Appendix XXII (contd)

- Most stunner control devices utilise low voltage impedance sensing as an electronic switch prior to the application of high voltages; in unshorn sheep, contact impedance may be too high to switch on the required high voltage (especially during stage two).

- The procedure may be physically demanding, leading to operator fatigue and poor electrode placement.

Conclusion

- A suitable method for calves, sheep and goats, and especially for pigs (over one week of age).

Article 11

Electrical – single application

Introduction

Method 1 comprises the single application of sufficient electrical current to the head and back, to simultaneously stun the animal and fibrillate the heart. Provided sufficient current is applied in a position that spans both the brain and heart, the animal will not recover consciousness.

Method 2 stuns and kills by drawing inverted and shackled poultry through an electrified waterbath stunner. Electrical contact is made between the 'live' water and earthed shackle and, when sufficient current is applied, poultry will be simultaneously stunned and killed.

Method 3 comprises the single application of sufficient electrical current to the head of poultry in a position that spans the brain, causing unconsciousness; this is followed by a killing method (Article 17).

Method 1

Requirements for effective use

Community position:
There is no scientific evidence presented on the effectiveness of currents with a frequency below 50 Hz. Therefore replace "30-60 Hz" with "50-60 Hz". For a clear scientific basis see the EFSA report
http://www.efsa.eu.int/science/ahaw/ahaw_opinions/495_en.html

- The stunner control device should generate a low frequency (30 – 60 Hz) current with a minimum voltage of 250 volts true RMS under load.

- Appropriate protective clothing (including rubber gloves and boots) should be worn.

- Animals should be individually and mechanically restrained close to an electrical supply as the maintenance of physical contact between the stunning electrodes and the animal is necessary for effective use.

Community position:
To provide proper animal welfare safeguards the time "3 seconds" should be replaced with "10 seconds".

-

- The rear electrode should be applied to the back, above or behind the heart, and then the front electrode in a position that is forward of the eyes, with current applied for a minimum of 3 seconds.
- Electrodes should be cleaned regularly between animals and after use, to enable optimum electrical contact to be maintained.
- Water or saline may be necessary to improve electrical contact with sheep.
- An effective stun and kill should be verified by the absence of brain stem reflexes.

Advantages

- Stuns and kills simultaneously.
- Minimises post-stun convulsions and therefore is particularly effective with pigs.
- A single team member only is required for the application.

- Non-invasive technique minimises biosecurity risk.

Disadvantages

- Requires individual mechanical animal restraint.
- The electrodes must be applied and maintained in the correct positions to produce an effective stun and kill.
- Requires a reliable supply of electricity.

Conclusions

- A suitable method for calves, sheep, goats, and pigs (over 1 week of age).

Method 2

Requirements for effective use

- A mobile waterbath stunner and a short loop of processing line are required.
- A low frequency (30-60 Hz) current applied for a minimum of 3 seconds is necessary to stun and kill the birds.
- Poultry need to be manually removed from their cage, house or yard, inverted and shackled onto a line which conveys them through a waterbath stunner with their heads fully immersed.
- Required minimum currents to stun and kill dry birds are:
    - Quail - 100 mA/bird
    - Chickens – 160 mA/bird
    - Ducks & Geese – 200 mA/bird
    - Turkeys – 250 mA/bird.

  A higher current is required for wet birds.
- An effective stun and kill should be verified by the absence of brain stem reflexes.

Advantages

- Stuns and kills simultaneously.
- Capable of processing large numbers of birds reliably and effectively.
- Non-invasive technique minimises biosecurity risk.

Disadvantages

- Requires a reliable supply of electricity.
- Handling, inversion and shackling of birds are required.

Conclusion

A suitable method for large numbers of poultry.

Appendix XXII (contd)

Method 3

Requirements for effective use

- The stunner control device should generate sufficient current (more than 300 mA/bird) to stun.
- Appropriate protective clothing (including rubber gloves and boots) should be worn.
- Birds should be restrained, at a minimum manually, close to an electrical supply.
- A stunning current should be applied in a position that spans the brain for a minimum of 3 seconds; immediately following this application, the birds should be killed (Article 17).
- Electrodes should be cleaned regularly and after use, to enable optimum electrical contact to be maintained.
- Birds should be monitored continuously after stunning until death to ensure the absence of brain stem reflexes.

Advantages

- Non-invasive technique (when combined with neck dislocation) minimises biosecurity risk.

Disadvantages

- Requires a reliable supply of electricity.
- The electrodes must be applied and maintained in the correct position to produce an effective stun.

Conclusion

Suitable for small numbers of poultry.

Article 12

CO_2 / air mixture

Introduction

Controlled atmosphere killing is performed by exposing animals to a predetermined gas mixture, either by placing them in a gas-filled container or apparatus (Method 1) or by the gas being introduced into a poultry house (Method 2).

Inhalation of carbon dioxide (CO_2) induces respiratory and metabolic acidosis and hence reduces the pH of cerebrospinal fluid (CSF) and neurones thereby causing unconsciousness and, after prolonged exposure, death.

Method 1

Requirements for effective use in a container or apparatus

- Containers or apparatus should allow the required gas concentration to be maintained and accurately measured.

- When animals are exposed to the gas individually or in small groups in a container or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the animals and allow them to be observed.

- Animals should be introduced into the container or apparatus after it has been filled with the required CO_2 concentration, and held in this atmosphere until death is confirmed.

- Team members should ensure that there is sufficient time allowed for each batch of animals to die before subsequent ones are introduced into the container or apparatus.

- Containers or apparatus should not be overcrowded and measures are needed to avoid animals suffocating by climbing on top of each other.

Advantages

- CO_2 is readily available.

- Application methods are simple.

Disadvantages

- The need for special equipment

- The aversive nature of high CO_2 concentrations

- No immediate loss of consciousness

- The risk of suffocation due to overcrowding

- Difficulty in verifying death while the animals are in the container or apparatus.

Conclusion

Suitable for use in poultry and neonatal sheep, goats and pigs.

Method 2

Requirements for effective use in a poultry house

- Prior to introduction of the CO_2, the poultry house should be appropriately sealed to allow control over the gas concentration.

- The house should be gradually filled with CO_2 so that all birds are exposed to a concentration of >40% until they are dead; a vaporiser may be required to prevent freezing.

- Devices should be used to accurately measure the gas concentration at the highest level of birds.

Advantages

- Applying gas to birds *in situ* eliminates the need to manually remove live birds.

- CO_2 is readily available.

- Gradual raising of CO_2 concentration minimises the aversiveness of the induction of unconsciousness.

Appendix XXII (contd)

Disadvantages

Community position:
The following bullet points should be added to improve clarity and facilitate proper application and interpretation of the guidelines:
"Difficulty in ensuring even distribution and concentration of gas throughout all parts of the shed.
Gradual rise in gas concentration may produce a slow induction of unconscious ness
Noise of gas filling the shed and any aversion to the gas itself may produce excitement in birds, causing panic and the birds to crush or smother one another
Shutting off shed ventilation prior to filling the shed with gas may predispose to development of hyperthermia".

- Difficulty in determining volume of gas required to achieve adequate concentrations of CO_2 in some poultry houses
- Difficulty in verifying death while the birds are in the poultry house.

Conclusion

Suitable for use in poultry in closed-environment sheds

Article 13

Nitrogen/inert gas mixed with CO_2

Introduction

Community position:
In the first line the following notation could be clearer "(e.g. argon)".

CO_2 may be mixed in various proportions with nitrogen or an inert gas eg argon, and the inhalation of such mixtures leads to hypercapnic-hypoxia and death when the oxygen concentration by volume is ≤2%. This method involves the introduction of animals into a container or apparatus containing the gases. Such mixtures do not induce immediate loss of consciousness, therefore the aversiveness of various gas mixtures containing high concentrations of CO_2 and the respiratory distress occurring during the induction phase, are important animal welfare considerations.

Pigs and poultry appear not to find low concentrations of CO_2 strongly aversive, and a mixture of nitrogen or argon with ≤30% CO_2 by volume and ≤2% O_2 by volume can be used for killing poultry and neonatal sheep, goats and pigs.

Requirements for effective use

Community position:
The words "to be" could be inserted before the word "accurately".

- Containers or apparatus should allow the required gas concentrations to be maintained, and the O_2 and CO_2 concentrations accurately measured.

- When animals are exposed to the gases individually or in small groups in a container or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the animals and allow them to be observed.

Community position:
A new sentence should be added to the next bullet point "Apparatus and containers should be designed and used so as to ensure that the O_2 concentration in the chamber does not exceed 2% while the killing procedure is being carried out."

-

- Animals should be introduced into the container or apparatus after it has been filled with the required gas concentrations (with ≤2% O_2), and held in this atmosphere until death is confirmed.

- Team members should ensure that there is sufficient time allowed for each batch of animals to die before subsequent ones are introduced into the container or apparatus.

- Containers or apparatus should not be overcrowded and measures are needed to avoid animals suffocating by climbing on top of each other.

Advantages

- Low concentrations of CO_2 cause little aversiveness and, in combination with nitrogen or an inert gas, produces a fast induction of unconsciousness.

Disadvantages

- Need for a properly designed container or apparatus

- Difficulty in verifying death while the animals are in the container or apparatus

Community position:
The following bullet point should be added:
"Health and safety implications of using imperceptible inert gases in confined spaces".

-

- No immediate loss of consciousness
- Exposure times required to kill are considerable.

Conclusion

A suitable method for poultry and neonatal sheep, goats and pigs.

Article 14

Nitrogen and/or inert gasses

Introduction

This method involves the introduction of animals into a container or apparatus containing nitrogen or an inert gas such as argon. The controlled atmosphere produced leads to unconsciousness and death from hypoxia.

Research has shown that hypoxia is not aversive to pigs and poultry, and it doesn't induce any signs of respiratory distress prior to loss of consciousness.

Requirements for effective use

Community position:
The words "to be" should be inserted before the word "accurately".

- Containers or apparatus should allow the required gas concentrations to be maintained, and the O_2 concentration accurately measured.
- When animals are exposed to the gases individually or in small groups in a container or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the animals and allow them to be observed.
- Animals should be introduced into the container or apparatus after it has been filled with the required gas concentrations (with $\leq 2\%$ O_2), and held in this atmosphere until death is confirmed.
- Team members should ensure that there is sufficient time allowed for each batch of animals to die before subsequent ones are introduced into the container or apparatus.
- Containers or apparatus should not be overcrowded and measures are needed to avoid animals suffocating by climbing on top of each other.

Advantages

- Animals are unable to detect nitrogen or inert gases, and the induction of hypoxia by this method is not aversive to animals.

Disadvantages

- Need for a properly designed container or apparatus
- Difficulty in verifying death while the animals are in the container or apparatus

- No immediate loss of consciousness
- Exposure times required to kill are considerable.

Appendix XXII (contd)

Conclusion

A suitable method for poultry and neonatal sheep, goats and pigs.

Article 15

Lethal injection

Introduction

A lethal injection using high doses of anaesthetic and sedative drugs causes CNS depression, unconsciousness and death. In practice, barbiturates in combination with other drugs are commonly used.

Requirements for effective use

- Doses and routes of administration that cause rapid loss of consciousness followed by death should be used.
- Prior sedation may be necessary for some animals.

Community position:
It should be clarified whether the intra-cardiac injection of anaesthetic and sedative drugs in conscious animals can be recommended or not.

-
- Intravenous administration is preferred, but intraperitoneal or intramuscular administration may be appropriate, especially if the agent is non-irritating.
- Animals should be restrained to allow effective administration.
- Animals should be monitored to ensure the absence of brain stem reflexes.

Advantages

- The method can be used in all species.
- Death can be induced smoothly.

Disadvantages

- Restraint and/or sedation may be necessary prior to injection.
- Some combinations of drug type and route of administration may be painful, and should only be used in unconscious animals.

Community position:
The words "the use of some drugs"" could replace the word "use".

-
- Legal requirements may restrict use to veterinarians.

Conclusion

A suitable method for killing small numbers of cattle, sheep, goats, pigs and poultry.

Article 16

Addition of anaesthetics to feed or water

Introduction

An anaesthetic agent which can be mixed with poultry feed or water may be used to kill poultry in houses. Poultry which are only anaesthetised need to be killed by another method such as cervical dislocation

Requirements for effective use

- Sufficient quantities of anaesthetic need to be ingested rapidly for effective response.

- Intake of sufficient quantities is facilitated if the birds are fasted or water is withheld.
- Must be followed by killing (see Article 17) if birds are anaesthetised only.

Advantages

- Handling is not required until birds are anaesthetised.
- May be biosecurity advantages in the case of large numbers of diseased birds.

Disadvantages

- Non-target animals may accidentally access the medicated feed or water when provided in an open environment.
- Dose taken is unable to be regulated and variable results may be obtained.
- Animals may reject adulterated feed or water due to illness or adverse flavour.
- May need to be followed by killing.
- Care is essential in the preparation and provision of treated feed or water, and in the disposal of uneaten treated feed/water and contaminated carcasses.

Conclusion

A suitable method for killing large numbers of poultry in houses.

Article 17

Killing methods in unconscious animals

Method 1 Cervical dislocation (manual and mechanical)

Introduction

Poultry may be killed by either manual cervical dislocation (stretching) or mechanical neck crushing with a pair of pliers. Both methods result in death from asphyxiation and/or cerebral anoxia.

Requirements for effective use

- Killing should be performed either by manually or mechanically stretching the neck to sever the spinal cord or by using mechanical pliers to crush the cervical vertebrae with consequent major damage to the spinal cord.

Community position:
The following bullet point should be added: "palpate neck to ensure disruption of the vertebral column".

-
- Consistent results require strength and skill so team members should be rested regularly to ensure consistently reliable results.
- Birds should be monitored continuously until death to ensure the absence of brain stem reflexes.

Advantages

- It is a non-invasive killing method
- Can be performed manually on small birds.
-

Appendix XXII (contd)

Disadvantages

Community position:
The following bullet point should be added: "A potentially painful method which may not result in immediate death".

- Operator fatigue

Community position:

The words "such as adult ducks, geese and turkeys" should be added to the next bullet point. The "Panel on Euthanasia" of the American Veterinary Society only allows the killing by cervical dislocation of small birds or chicks. The physical effort for the cervical dislocation for bigger birds is too great to kill them without causing unnecessary pain or suffering. Moreover, the birds would need to be tightly restrained which could cause further pain or suffering. AVMA panel on Euthanasia (2001): Report 2000. J. Am. Vet. Med. Ass. 218, S. 669 - 696

-

- The method is more difficult in larger birds.

Conclusion

This method is suitable for killing unconscious poultry.

Method 2 Decapitation

Introduction

Decapitation results in death by cerebral ischaemia using a guillotine or knife.

Requirements for effective use

- The required equipment should be kept in good working order

Advantages

- The technique is effective and does not require monitoring

Disadvantages

- Contamination of the working area with body fluids

Conclusion

This method is suitable for killing unconscious poultry.

Method 3 Pithing

Introduction

Pithing is a method of killing animals which have been stunned by a penetrating captive bolt. Pithing results in the physical destruction of the brain and upper regions of the spinal cord, through the insertion of a rod or cane through the bolt hole.

Requirements for effective use

- Pithing cane or rod
- Access to the head of the animal and to the brain through the skull
- Animals should be monitored continuously until death to ensure the absence of brain stem reflexes.

Advantages

- The technique is effective in producing immediate death

Disadvantages

- Delayed and/or ineffective pithing due to convulsions
- Contamination of the working area with body fluids

Community position:
An extra disadvantage should be added: Potential danger to operators due to reflex kicking during the pithing process.

-

Conclusion

This method is suitable for killing unconscious animals which have been stunned by a penetrating captive bolt.

Method 4 Bleeding

Introduction

Bleeding is a method of killing animals through the severance of the major blood vessels in the neck or chest that results in a rapid fall in blood pressure, leading to cerebral ischaemia and death.

Requirements for effective use

- Sharp knife
- Access to the neck or chest of the animal
- Animals should be monitored continuously until death to ensure the absence of brain stem reflexes.

Advantages

- The technique is effective in producing death after an effective stunning method which does not permit pithing.

Disadvantages

- Delayed and/or ineffective bleeding due to convulsions
- Contamination of the working area with body fluids.

Conclusion

This method is suitable for killing unconscious animals.

Appendix XXIII

APPENDIX 3.6.5

GENERAL GUIDELINES FOR THE DISPOSAL OF CARCASSES

Introduction

The mass destruction and disposal of animals in the event of an animal disease outbreak are always subject to intense public and media scrutiny thereby obligating the *Veterinary Administration* of a Member Country to not only conduct carcass disposal operations within acceptable scientific principles to destroy the causative pathogen of disease but also to satisfy animal welfare, public and environmental concerns.

The guidelines in this Appendix are general and generic in nature. They are recommended for adoption after consideration of the application best suited to prevailing circumstances of a specific disease outbreak. The choice of one or more of the recommended technologies should be in compliance with the mandates provided for within relevant local and national legislation and be attainable with the resources available within the Member Country. The guidelines should also be read and applied in conjunction with the procedures described for the humane killing of animals in Appendix XXX of the *Code*.

The chapter aims to briefly describe the definitions applicable to the disposal of carcasses, outline the regulatory and jurisprudence requirements that should be considered, identify the most important risk factors associated with the disposal of carcasses, list the social factors and practical considerations relevant to carcass disposal, give guidelines on appropriate technologies that could be applied and give guidance on the decision-making process in electing the most appropriate technology for the disposal of carcasses under specific circumstances.

Where indicated within the relevant chapters of the *Code,* the vaccination of animals in combination with or without a stamping-out policy to contain a disease outbreak could be the preferred choice above mass destruction. The eventual decision to embark on the mass destruction and disposal of animals to contain a disease outbreak should be carefully evaluated against available alternatives, environmental, socio-political and socio-economical concerns, trade implications as well as prevailing ethical and ethnic beliefs and preferences.

Definitions

For the purpose of this Appendix the following definitions relevant to the disposal of carcasses shall apply:

- **Carcass -** means the body of an animal subsequent to euthanasia or death that requires safe destruction.
- **Disposal -** means the inactivation of the pathogen with reduction of the carcass and related materials to constituent components.
- **Technology -** means the process by which disposal is achieved.
- **Transport -** means the bio-secure removal of animals or carcasses or material from the site of infection to the site of disposal.
- **Bio-security -** means the absolute containment of infection.

Appendix XXIII (contd)

- **Human safety -** means elimination of risks to the health and well-being of the persons involved in animal disposal procedures.

- **Animal welfare -** means reference to guidelines established for humane killing as defined in Appendix XXX.

- **Mass destruction -** means an emergency destruction and disposal of a large number of animals for disease control purposes

Regulations and jurisdiction

The laws regulating animal health, prevention and eradication of animal diseases, and the organisation of the *Veterinary Administration* should give the *Veterinary Services* the authority and the legal powers to carry out the necessary activities for an efficient and effective disposal of carcasses. For most of the disposal options, legislation of other governmental bodies at national or local level is in force and should be respected. Therefore close co-operation between the *Veterinary Service* and these authorities is indispensable to develop a coherent set of legal measures for carcass disposal in peace time in order to apply these undisturbed where and when it is necessary. In this context the following aspects should be clearly regulated:

- Right of entry on a farm and its premises for personnel of the *Veterinary Service* and of contractors working for the *Veterinary Service.*

- Total movement ban to be applied on an infected or suspected farm and the authority to make exemptions under certain bio-security conditions - for instance for transport of carcasses to another location for disposal..

- The obligation for the involved farmer, his relatives and his personnel to co-operate with and to apply all the measures ordered by the *Veterinary Service*.

As regard to infected and suspected animals and their products:

- the transfer of the ownership of these to the competent authority (for instance through confiscation or buying up with compensation of the farmer) and

- the right to kill these animals on the farm or wherever the *Veterinary Service* determines.

If burning of the carcasses is the option of choice:

- the Veterinary Service should have the authority to determine the place where the pyre is situated,

- national and local governmental organisations competent for the protection of the environment should have given their approval for this solution in advance and should have adopted the necessary legal framework to allow this and

- all involved authorities should have determined on the conditions for removal of the ashes.

If mass burial, mounding or open farm burial is the preferred option:

- the Veterinary Service should have the authority to determine the place of burial in accordance with other involved authorities,

- national and local governmental organisations competent for the protection of the environment and subsoil water reserves should have agreed with this solution and should have adopted the necessary legislation and

- all involved authorities should have determined together the regime applicable to the site after the burial.

If rendering or any other centralised processing is the preferred option:

- the Veterinary Service should have the authority to require the necessary capacity at the processing company and to determine priorities,

- national and local governmental organisations regulating these types of processing should have agreed with the increased production volumes and other related consequences beforehand and should have covered the legal aspects and

- all involved authorities should have determined on the conditions applicable to the products from these carcasses.

It might happen that the chosen option for carcass disposal has to be applied near the border of a neighbouring country. In such cases the competent authorities of this country should be consulted and common legal solutions should be found in order to prevent misunderstanding and conflict.

If there is insufficient capacity in the country for processing of carcasses and if other options for carcass disposal are also limited, a solution could be the processing in another country. However, when an outbreak of an infectious animal disease occurs in a country, governments take preventive measures against import of potentially infected animals and products from the infected region. Those measures will also prevent the importation and transport of carcasses to a processing plant. If the export option is the choice, the conditions should be well established between the two involved countries and all legal aspects cleared beforehand. It should be realised that strong opposition can be expected from the farming community in the importing country against such transports. An agreement and preparation of the necessary legal aspects in peace time will help to apply this solution rapidly when it is needed. Clear communication about the process to be followed will help to elicit public support.

Pre-outbreak activities

The decision to embark on the mass destruction and disposal of animals in the event of a major disease outbreak or the mass disposal of animals in the event of natural disasters such as floods, and the implementation of the decision, need often to be taken in a short limit of time and activities to execute the decision, must similarly proceed with the minimum delay. The success or failure however, is primarily determined by the structures, policies and infrastructure that were established and agreed upon well in advance of such an event within contingency plans and working relationships and responsibilities established in preparation with other supportive structures.

- *Technical preparedness* – implies a predetermined decision process enunciated in a document, training of staff in the technical aspects of applicable technologies and the development of instructional manuals such as standing operating procedures (SOP's) for events of disposal. The sensitivity and public scrutiny on the process of carcass disposal requires that a trained and competent official must be available on site. Such an official must be familiar with procedures to conduct the chosen technologies for carcass disposal.

Appendix XXIII (contd)

- *Financial preparedness* - the factors of a compensation mechanism to assist affected producers; access to emergency funding permitting rapid and effective action; and access to an expanded human resource through agreements with private veterinarians, are considered critical to the success of the program. To be effective, these factors must be considered, resolved and in place prior to a disease occurrence. Transparency on the criteria for compensation and the minimum delay in the execution of payments are critical factors to ensure cooperation from affected farmers.

- *Pre-established partnerships* - a relationship with industry is essential to obtain compliance with animal health policies. Partnerships should not only include farmer associations or commodity representatives but also animal welfare organisations, supportive structures such as security services, disaster management units within government structures, the media and consumer representative groupings. This relationship is encouraged and essential to enhance the receptivity to future risk communications. In some countries tourism is a very significant contributor to the national economy and can be adversely affected by animal disposal and emergency operations.

- *Communication plan* - the *Veterinary Administration* must accept that the information on any event of mass culling and disposal of animals cannot and should not be withheld from public scrutiny. Sharing the information based on scientific facts on an ongoing basis is essential. Information sharing with politicians and the media is especially important but information sharing with officials involved in the outbreak, affected farmers and professional organizations is equally essential but often neglected or forgotten. A well informed and knowledgeable spokesman should be available at all times to answer questions from the media and the public. Consistency in the information given is essential and should be guided by an available set of pre-empted well debated questions and answers that should be daily updated. An essential pre-requisite is to ensure ownership by politicians for the policies applied for the mass destruction and disposal of animals to contain a disease outbreak. The support by politicians should already be established in policy formulation and budgetary processes by the *Veterinary Administration* of the Member Country.

- *Equipment* – a supply of essential emergency equipment should be available immediately while contracts with rendering plants should be established as a default standing arrangement. The management of equipment should include provisions for expansion, temporary storing facilities, transport, and transport on farm, drivers, disinfection, mobile handling facilities for animals such as mobile crush-pens, protective and disposable material and logistical support. Procurement procedures should be simplified and special authorizations provided for the operation to enable the minimum delay in obtaining essential equipment and to supplement or replace existing equipment. Equipment would also include the type of burning material used for pyre burning of carcasses. In some countries sufficient wood would still be available but usage thereof is subject to environmental legislation and environmental concerns. Old vehicle tyres are a cheap and readily accessible alternative to wood but could be a source of environmental pollution and should only be used if sanctioned by applicable local or national legislation. The prior identification of sources of burning material are therefore essential so that it could be obtained with the minimum loss of time and effort when needed.

- *Transport arrangements* – The transport needed during mass disposal of animals are generally not included in the normal stock of vehicles of a *Veterinary Administration.* Heavy trucks, tractors, bulldozers, front-end loaders and the like, are all types of vehicles needed for transport of animals, collection of burning material, filling and closure of disposal sites and transport from the farm to a disposal site. It is important to ensure that the vehicles used do not pose a source for dissemination of the infection.

Risk factors

The list of risk factors has not the pretension to be complete. Other risk factors may influence the choice of a technique for carcass disposal as well.

- ***Speed*** - early detection of new infections, immediate killing of infected animals and rapid removal of the carcasses with inactivation of the pathogen are of utmost importance for the eradication of infectious diseases. Viral pathogens will not further multiply after the host is killed, but active and passive spread of the pathogen from the carcasses and their surroundings should be blocked as soon and as effectively as possible.

- ***Occupational health safety*** - carcasses in decomposition soon become a health risk for the persons who have to handle them during the process of disposal. Disposal should be organised in such a way that the workers are safeguarded against the risks of handling decomposed dead bodies. However special attention should be given to zoonotic aspects of certain pathogens as for instance avian influenza. Workers should be sufficiently protected against infection with a zoonotic pathogen (protective clothing, gloves, face masks, spectacles, vaccination, anti viral medicines, regular health checks).

- ***Pathogen inactivation*** - the chosen disposal procedure must give optimal safety as regards to the inactivation of the pathogen. If this cannot be achieved instantly, the spreading of the pathogen from the process should be blocked. Scientific information about the reduction of the pathogenic agent over time under the expected climatological conditions for any of the technologies should be the basis for the lifting of restrictions for the products or sites

- ***Environmental concerns*** - the different technologies for carcass disposal have different effects on the environment. For instance pyre burning will produce smoke and smells; burial might lead to gas production; escape of these gases and as a result smell; but also risk of contamination of air, soil, surface and sub surface water. Increased operating hours or increased throughput in a rendering plant may lead to increased smell or disturbances in the normal functioning of the waste water treatment and other protective facilities of the plant.

- ***Availability of capacity*** - practically all the technologies for carcass disposal have limitations on capacity. When the number of carcasses to be disposed of is high, the capacity of the acceptable technologies will soon be the bottle neck. An assessment of possibilities and capacities in peace time is very important to be able to take quick decisions in case of emergency. Temporary storage of carcasses in cold stores could sometimes relieve the lack of processing capacity.

- ***Cost*** - technologies for carcass disposal and specially those using sophisticated equipment are very costly. Budgetary provisions should be made for emergencies. When the Veterinary Service during a disease outbreak seeks the cooperation of private companies offering the needed capacity, the costs might escalate tremendously. Therefore it is necessary to negotiate a contract in peace time with those suppliers about capacities and costs when preparing a strategy for eradication.

- ***Public reaction*** - carcass disposal can easily lead to adverse reactions from the public when pictures of half burned or hoisted carcasses are shown on TV or in press. Urbanised populations estranged from rural practices will react often very emotionally on these images. In poorer countries the destruction of valuable meat of not yet sick animals may provoke public misunderstanding.

Appendix XXIII (contd)

- ***Acceptance by farmers*** - the owners of an infected farm will in general prefer technologies at a distance and not on their own farm. Farmers outside an infected zone will prefer disposal within the infected area. All farmers will be very sensitive with regard to the safety measures taken to prevent spread of the disease by the used technology and the transport of the carcasses to the processing plant or disposal site. Proper compensation of owners for the loss of their animals or for the disposition of burial or burning sites will improve acceptability.

- ***Transport*** - for the application of all technologies for disposal, cranes, shovels and trucks must be used to transport the carcasses. This equipment can transfer the infection to other farms. Cleaning and disinfection of the outside surfaces of these vehicles when leaving an infected premise should receive special attention. The hygiene of the driver, his cabin, his lockers and his clothing and footwear should also be part of this process. The trucks transporting carcasses should be leak proof and be completely covered in order to prevent spread of the pathogen from the truck. The Veterinary Service should supervise the departure of the vehicle from the farm, the route the transport passes and the arrival at the disposal plant or site.

- ***Wildlife*** - many infectious diseases can affect wild animals as well as domesticated animals. Sometimes farm animals become infected through contact with game, but the population of wild animals might also become infected from an outbreak of a disease on a farm. When disposing of carcasses full attention should be given to the prevention of contamination of wildlife. Predators could try to get access to dead carcasses which might cause active or passive spread of the infection to other wild or domesticated animals.

Social factors related to carcass disposal

Culling and destroying of animals for the eradication of infectious disease often produce vehement reactions from the public. Reactions can be expected from the owners of animals which have to be culled, from farmers who are scared that their animals might contract the disease, animal welfare advocates who try to protect the lives of animals, people who abhor pictures of the culling of animals and the transport, burning and burial of carcasses, organisations who fight for environmental protection, culling perceived as a waste of edible food, etc.

In general a stamping out policy is applied to defend the export interests of the animal husbandry industry and is economically motivated. However, in some countries the general public and politicians express their doubts or their opposition against economical reasons as the leading argument to apply this strategy.

Even not all farmers will support the economic necessity of stamping out. For many farmers the rapid regaining of export markets is of no interest. Animals often represent a much more important and differentiated value than pure economics. For an animal breeder his animals represent a professional achievement based on the skills of himself and his ancestors. Many hobby farmers consider their animals as personal companions. In traditional communities animals are kept not for production but for a variety of reasons like a beast of draught or burden, for ceremonial reasons or as a symbol of wealth. For some religions the killing of certain animals is not acceptable. The export related economic argument will fail to convince such owners of the need for culling especially when animals, not showing any symptoms of disease but identified as carriers or serological positive, are included in the culling operation. Loss of certain animals cannot be compensated financially.

Practical considerations

In addition to the risk factors and pre-outbreak activities identified above, several practical issues, often not considered or often accepted as obvious but not attended to, need to be noted. The list is not exhaustive but gives an indication of some of the easily forgotten but essential considerations:

- ***Selection of disposal site*** – sufficient top soil to cover the site; water drainage; prevailing wind conditions; easy access to transport; availability of meteorological data; separation from sensitive public sites.
- ***Selection of contractors for transport –*** availability; can they supply in all the needs; exclusive use of vehicles or would they also be used for other purposes (risk of disease transmission); access to available roads; suitable for the purpose to be used.
- ***Logistical preparedness for the appropriate technology*** – availability of burning material (wood, old tyres); sufficient manual labour available; sites and availability of disinfection tents for personnel; storage and disposal of protective clothing; housing for personnel to prevent them from going back to home and spread infection; facilities for entry and exit control; availability of electricity for night operations; personal facilities for personnel such as toilets, drinking water; availability of communication – mobile phone reception; protection (eg vaccination) of personnel; rendering capacity at rendering plants; additional cold storage and holding facilities at rendering plants and abattoirs; availability of freezing facilities before rendering.
- ***Procedures and policies for disposal of other products*** – manure, eggs; milk; non-animal products; animal feed.
- ***Wildlife*** – do they pose a risk in the immediate environment; expertise availability for culling of wildlife; availability of capture teams?

Recommended technologies for the disposal of carcasses

These technologies are presented as a hierarchy based on their reliability for pathogen inactivation.

- ***Rendering -*** This is a closed system for mechanical and thermal treatment of animal tissues leading to stable, sterilized products, e.g. animal fat and dried animal protein. It grinds the tissue and sterilizes it by heat under pressure. The technology exists in fixed facilities and is in normal usage. It produces an effective inactivation of all pathogens with the exception of prions where infectivity is reduced. A medium sized rendering plant could process 12 tonnes per hour of operations. The availability of the capacity should be determined in advance. Such a plant can operate within environmental standards.
- ***Incineration -*** This technology can be applied as:
    - Fixed, whole-carcass incineration,
    - Mobile air curtain whole carcass incineration,
    - Municipal incinerators,
    - Co-incineration

  Fixed whole carcass incineration occurs in an established facility in which whole carcasses or carcass portions can be completely burned and reduced to ash. Effective inactivation of pathogens is produced. Without additional technology, the exhaust emissions are not subjected to environmental control. However these emissions can be subjected to air scrubbing procedures to meet environmental standards. Fixed facility incineration has been used to dispose of BSE infected carcasses, as well as rendered meat-and-bone meal (MBM) and tallow from cattle carcasses considered to be at risk of BSE. Fixed facility incineration is wholly contained and usually highly controlled. It is typically fuelled by diesel, natural gas, or propane. The exhausts may be fitted with afterburner chambers to completely burn hydrocarbon gases and particulate matter from the main combustion chamber. Whole carcass disposal can be problematic given the batch-feed requirements at most biological waste incineration plants. Many waste incineration facilities refuse whole animals which are 70% water, but prefer waste of 25% water. Therefore, combining rendering and incineration is a promising approach. The resultant ash is less problematic and is considered safe. Although this is a more controlled procedure, there is still a potential fire hazard.

Appendix XXIII (contd)

Municipal incinerators are pre-established facilities which are normally used for the burning of household or industrial waste. They may not be currently licensed to burn carcasses.

Co-incineration is a process in which meat and bone meal, carcasses or parts of carcasses are burned in conjunction with other substances such as hazardous waste incineration, clinical waste incineration, and other industrial incinerations such as power plants, cement kilns, blast furnaces and coke ovens. In practice meat and bone meal has been used as a secondary fuel on a large scale in cement kilns and power plants.

Air curtain incineration - air curtain incineration involves a machine that fan-forces a mass of air through a manifold, thereby creating a turbulent environment in which incineration is accelerated up to six times faster than open-air burning. The equipment for this process can be made mobile which can be taken on-site but the potential fire hazard must be considered. Because it can be used on site, there is no requirement for transportation of the animal material. It also produces effective inactivation of pathogens and may actually achieve higher temperatures (1000 ^{0}C). Fuelled by diesel engines, high velocity air is blown into either a metal refractory box or burn pit. The materials required are wood (in a wood:carcass ratio of from 1:1 to 2:1), diesel fuel for both the fire and the air-curtain fan, and properly trained personnel. For incineration of 500 adult swine, the requirements are 30 cords of dry wood and 200 gallons of diesel fuel. The product is ash. Since the procedure is not wholly contained, it is subject to variable factors such as human operation, weather, and local community preferences.

Pyre burning - this is an open system of burning carcasses either on-farm or in collective sites fuelled by additional materials of high energy content. This is a well established procedure that can be conducted on site with no requirement for transportation of the input material. However, this process could be contrary to environmental standards for air, water and soil. It takes an extended period of time and has no verification of pathogen inactivation. In fact, there is a possibility of particulate transmission from incomplete combustion. Further, because the process is open to view, there is a negative reaction and lack of acceptance by the public.

Comparison of incineration methods

With all three incineration methods described above, the greater the percentage of animal fat, the more efficiently a carcass will burn. (Swine have a higher fat content than other species). For fixed facility incinerators, the capacity depends on the chamber's size and can range from 50 kg / hour up to 10 tonnes of poultry carcasses / day. Preprocessed, relatively homogeneous carcass material is more easily handled than large numbers of whole animal carcasses. Depending on the design and on-site management, air-curtain incinerators can burn 4 - 6 tons of carcasses / hour.

- ***Open-air burning*** can be relatively inexpensive, but it is not suitable for TSE infected carcasses. It is labour and fuel intensive, and dependent on favourable weather. It has environmental problems and a poor public perception. It is generally accepted that open-air burning pollutes. Although this is dependent on a number of factors. This may be more perception than established fact. Open air burning can also pose significant public perception, psychological, and economic problems

- ***Fixed facility incineration*** destroys TSE infected carcasses and is highly biosecure. However it is expensive and difficult to operate and manage from a regulatory perspective. Properly operated fixed facility incineration pose fewer pollution concerns

- ***Air-curtain incineration*** is mobile, usually environmentally sound, and suitable for combination with debris removal. However it is fuel intensive, logistically challenging, and is not validated to dispose of TSE infected carcasses. Air curtain technology in general has been shown to cause little pollution with fire boxes burning cleaner than trench burners. It has higher combustion efficiencies with less carbon monoxide and particulate matter emissions.

- ***Composting -*** carcass composting is a natural biological decomposition process that takes place in the presence of oxygen. In the first phase, the temperature of the compost pile increases, organic materials break down into relatively small compounds, soft tissue decomposes, and bones soften partially. In the second phase, the remaining materials, mainly bones, break down fully to a dark brown or black humus containing primarily non-pathogenic bacteria and plant nutrients.

  Composting systems require a variety of ingredients including carbon sources, bulking agents and biofilter layers. Carbon sources can include materials such as sawdust, straw, cured cornstalks, poultry litter, ground corn cobs, wheat straw, hay, shavings, paper, leaves, vermiculite, and matured compost. A 50:50 mixture of separated solids from manure and a carbon source can be used as a base material for carcass composting. The finished compost retains nearly 50% of the original carbon source which can be recycled in the compost process. A carbon:nitrogen (C:N) ratio in the range of 25:1 - 40:1 generates enough energy and produces little odour during the composting process. As a general rule the weight of carbon source materials to mortalities is approximately 1:1 for high C:N materials such as sawdust, 2:1 for medium C:N materials such as litter and 4:1 for low CN materials such as straw.

  Bulking agents have bigger particle sizes than carbon sources and maintain adequate air spaces (around 25-35% porosity) within that compost pile by preventing packing of materials. Bulking agents include spent horse bedding, wood chips, rotting hay bales, peanut shells, and tree trimmings. The ratio of bulking agents to carcasses should result in a bulk density of the final compost mixture that does not exceed 600 Kg/m^3. The weight of the compost mixture in a 19 litre bucket should not be more than 11.4 kg.

  A biofilter is a layer of carbon source or bulking material that enhances microbial activity with proper moisture, pH, nutrients, and temperature. It deodorizes gases released at ground level and prevents access by insects and birds thus minimizing transmission of disease agents.

The site selection criteria include a well drained area at 90 cm above the high water table level, at least 90 metres from sensitive water resources, and an adequate slope (1-3%) to allow proper drainage and prevent pooling of water. Runoff should be collected and treated. The location should be downwind of nearby residences. The site should have full accessibility but have minimal interference with other operations and traffic. Storage time of mortalities should be minimized. Co-composting materials should be ground to 2.5 - 5.0 cm and mixed. Compost materials should be lifted and dropped rather than be pushed into place. Compost piles should be covered by a biofilter layer during both phases of composting. The moisture content of the carcass compost pile should be 40-60% (wet basis).

Appendix XXIII (contd)

A temperature probe should be inserted straight down into each quadrant of the pile and internal temperatures should be monitored daily and weekly during both phases of composting. During the first phase, the temperature at the core of the pile should rise to at least 55-60 °C within 10 days and remain there for several weeks. A temperature of 65°C at the core, maintained for 1 - 2 days, will reduce pathogenic bacterial activity and weed seed germination. However spore formers such as *Bacillus anthracis* and other pathogens such as *Mycobacterium tuberculosis* will survive. Proper aeration is important in maintaining uniform temperature and moisture content throughout the pile. After the first phase of composting, the volume and weight of the pile may be reduced by 50-75%. Following the first phase, the entire compost pile should be mixed, displaced and reconstituted for the secondary phase. If necessary, moisture can be added.

The end of the second phase is marked by an internal temperature of 25-35°C, a reduction in bulk density of approximately 25%, a colour of dark brown to black and the lack of an unpleasant odour. Although heat generated during carcass composting results in some microbial destruction, it is not sufficient to completely sterilize the end product. Pathogenic bacterial activity is reduced when the temperature in the middle of the pile reaches 65 °C within one to two days. An average temperature of 55-60 °C for a day or two reduces pathogenic viruses, bacteria, protozoa (including cysts) and helminth ova to an acceptably low level, but endospores produced by spore-forming bacteria would not be inactivated.

- ***Trench burial and mass burial -*** this is a system to deposit whole carcasses below ground level and to be covered by soil, with no additional inactivation of pathogens. It is an established procedure which if conducted on site does not require transportation and is used to control the spread of disease. It does however require an environmental assessment because of the potential contamination of groundwater, or of aquifers if leachate is not controlled. Further, it does not inactivate all pathogenic agents.

- ***Licensed commercial landfill -*** this process involves deposition of carcasses in predetermined and environmentally licensed commercial sites. Because the site has been previously licensed, all environmental impacts such as leachate management, gas management, engineered containment, flooding and aquifers have already been considered. However, the area is open and uncovered for extended periods, there is a potential emission of aerosols, and there is resistance from the public to such an approach.

- ***Mounding -*** this process is one of mass burial above ground and it has similar considerations to those of mass burial and composting.

- ***Fermentation -*** this process is a closed system of anaerobic microbiological decompositions which requires prior mechanical and thermal treatment and which results in the production of biogas. This process does not inactivate pathogens, but typically uses non-dried rendered product as the input material.

- ***Alkaline hydrolysis -*** alkaline hydrolysis uses sodium hydroxide or potassium hydroxide to catalyse the hydrolysis of biological material into a sterile aqueous solution consisting of small peptides, amino acids, sugars, and soaps. Heat is applied (150°C) to accelerate the process. The only solid byproducts are the mineral constituents of the bones and teeth of vertebrates. This residue (2% of the original weight of the carcass) is sterile and easily crushed into a powder. The temperature and alkali conditions of the process destroy the protein coats of viruses and the peptide bonds of prions. Both lipids and nucleic acids are degraded. Significantly large carbohydrate molecules, such as cellulose, although sterilized by the process, are not digestible by alkaline hydrolysis eg paper, string, undigested plant fibres, and wood shavings.

The process is carried out in an insulated steam-jacketed, stainless steel pressure vessel with a sealed lid. The vessel operates at 70psig to achieve 150°C. The process does not release any emissions into the atmosphere and only causes minor odour production. The end product solution can be released into the sanitary sewer with proper monitoring of pH and temperature according to guidelines. The total process time for alkaline hydrolysis digestion of carcass material is 3-8 hours depending on the disease agent eg bacterial and viral contaminated waste (4 hours), transmissible spongiform encephalopathy waste (6 hours). A mobile trailer unit has a capacity of digesting 4000 pounds of carcasses every 8 hours.

- ***Lactic acid fermentation*** - lactic acid fermentation is a means to preserve carcasses up to 25 weeks until they can be rendered. Fermentation is an anaerobic process. Carcasses are ground to fine particles, mixed with a fermentable carbohydrate source and a culture inoculant, and added to a fermentation container. For lactic acid fermentation, lactose, glucose, sucrose, whey, whey permeates, and molasses are suitable carbohydrate sources. The carbohydrate source is fermented to lactic acid by *Lactobacillus acidophilus*.

  Under optimum conditions with a temperature of about 35 °C, the pH of fresh carcasses is reduced to less than 4.5 within two days. Some microorganisms are destroyed by the acid pH while the remainder will be destroyed by heat during rendering.

- ***Anaerobic digestion*** - this process is suited for large-scale operations. It reduces odours and reduces pollution by greenhouse gases due to the combustion of methane. It can eliminate carcasses and at the same time produce energy but may require size reduction and sterilization of carcasses on-site before applying anaerobic technology. Anaerobic digestion transforms waste into fertilizer. Although anaerobic digestion is less expensive with mesophilic organisms at 35°C, the use of thermophilic organisms at 55 °C is preferred because the additional heat destroys some pathogens. It is necessary to use additional heat treatment at the end of the process to fully inactivate pathogens however, even with this, prions are not inactivated. Carcasses have a higher nitrogen content than most other wastes and therefore result in a high ammonia concentration which can inhibit anaerobic digestion. This limits the loading rate for anaerobic digesters that are treating carcass wastes.

- ***Non-traditional and novel technologies***

  - ***Pre-processing*** - this involves on farm pre-processing prior to transportation of carcasses to central facilities because of the complexity and cost (eg rendering or incineration). Preprocessing could include the grinding of carcasses. (A large portable grinder can grind up to 15 tons of animal carcasses per hour). This could then be transported in sealed containers, or be subjected to fermentation or freezing. The primary objectives are to minimize on-site contamination risks and to maximize the number of options for disposal.

  - ***Carcass disposal at sea -*** disposal in a coastal sea or on a continental plateau cannot occur without the authorization of the coastal State which must make a regulation on the dumping and which must consult with other neighbouring States. International Conventions express a fundamental principle which countries should be obliged to respect even if they are not signatories. These Conventions do not directly prohibit disposal of carcasses at sea, but do define the conditions to be met. It is possible for this disposal if it is technically and scientifically proven that the products to be disposed are not harmful, and if the State has authorised this disposal with a permit.

Appendix XXIII (contd)

- ***Bio-refining*** - this is a high pressure, high temperature hydrolytic process, conducted in a sealed pressurized vessel. The waste material is treated at 180 °C at 12 bar pressure for 40 minutes, heated by indirect steam application to the biolytic reactor. The process can accommodate whole animal carcasses, MBM, food processing wastes, other compostable material, paper and comparable materials, and cereal straws either alone or in combination. In the dehydration cycle, the steam water is condensed and either used for other purposes or discarded. Each cycle lasts four hours. The capacity of each reactor is 20,000 tonnes of raw material per year. The process inactivates all microbiological agents. It is currently under evaluation for its efficiency in inactivating the prions of transmissible spongiform encephalopathies.

Special considerations for prion diseases

One of the problems in demonstrating the effectiveness of the inactivation of prions is the lack of a simple, rapid and inexpensive test for the presence of the infective agent, especially at low concentrations. The ultimate test is bioassay in a sensitive detector species by an efficient route, but usually this is only relevant in research. Typically this is done using panels of mice bred to be susceptible to particular types of transmissible spongiform encephalopathies (TSEs). However it must be recognized that the mouse to cattle species barrier has been demonstrated to be 500, therefore affecting sensitivity.

Although rendering at 133°C and three bars of pressure for 20 minutes is a defined standard, reductions of infectivity by this technology are in the order of 1:200 – 1:1000. Commercial incinerators have an inactivation rate of one million fold, while burning on pyres has a reduction rate of 90 %. (It should be noted that pyres are not suitable for sheep because of the wool and fat.) Alkaline hydrolysis produces a 3-4 log reduction in infectivity over a three hour period. Landfill and deep burial are suggested to have a reduction in infectivity of 98 – 99.8 % over three years. Based on this information, rendering, incineration, and alkaline hydrolysis are the most reliable technologies at this time. The significance of small amounts of infectivity become evident when you consider that experimentally it has been shown that exposure of sensitive species to as little as 1.0, 0.1 or even 0.01 grams of infected nervous tissue can induce infection.

Given all of the above (except complete burning in closed furnaces), it must be recognized that no process has been demonstrated to be 100 % effective in removing TSE infectivity and there will be some residual levels of infectivity remaining after treatment.

Guidelines for decision-making for the disposal of carcasses

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

The disposal of large numbers of carcasses will be expensive. As well, fixed and variable costs will vary with the choice of the disposal method. Each method used will result in indirect costs on the environment, local economies, producers, and the livestock industry. Decision makers need to understand the economic impact of various disposal technologies.

Appendix XXIII (contd)

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

- ***Process for decision- making***:

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

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

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

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

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

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

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

Appendix XXIII (contd)

Table 1: **Decision Making Process**

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

Appendix XXVI

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

Original: English
December 2004

REPORT OF THE THIRD MEETING OF THE OIE WORKING GROUP ON ANIMAL WELFARE

Paris, 7-9 December 2004

The OIE Working Group on Animal Welfare held its third meeting at the OIE Headquarters on 7-9 December 2004.

The members of the Working Group and other participants are listed in Appendix A. The Agenda adopted is given in Appendix B. Dr D. Bayvel chaired the meeting.

Dr B. Vallat, Director General of the OIE, welcomed the members of the Working Group and thanked them for agreeing to continue their work on this important mandate of the OIE. He also welcomed Mr R. Cotta (from the International Federation of Agricultural Producers [IFAP]) as an observer to the Working Group.

1. Priorities

Dr Vallat noted that Member Countries were awaiting the new standards to be proposed for adoption in May but he acknowledged the difficulty of addressing the needs of all Member Countries. He discussed with the Working Group the likely priorities for the upcoming year to balance the demands of Member Countries and OIE resources. He considered that the housing of animals needed to be addressed but that the Working Group needed to decide on an approach (either generic or specific) which would allow progress to be made. The welfare of laboratory animals already had a rich literature which could be drawn upon and the subject is important to the work of the c.160 OIE Reference Laboratories. He noted also that *ad hoc* groups on the welfare of aquatic animals would be meeting in 2005.

The Working Group discussed priorities for new standards, including on zoo animals, wildlife, poultry, companion animals (including urban animal control especially in developing countries) and laboratory animals. The Working Group recalled that it had made animal housing a priority for standards development, and discussed whether work should commence with generic guidelines or species specific guidelines. It was noted that the generic approach had been successful to date and was considered the preferred approach to gaining broad agreement among Member Countries.

It also acknowledged that there may be an expectation from Member Countries that the four priority issues already commenced be further developed.

2. Proposed standards on prioritised issues

The Working Group then examined the guidelines proposed by each of the four *ad hoc* groups which had met to date. For information, the reports of the four *ad hoc* groups are at:

- Slaughter for human consumption (Appendix D)
- Land transport of animals (Appendix E)
- Transport of animals by sea (Appendix F)
- Humane killing of animals for disease control purposes (Appendix G).

Appendix XXVI (contd)

The Working Group proposed some modifications to the recommendations of the four *ad hoc* groups, the significant ones of which were made in consultation with the members of the *ad hoc* groups. The Working Group congratulated the experts on their work to date and was of the strong view that the recommendations (as modified by the Working Group) be put to the OIE International Committee for adoption at the 73rd General Session.

A list of proposed definitions (both generic and chapter specific) is at Appendix C, and the modified recommendations are at Appendix I for consideration by the Terrestrial Animal Health Standards Commission at its meeting in January 2005.

2.1. Slaughter for human consumption

The Working Group noted that the text below taken from the report of the first meeting of the *ad hoc* group provided the context in which that *ad hoc* group addressed the religious aspects of its guidelines, and proposed that it be included in the guidelines:

"The ad hoc *group approached its work by assessing the animal welfare concerns associated with every procedure during the pre-slaughter and slaughter processes, reviewing them on the basis of the available scientific data, independent of any religious or cultural context. Once those animal welfare concerns were qualified, the ad hoc group considered the specific issues associated with slaughter without stunning, such as the necessary restraint, the pain likely to be associated with the cut (for which it noted that there were no definitive data) and distress prior to unconsciousness (using available data to estimate the length of this period).*

The ad hoc *group acknowledged the significance of religious requirements, cultural and ethnic factors associated with some forms of slaughter. The* ad hoc *group felt it important that these should not be treated as exempt from these guidelines, which are intended to provide a framework within which variations to certain steps in the process may be practised to improve animal welfare.*

The ad hoc *group believed that methods of lairaging, and the moving and restraining of animals prior to and during religious slaughter are separate issues from religious slaughter requirements; with regard to restraint, there is a wide variation in methods, ranging from those with acceptable animal welfare to some which are totally unacceptable under any slaughter method. The* ad hoc *group also contended that some distressful and painful methods applied to conscious animals such as shackling and hoisting by the hind leg(s) or dragging by the leg(s) are not part of any religious requirements, are unacceptable in all circumstances, and should be phased out."*

The Working Group made several recommendations to the *ad hoc* group regarding definitions and illustrations and requested that the unloading of non-ambulatory animals be addressed in the future.

2.2. Land transport of animals

To reduce the risks to animal health and welfare through the movement of animals, the Working Group considered that it was desirable to minimise both the frequency and length of animal journeys. Ideally, animals should always be transported for as short a distance as possible and, if to be killed, be humanely killed as close as possible to the point of production, consistent with the *Terrestrial* and *Aquatic Codes* guidelines for the slaughter of animals for human consumption or the guidelines for the humane killing of animals for disease control purposes. In this regard, the Working Group proposed some additional text for the guidelines for land and sea transport.

The Working Group noted the benefits of identifying a person with overall responsibility for the welfare of the animals. The Working Group also noted that the *ad hoc* Group would be addressing species-specific issues in future.

2.3. Transport of animals by sea

The Working Group made several recommendations to the *ad hoc* Group regarding the accreditation of those responsible for the welfare of the animals.

2.4. Humane killing of animals for disease control purposes

The Working Group made several recommendations to the *ad hoc* Group regarding definitions, illustrations and several of the procedures described.

The Working Group noted that killing for disease control purposes could also apply to depopulation of animals for other purposes.

3. Other business

3.1. International Declaration on Animal Welfare

Dr D. Wilkins provided background information on the initiative of the World Society for the Protection of Animals (WSPA) for an International Declaration on Animal Welfare. He indicated the widespread support the initiative had received from animal welfare NGOs and that WSPA was planning a second Ministerial Conference in 2005 to carry on the work of the 2003 Manila Conference.

The Working Group considered favourably a WSPA request that the OIE support the principles underpinning the Declaration and encourage OIE Member Countries to be involved in the development of United Nations Convention. The Working Group considered that the OIE Director-General and the Terrestrial Animal Health Standards Commission were in the best position to determine a preferred approach for the OIE to take on this issue.

3.2. International Food and Agriculture Trade Policy Council

Dr Wilkins reported on his presentation and the subsequent discussion at the recent International Food and Agriculture Trade Policy Council (IPC) meeting in Brazil.

3.3. Animal welfare in the veterinary curriculum

Dr Wilkins reported on the work of WSPA with universities in many countries on introducing animal welfare into the veterinary curriculum through a ‘concepts in animal welfare’ syllabus. He noted the difficulty in making progress in some regions (e.g. in Africa) due to their other priorities. Dr Rahman reported on relevant activities in India including those of the Commonwealth Veterinary Association; he indicated that the OIE’s work was central to these activities. Professor Fraser advocated the provision of scholarships for post-graduate studies for veterinarians from developing countries.

Members agreed on the importance of the veterinary profession in promoting this work. Dr Wilkins advised that WSPA was keen to work with the OIE on this initiative, for example through the International Association of Veterinary Schools and at the OIE General Session.

The Working Group agreed that the issue should remain on the work programme and that it should be strongly promoted by the OIE.

On a related issue, Dr Gavinelli reported that the OIE’s work on animal welfare was now being referenced in various trade agreements being negotiated by the European Communities.

3.4. OIE Global Animal Welfare Conference

The Working Group discussed the distribution of the Conference CD-ROM.

Appendix XXVI (contd)

3.5. OIE Animal Welfare Website

The Working Group discussed the new OIE animal welfare Website and noted the need to reference aquatic animals.

3.6. Working Group Membership

The OIE Director General discussed with the Working Group the need to include expertise from the private sector. He welcomed the observer from the IFAP but noted the greater difficulty in including expertise from the processing sector on the Working Group.

The Working Group agreed that it needed to have a balanced membership to bring an international perspective to its meetings, to help determine priorities and enhance communications. It believed that the *ad hoc* group system provided the ideal mechanism for utilising specific technical expertise and for ensuring the scientific basis of OIE standards.

3.7. Communications and consultation

The Working Group noted the presentations on animal welfare made by members of the Working Group and officers of the OIE Central Bureau at various conferences and seminars.

3.8. International relationships

The Director General advised the Working Group of the planned OIE collaboration with the International Air Transport Association (IATA), Animal Transport Association (AATA), World Association of Zoos and Aquaria (WAZA) and other organisations, in an effort to harmonise animal transport standards.

Dr Bayvel reported that the International Egg Commission (IEC) had discussed with him its standards which it believed should be taken into account by the OIE.

Dr Wilson reported on discussions with the International Dairy Federation (IDF) on its involvement in the OIE's work.

Dr Bayvel reported on his discussions with the American Association for Laboratory Animal Science (AALAS) on laboratory animal welfare.

Professor Fraser reported on his work at the FAO in developing a paper on animal welfare assurance programmes in food production, and options for developing and developed countries.

The Working Group noted the desirability of the OIE and FAO coordinating their animal welfare work.

4. Strategic Planning

The Working Group discussed priorities for 2005/2006. The outcomes for 2004 and the agreed work programme are at Appendix H.

The Working Group agreed that its annual meetings would be enhanced by opportunistic meetings of members and by the outcomes of teleconferences between the Chair and Central Bureau staff being circulated to all members.

It was also agreed to formally review the performance of the working group using a standard evaluation instrument.

5. Next meeting

The Working Group agreed that its next meeting would be planned for December 2005, to allow it to review the work of animal welfare *ad hoc* groups meeting during the year and to draft the workplan for 2006.

…/Appendices

Appendix XXVI (contd)

Appendix A

THIRD MEETING OF THE OIE WORKING GROUP ON ANIMAL WELFARE

Paris, 7-9 December 2004

———

List of participants

MEMBERS OF THE OIE WORKING GROUP

Dr David Bayvel (Chair)
Director Animal Welfare
MAF Biosecurity Authority
Box 2526
Wellington
NEW ZEALAND
Tel.: (64-4) 4744251
Fax: (64-4) 4989888
E-mail: bayveld@maf.govt.nz

Prof David Fraser
Professor and Chair in Animal Welfare
Faculty of Agricultural Sciences and
W. Maurice Young Centre for Applied Ethics
University of British Columbia
2357 Main Mall
Vancouver V6T 1Z4
CANADA
Tel.: (1-604) 822 2040
Fax.: (1-604) 822 4400
E-mail: dfraser@interchange.ubc.ca

Dr Andrea Gavinelli
Administrator
European Commission
Directorate General Health and Consumer Protection
Unit E2 – Animal Health and Welfare, Zootechnics
Rue Froissart 101 – 2/54
1040 Brussels
BELGIUM
Tel.: (32-2) 2966426
Fax: (32-2) 2953144
E-mail: Andrea.Gavinelli@cec.eu.int

Prof Dr Tore Håstein
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
E-mail : tore.hastein@vetinst.no

Dr Walter N. Masiga
Box 47926
Nairobi
KENYA
Tel: 0722 701743
2542 891278
E-mail: masiga@iconnect.co.ke

Dr Sira Abdul Rahman
Retd. Dean Bangalore Veterinary College
No 123, 7th B Main Road
4th Block(West)
Jayanagar, Bangalore 560 011
INDIA
Tel/Fax: (91-80) 26635210
E-mail: shireen@blr.vsnl.net.in

Prof Hassan Aidaros
Professor of Preventive Medicine and
Chairman of the OIE REVC for Middle East
5 Mossadak st
12311 Dokki
Cairo
EGYPT
Tel: 2012 218 5166
Fax: 202 760 7055
E-mail: Haidaros@netscape.net

Dr David Wilkins
Secretary
ICFAW
c/o WSPA, 89, Albert Embankment
London SE1 7TP
UNITED KINGDOM
Tel: (44) 1403 241235
Fax: (44) 1403 241235
Email : wilkinsvet@lycos.co.uk

OTHER PARTICIPANTS

Dr Alex Thiermann
President of the OIE Terrestrial Animal Health Standards Commission
OIE
12, rue de Prony
75017 Paris
FRANCE
Tel: 33-(0)1 44 15 18 69
Fax: 33-(0)1 42 67 09 87
E-mail: a.thiermann@oie.in t

Mr Ricardo Cotta Ferreira (Observer)
International Advisor CNA
Federação da Agricultura e Pecuária do Estado de Minas Gerais
Av. Carandaí, 1115 3o andar
Belo Horizonte-MG
BRAZIL
Zip 30130-915
Tel: (55) 31-30743052
Fax: (55) 31-30743030
Email: ricardo@faemg.org.br

Appendix XXVI (contd)

Appendix A (contd)

OIE HEADQUARTERS

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

Dr David Wilson
Head
International Trade Department
OIE
Tel.: 33 (0)1 44.15.18.80
Fax: 33 (0)1 42.67.09.87
E-mail: d.wilson@oie.int

Dr Antonio Petrini
Chargé de mission
International Trade Department
OIE
Tel.: 33 (0)1 44.15.18.89
Fax: 33 (0)1 42.67.09.87
E-mail: a.petrini@oie.int

Appendix XXVI (contd)

Appendix B

THIRD MEETING OF THE OIE WORKING GROUP ON ANIMAL WELFARE

Paris, 7-9 December 2004

———

Adopted agenda

1. Introduction/Formalities
2. Reports from OIE Animal Welfare *ad hoc* Groups
3. Strategic Planning
4. Other Business
   - 4.1. International Declaration for Animal Welfare
   - 4.2. Animal welfare in the veterinary curriculum
   - 4.3. CDROM OIE Global Conference on Animal Welfare
   - 4.4. OIE Web site on Animal Welfare
   - 4.5. Communication and consultation
   - 4.6. Membership of Animal Welfare Working Group: Clarification of rationale
   - 4.7. Link with FAO animal welfare activities
   - 4.8. International relationships
     - 4.8.1. International Air Transport Association (IATA)/Animal Transport Association (AATA)/World Association of Zoos and Aquaria (WAZA)
     - 4.8.2. International Egg Commission (IEC)
     - 4.8.3. International Food and Agriculture Trade Policy Council (IPC). Task Force
     - 4.8.4. Laboratory animal science
   - 4.9. 2004 Work Plan Review
   - 4.10. 2005 Work Plan Preparation: *ad hoc* Groups
   - 4.11. Other
     - 4.11.1. Animal welfare assurance programmes

4.11.2. New OIE policy on document circulation

5. Next meeting

Appendix XXVI (contd)

Appendix C

CHAPTER 1.1.1.

GENERAL DEFINITIONS

Animal handler

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

Container

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

Death

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

Journey

An animal transport journey commences when the first animal is loaded onto a *vehicle/vessel* or into a *container* and ends when the last animal is unloaded, and includes any stationary resting / holding periods of less than 48 hours.

The same animals do not commence a new journey until after a period of over 48 hours for rest and recuperation, with adequate feed and water.

Killing

Any procedure which causes the death of an animal.

Lairage

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

Loading/Unloading

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

Post-journey period

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

Pre-journey period

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

Resting point

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

Restraint

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

Appendix XXVI (contd)

Appendix C (contd)

Slaughter

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

Space allowance

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

Stocking density

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

Stunning

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

Transport

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

Transporter

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

Travel

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

Vehicle/vessel

Any train, truck, or ship that is used for carrying animal(s).

Slaughterhouse (to be harmonised by the Code Commission with the existing definition for *approved abattoir*)

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

Appendix XXVI (contd)

Appendix C (contd)

CHAPTER SPECIFIC DEFINITIONS

1. Definitions specific to slaughter for human consumption

Halal slaughter

Slaughter of a religiously acceptable species, by a Muslim slaughterman, with or without prior stunning, by cutting the neck in order to sever the jugular veins and carotid arteries, oesophagus and trachea, without severing the spinal cord.

Kosher slaughter

Slaughter of a religiously acceptable species, by a trained and accredited Jewish slaughterman, by cutting the neck, using a specifically approved blade, in order to sever the oesophagus, trachea, jugular veins and carotid arteries without severing the spinal column.

Jhatka slaughter

Slaughter of an acceptable species by decapitation, according to the Sikh religion.

2. Definitions specific to land transport of animals

Animal

For the purposes of this chapter, 'animal' refers to the following live domesticated animals: cattle, buffalo, camels, sheep, goats, pigs, poultry and equines. These guidelines will also be largely applicable to some other animals e.g. deer, other camelids and ratites. Wild, feral and partly domesticated animals may need different conditions.

3. Definition specific to transport of animals by sea

Animal

For the purposes of this chapter, 'animal' refers to the following live domesticated animals: cattle, buffalo, deer, camelids, sheep, goats, pigs and equines. These guidelines may also be applicable to other domesticated animals.

4. Definitions specific to humane killing of animals for disease control purposes

RMS

Root mean square – a means of calibrating the amount of alternating current to a direct current unit.

Appendix XXVI (contd)

Appendix D

Original: English
July 2004

REPORT OF THE SECOND MEETING OF THE OIE *AD HOC* GROUP ON THE SLAUGHTER OF ANIMALS FOR HUMAN CONSUMPTION

Paris 20–22 July 2004

The OIE *ad hoc* Group on the Slaughter of Animals for Human Consumption held its second meeting at the OIE Headquarters from 20–22 July 2004.

The members of the OIE *ad hoc* Group and other participants are listed at Appendix I. The Agenda adopted is given at Appendix II.

On behalf of the Director General of the OIE, Dr A. Thiermann welcomed the members and thanked them for continuing their work on this very important topic within the OIE's programme on animal welfare.

The *ad hoc* Group took into account comments from New Zealand, the USA, Canada and the International Coalition for Farm Animal Welfare (ICFAW) in revising the draft guidelines on the slaughter of animals for human consumption developed at the first meeting. Some definitions were also revised.

The revised guidelines are at Appendix IV.

…/Appendices

Appendix XXVI (contd)

Appendix D (contd)

Appendix I

SECOND MEETING OF THE OIE *AD HOC* GROUP ON THE SLAUGHTER OF ANIMALS FOR HUMAN CONSUMPTION

Paris, 20-22 July 2004

List of participants

MEMBERS OF THE *AD HOC* GROUP

Prof. Arnon Shimshony (Chair)
P.O. Box 13327
Tel Aviv 61132
ISRAEL
Tel: (972) 3 64 81 515
Fax: (972) 3 64 45 518
E-mail: ashimsh@agri.huji.ac.il

Prof David Mellor
Animal Welfare Science and Bioethics Centre
Massey University
Private Bag 11 222
Palmerston North
NEW ZEALAND
Tel: 64 6350 4807
Fax: 64 6350 5657
E-mail : D.J.Mellor@massey.ac.nz

Dr Mohan Raj
Senior Research Fellow
Department of Clinical Veterinary Science
University of Bristol, Langford BS40 5DU
UNITED KINGDOM
Tel: 44 11 7928 9241
Fax: 44 19 3483 8281
E-mail:M.Raj@bristol.ac.uk

Dr Mohammed Chaudry
The Islamic Food and Nutrition Council of America
IFANCA Suite 309
5901 N. Cicero Avenue
Chicago, IL 60646
UNITED STATES OF AMERICA
Tel: 1 773 283 3708
Fax: 1 773 283 3973
E-mail: mchaudry@ifanca.org

Prof Neville Gregory
Royal Veterinary College
Hawkshead Lane
Hatfield
Hertfordshire
AL9 7TA
UNITED KINGDOM
E-mail:neville.gregory@bbsrc.ac.uk

Dr Temple Grandin
Grandin Livestock Handling Systems Inc
2918 Silver Plume Drive, Suite C3
Fort Collins Colorado 80526
UNITED STATES OF AMERICA
Tel: 1 970 229 0703
Fax:1 970 491 5326
E-mail:

OTHER PARTICIPANTS

Dr Alex Thiermann
President of the OIE Terrestrial Animal Health Standards Commission
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: a.thiermann@oie.int

OIE HEADQUARTERS

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

Dr Antonio Petrini
Chargé de mission
International Trade Department
OIE
Tel.: 33 (0)1 44.15.18.89
Fax: 33 (0)1 42.67.09.87
E-mail: a.petrini@oie.int

Appendix XXVI (contd)

Appendix D (contd)

Appendix II

SECOND MEETING OF THE OIE *AD HOC* GROUP ON THE SLAUGHTER OF ANIMALS FOR HUMAN CONSUMPTION

Paris, 20-22 July 2004

Agenda adopted

1. Introduction

1.1. Discussion on the report of the recent meeting of the OIE Working Group on Animal Welfare

1.2. Discussion on the outcomes of the OIE Global Conference on Animal Welfare

1.3. Discussion on the OIE 72nd General Session (Animal Welfare)

1.4. Comments from Member Countries (Canada, USA, New Zealand)

1.5. Comments from ICFAW

2. Development of specific guiding principles and standards

3. Work programme

4. Conclusions

Appendix XXVI (contd)

Appendix D (contd)

Appendix III

INTRODUCTION TO OIE GUIDELINES FOR THE WELFARE OF ANIMALS

Article 4

Definitions

For the purposes of this *Terrestrial Code*, the following definitions apply:

Slaughterhouse: premises, including facilities for moving or lairaging animals, used for the slaughter of *animals* for human consumption or animal feeding, and approved by the *Veterinary Services* or other competent authority.

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

Restraint: the application to an animal of any procedure designed to restrict its movements in order to facilitate effective management.

Stunning: any mechanical, electrical, chemical or other procedure which causes immediate loss of consciousness which lasts until death.

Killing: any procedure which causes the death of an animal.

Slaughter: any procedure which causes the death of an animal by bleeding.

Death: irreversible loss of brain activity as demonstrated by loss of brain stem reflexes.

***Halal* slaughter:** slaughter of a religiously acceptable species, by a Muslim slaughterman, with or without prior stunning, by cutting the neck in order to sever the jugular veins and carotid arteries, oesophagus and trachea, without severing the spinal cord.

Kosher slaughter: slaughter, of a religiously acceptable species, by a trained and accredited Jewish slaughterman, by cutting the neck, using a specifically approved blade, in order to sever the oesophagus, trachea, jugular veins and carotid arteries without severing the spinal column.

Jhatka slaughter: slaughter of an acceptable species by decapitation according to the Sikh religion.

Appendix XXVI (contd)

Appendix D (contd)

Appendix III (contd)

GUIDELINES FOR THE SLAUGHTER OF ANIMALS FOR HUMAN CONSUMPTION

Article 1

General principles for slaughter

These guidelines address the need to ensure the welfare of food animals during pre-slaughter and slaughter processes, until they are dead.

These guidelines apply to those domestic animals commonly slaughtered in slaughterhouses, that is: cattle, buffalo, sheep, goats, deer, horses, pigs, ratites and poultry. Other animals, wherever they have been reared, should be managed to ensure that their transport, lairaging, restraint and slaughter is carried out without causing undue stress to the animals; the principles underpinning these guidelines apply also to these animals.

Personnel

Persons engaged in the unloading, moving, lairaging, care, restraining, stunning, slaughter and bleeding of animals play an important role in the welfare of those animals. For this reason, there should be a sufficient number of personnel, who should be patient, considerate, competent and familiar with the guidelines in this document and their application within the national context.

The management of the slaughterhouse and the *Veterinary Services* should ensure that slaughterhouse staff carry out their tasks in accordance with the principles of animal welfare.

Animal behaviour

Animal handlers should be experienced and competent in handling and moving farm livestock, and understand the behaviour patterns of animals and the underlying principles necessary to carry out their tasks.

The behaviour of individual animals or groups of animals will vary, depending on their breed, sex, temperament and age and the way in which they have been reared and handled. Despite these differences, the following behaviour patterns which are always present to some degree in domestic animals, should be taken into consideration in handling and moving the animals.

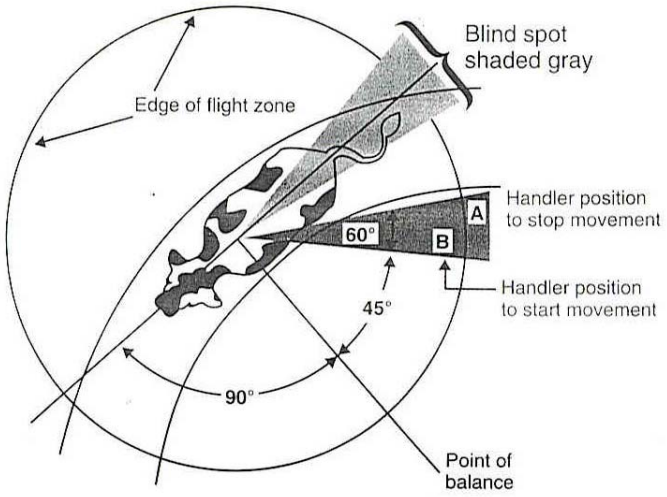
Most domestic livestock are kept in herds and follow a leader by instinct.

Animals which are likely to be hostile to each other in a group situation should not be mixed at slaughterhouses.

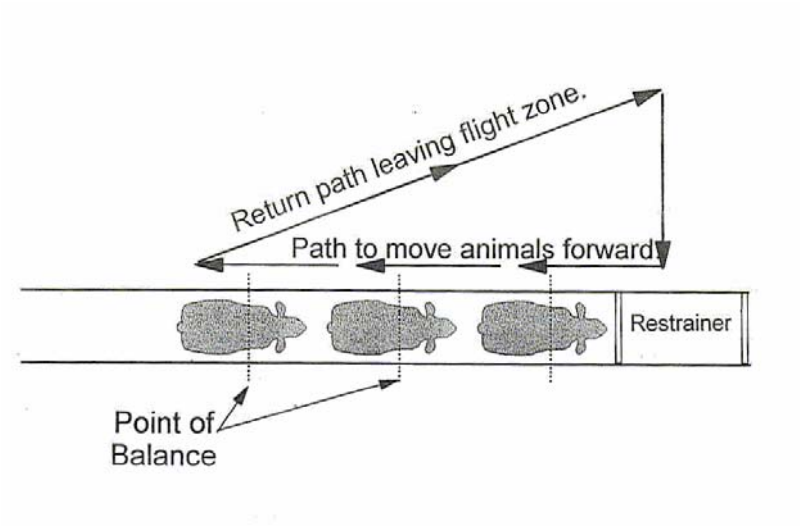
The desire of some animals to control their personal space should be taken into account in designing facilities.

Domestic animals will try to escape if an animal handler approaches closer than a certain distance. This critical distance, which defines the flight zone, varies among species and individuals of the same species, and depends upon previous contact with humans. Animals reared in close proximity to humans i.e. tame have no flight zone, whereas those kept in free range or extensive systems may have flight zones which may vary from one metre to many metres. Animal handlers should avoid sudden penetration of the flight zone which may cause a panic reaction which could lead to aggression or attempted escape.

An example of a flight zone (cattle)



Handler movement pattern to move cattle forward



Animal handlers should use the point of balance at an animal's shoulder to move animals, adopting a position behind the point of balance to move an animal forward and in front of the point of balance to move it backward.

Domestic animals have wide-angle vision but only have limited forward binocular vision and poor perception of depth. This means that they can detect objects and movements beside and behind them, but can only judge distances directly ahead.

Appendix XXVI (contd)

Appendix D (contd)

Appendix III (contd)

Although all domestic animals have a highly sensitive sense of smell, they react in different ways to the smells of slaughterhouses. Smells which cause fear or other negative responses should be taken into consideration when managing animals.

Domestic animals can hear over a greater range of frequencies than humans and are more sensitive to higher frequencies. They tend to be alarmed by constant loud noise and by sudden noises, which may cause them to panic.

Distractions and their removal

Distractions that may cause approaching animals to stop, baulk or turn back should be designed out from new facilities or removed from existing ones. Below are examples of common distractions and methods for eliminating them:

- Reflections on shiny metal or wet floors - move a lamp or change lighting.
- Dark entrances to chutes, races, stun boxes or conveyor restrainers - illuminate with indirect lighting which does not shine directly into the eyes of approaching animals.
- Animals seeing moving people or equipment up ahead - install solid sides on chutes and races or install shields.
- Chains or other loose objects hanging in chutes or on fences - remove them.
- Uneven floors or a sudden drop in floor levels at the entrance to conveyor restrainers – avoid uneven floor surfaces or install a solid false floor under the restrainer to provide an illusion of a solid and continuous walking surface.
- Sounds of air hissing from pneumatic equipment - install silencers or use hydraulic equipment.
- Clanging and banging of metal objects - install rubber stops on gates and other devices to reduce metal to metal contact.
- Air currents from fans or air curtains blowing into the face of animals - redirect or reposition equipment.

Article 2

Moving and handling animals

The following principles should apply to unloading animals, moving them into lairage pens, out of the lairage pens and up to the slaughter point:

- The conditions of the animals should be assessed upon their arrival for any animal welfare problems.
- Injured or sick animals, requiring immediate slaughter, should be killed humanely at the site where they are found.
- The use of force on animals that have little or no room to move should not occur.

- The use of instruments which administer electric shocks (e.g. goads and prods) and their power output should be restricted to that necessary to assist movement of the animals. If such use is necessary, it should be limited to the hindquarters of pigs and large ruminants, and never on sensitive areas such as the eyes, mouth, ears, anogenital region or belly. Such instruments should not be used on horses, sheep and goats of any age, or on calves or piglets.

- Performance standards should be established in which numerical scoring is used to evaluate the use of such instruments and to measure the percentage of animals moved with an electric instrument. In properly designed and constructed facilities with competent animal handlers, it should be possible to move 75% or more of the animals without the use of electric instruments.

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

- Shouting or yelling at animals to encourage them to move should not occur as such actions may make the animals agitated, leading to crowding or falling.

- Implements which cause pain and suffering such as large sticks, sticks with sharp ends, metal piping, fencing wire or heavy leather belts should not be used to move animals.

- Animals should be grasped or lifted in a manner which avoids pain or suffering and physical damage (e.g. bruising, fractures, dislocations). In the case of quadrupeds, manual lifting by a person should only be used in young animals or small species, and in a manner appropriate to the species; grasping or lifting such animals only by their wool, hair, feet, neck, ears or tails causing pain or suffering should not be permitted, except in an emergency where animal welfare or human safety may otherwise be compromised.

- Conscious animals should not be thrown or dragged.

- Animals should not be forced to move at a speed greater than their normal walking pace, in order to minimise injury through falling or slipping. Performance standards should be established where numerical scoring of the prevalence of animals slipping or falling is used to evaluate whether animal moving practices and/or facilities should be improved. In properly designed and constructed facilities with competent animal handlers, it should be possible to move 99% of animals without their falling.

- Animal handlers should not force an animal to walk over the top of other animals.

- Under no circumstances should animal handlers resort to violent acts to move animals, such as crushing or breaking animals' tails, grasping animals' eyes or pulling them by their ears. Animal handlers should never apply an injurious object or irritant substance to sensitive areas such as eyes, mouth, ears, anogenital region or belly.

Requirements for animals delivered in containers

- Containers in which animals are transported should be handled with care, and should not be thrown, dropped or knocked over. Where possible, they should be loaded and unloaded horizontally and mechanically.

Appendix XXVI (contd)

Appendix D (contd)

Appendix III (contd)

- Animals delivered in containers with perforated or flexible bottoms should be unloaded with particular care in order to avoid injury. Where appropriate, animals should be unloaded from the containers individually.

- Animals which have been transported in containers should be slaughtered as soon as possible; mammals and ratites which are not taken directly upon arrival to the place of slaughter should have drinking water available to them from appropriate facilities at all times. Delivery of poultry for slaughter should be scheduled such that they are not deprived of water at the premises for longer than 12 hours. Animals which have not been slaughtered within 12 hours of their arrival should be fed, and should subsequently be given moderate amounts of food at appropriate intervals.

Provision relevant to restraining and containing animals

Provisions relevant to restraining animals for stunning or slaughter without stunning, to help maintain animal welfare include:

- Provision of a non-slip floor

- Avoidance of excessive pressure applied by restraining equipment that causes struggling or vocalisation in animals

- Equipment engineered to reduce noise of air hissing and clanging metal

- Absence of sharp edges in restraining equipment that would harm animals

- Avoidance of jerking or sudden movement of restraining device.

Methods of restraint causing avoidable suffering, such as the following, should not be used in conscious animals because they cause severe pain and stress:

- suspending or hoisting animals (other than poultry) by the feet or legs
- indiscriminate and inappropriate use of stunning equipment
- mechanical clamping of an animal's legs or feet (other than shackles used in poultry and ostriches) as the sole method of restraint
- cutting leg tendons or blinding animals in order to immobilise them
- using puntilla to immobilise animals
- using electric currents to immobilise animals, except for proper stunning.

Article 3

Lairage design and construction

The lairage should be designed and constructed to hold an appropriate number of animals in relation to the throughput rate of the slaughterhouse without compromising the welfare of the animals.

In order to permit operations to be conducted as smoothly and efficiently as possible without injury or undue stress to the animals, the lairage areas should be designed and constructed so as to allow the animals to move freely in the required direction, using their behavioural characteristics and without undue penetration of their flight zone.

The following guidelines may help to achieve this.

Design

- The lairage should be designed to allow a one-way flow of animals from unloading to the point of slaughter, with a minimum of abrupt corners to negotiate.

- In red meat slaughterhouses, pens, passageways and races should be arranged in such a way as to permit inspection of animals at any time, and to permit the removal of sick or injured animals when considered to be appropriate, for which separate appropriate accommodation should be provided.

- Each animal should have room to stand up and lie down and, when confined in a pen, to turn around. The lairage should have sufficient accommodation for the number of animals intended to be held. Drinking water should always be available to the animals, and the method of delivery should be appropriate to the type of animal held. Troughs should be designed and installed in such a way as to minimise the risk of fouling by faeces, without introducing risk of bruising and injury in animals, and should not hinder the movement of animals.

- Holding pens should be rectangular rather than square, to allow as many animals as possible to stand or lie down against a wall. Where feed troughs are provided, they should be sufficient in number and feeding space to allow adequate access of all animals to feed. The feed trough should not hinder the movement of animals.

- Where tethers, ties or individual stalls are used, these should be designed so as not to cause injury or distress especially when the animals are lying down, standing up, drinking and feeding.

- Passageways and races should be either straight or slightly curved, as appropriate to the animal species. Passageways and races should have solid sides, but when there is a double race the shared partition should allow adjacent animals to see each other. For pigs and sheep, passageways should be wide enough to enable two or more animals to walk side by side for as long as possible. At the point where passageways are reduced in width, this should be done by a means which prevents excessive bunching of the animals.

- Animal handlers should be positioned alongside races and passageways on the inside radius of any curve, to take advantage of the natural tendency of animals to circle an intruder. Where one-way gates are used, they should be of a design which avoids bruising. Races should be horizontal but where there is a slope, they should be constructed to allow the free movement of animals without injury.

- There should be a waiting pen, with a level floor and solid sides, between the holding pens and the race leading to the point of stunning or slaughter, to ensure a steady supply of animals for stunning or slaughter and to avoid having animal handlers trying to rush animals from the holding pens. The waiting pen should preferably be circular, but in any case, so designed that animals cannot be trapped or trampled.

- Ramps or lifts should be used for loading and unloading of animals where there is a difference in height or a gap between the floor of the vehicle and the unloading area. The ramp should be well drained, non-slippery and adjustable to facilitate easy movement of animals without causing distress or injury.

Appendix XXVI (contd)

Appendix D (contd)

Appendix III (contd)

Construction

- Lairages should be constructed and maintained so as to provide protection from unfavourable climatic conditions, using strong and resistant materials such as concrete and metal which has been treated to prevent corrosion. Surfaces should be easy to clean. There should be no sharp edges or protuberances which may injure the animals.
- Floors should be well drained and not slippery; they should not cause injury to the animals' feet. Where necessary floors should be insulated or provided with appropriate bedding. Drainage grids should be placed at the sides of pens and passageways and not where animals would have to cross them. Discontinuities or changes in floor patterns or texture which could cause baulking in the movement of animals should be avoided.
- Lairages should be provided with adequate lighting, but care should be taken to avoid harsh lights and shadows, which frighten the animals or affect their movement. The fact that animals will move more readily from a darker area into a well-lit area might be exploited by providing for lighting that can be regulated accordingly.
- Lairages should be well ventilated, and the air flow should be arranged so that odours and draughts do not adversely affect the health and welfare of the animals.
- Care should be taken to protect the animals from excessively or potentially disturbing noises, for example by avoiding the use of noisy hydraulic or pneumatic equipment, and muffling noisy metal equipment by the use of suitable padding, or by minimising the transmission of such noise to the areas where animals are held and slaughtered.
- Where animals are kept in outdoor lairages without natural shelter or shade, they should be protected from the effects of adverse weather conditions.

Article 4

Care in lairages

Animals in lairages should be cared for in accordance with the following guidelines:

- As far as possible established groups of animals should be kept together. Each animal should have enough space to stand up, lie down and turn around. Animals hostile to each other should be separated.
- Where tethers, ties or individual stalls are used they should allow animals to stand up and lie down without causing injury or distress.
- Where bedding is provided, it should be maintained in a condition that minimises risks to the health and safety of the animals, and sufficient should be used so that animals do not become soiled with manure.
- Animals should be kept securely in the lairage and care should be taken to prevent them from escaping and from predators.
- Suitable drinking water should be available to the animals on their arrival and at all times to animals in lairages unless they are to be slaughtered without delay.
- If animals are not to be slaughtered as soon as possible, suitable feed should be available to the animals on arrival and at intervals appropriate to the species. Unweaned animals should be slaughtered as soon as possible.

- In order to prevent heat stress, animals subjected to high temperatures, particularly pigs and poultry, should be cooled by the use of water sprays, fans or other suitable means.

- That lairage area should be well lit in order to enable the animals to see clearly without being dazzled. During the night, the lights should be dimmed.

- The condition and state of health of the animals in a lairage should be inspected at least every morning and evening by a veterinarian or, under the latter's responsibility, by another competent person. Animals which are sick, weak, injured or showing visible signs of distress should be treated or killed immediately.

- Lactating dairy animals should be slaughtered as soon as possible. Dairy animals with obvious udder distension should be milked to minimise udder discomfort.

- Pregnant animals giving birth during the journey or in the lairage should be slaughtered as soon as possible or provided with conditions which are appropriate for suckling and the welfare of the newborn.

- Horned animals, if aggressive, should be penned separately.

Recommendations for specific species are described in detail in Articles 6-9.

Article 5

Management of foetuses during slaughter of pregnant animals

The welfare of foetuses during slaughter of pregnant animals needs to be safeguarded.

Foetuses should not be removed from the uterus sooner than five minutes after the maternal neck or chest cut, to ensure absence of consciousness. A foetal heartbeat will usually still be present and foetal movements may occur at this stage, but these are only a cause for concern if the exposed foetus successfully breathes air.

- If a live mature foetus is removed from the uterus, it should be prevented from inflating its lungs and breathing air (e.g. by clamping the trachea).

- When uterine, placental or foetal tissues, including foetal blood, are not to be collected as part of the post-slaughter processing of pregnant animals, all foetuses should be left inside the unopened uterus until they are dead. When uterine, placental or foetal tissues are to be collected, where practical, foetuses should not be removed from the uterus until at least 15-20 minutes after the maternal neck or chest cut.

- If there is any doubt about consciousness, the foetus should be killed with a captive bolt or a blow to the head with a suitable blunt instrument.

The above guidelines do not refer to foetal rescue. Foetal rescue, the practice of attempting to revive foetuses found alive at evisceration of the dam, should not be attempted during normal commercial slaughter as it may lead to serious welfare complications in the newborn animal. These include impaired brain function resulting from oxygen shortage before rescue is completed, compromised breathing and body heat production because of foetal immaturity, and an increased incidence of infections due to a lack of colostrum.

Appendix XXVI (contd)
Appendix D (contd)
Appendix III (contd)

Article 6
Summary of acceptable handling and restraining methods, and the associated animal welfare issues

	Presentation of animals	Specific procedure	Specific purpose	AW concerns/implications	Key AW requirements	Applicable species
No restraint	Animals are grouped	Group container	Gas stunning	Specific procedure is suitable only for gas stunning	Competent animal handlers in lairage; facilities; stocking density	Pigs, poultry
		In the field	Free bullet	Shooting distance, calibre and ballistics	Operator competence	Deer
		Group stunning pen	Head-only electrical Captive bolt	Uncontrolled movement of animals impedes use of hand operated electrical and mechanical stunning methods	Competent animal handlers in lairage and at stunning point	Pigs, sheep, goats, calves
	Individual animal confinement	Stunning pen/box	Electrical and mechanical stunning methods	Loading of animal; accuracy of stunning method, slippery floor and animal falling down	Competent animal handlers	Cattle, buffalo, sheep, goats, horses, pigs, deer, camelids, ratites
Restraining methods	Head restraint, upright	Halter/ head collar/bridle	Captive bolt Free bullet	Suitable for halter-trained animals; stress in untrained animals	Competent animal handlers	Cattle, buffalo, horses, camelids
	Head restraint, upright	Neck yoke	Captive bolt Electrical-head-only Free bullet Slaughter without stunning	Stress of loading and neck capture; stress of prolonged restraint, horn configuration; unsuitable for fast line speeds, animals struggling and falling due to slippery floor, excessive pressure	Equipment; competent animal handlers, prompt stunning or slaughter	Cattle
	Leg restraint	Single leg tied in flexion (animal standing on 3 legs)	Captive bolt Free bullet	Ineffective control of animal movement, misdirected shots	Competent animal handler,	Breeding pigs (boars and sows)

Appendix XXVI (contd)
Appendix D (contd)
Appendix III (contd)

	Presentation of animals	Specific procedure	Specific purpose	AW concerns/implications	Key AW requirements	Applicable species
Restraining methods	Upright restraint	Beak holding	Captive bolt Electrical-head-only	Stress of capture	Sufficient competent animal handlers	Ostriches
		Head restraint in electrical stunning box	Electrical-head-only	Stress of capture and positioning	Competent animal handler	Ostriches
	Holding body upright- manual	Manual restraint	Captive bolt Electrical-head-only Slaughter without stunning	Stress of capture and restraint; accuracy of stunning/slaughter	Competent animal handlers	Sheep, goats, calves, ratites, small camelids, poultry
	Holding body upright mechanical	Mechanical clamp / crush / squeeze/ V-restrainer (static)	Captive bolt Electrical methods Slaughter without stunning	Loading of animal and overriding; excessive pressure	Proper design and operation of equipment	Cattle, buffalo, sheep, goats, deer, pigs, ostriches
	Lateral restraint – manual or mechanical	Restrainer/cradle /cratch	Slaughter without stunning	Stress of restraint	Competent animal handlers	Sheep, goats, calves, camelids, cattle
	Upright restraint mechanical	Mechanical straddle (static)	Slaughter without stunning Electrical methods Captive bolt	Loading of animal and overriding	Competent animal handlers	Cattle, sheep, goats, pigs
	Upright restraint – manual or mechanical	Wing shackling	Electrical	Excessive tension applied prior to stunning	Competent animal handlers	Ostriches

Appendix XXVI (contd)
Appendix D (contd)
Appendix III (contd)

	Presentation of animals	Specific procedure	Specific purpose	AW concerns/implications	Key AW requirements	Applicable species
Restraining and /or conveying methods	Mechanical - upright	V-restrainer	Electrical methods Captive bolt Slaughter without stunning	Loading of animal and overriding; excessive pressure, size mismatch between restrainer and animal	Proper design and operation of equipment	Cattle, calves, sheep, goats, pigs
	Mechanical- upright	Mechanical straddle – band restrainer (moving)	Electrical methods Captive bolt Slaughter without stunning	Loading of animal and overriding, size mismatch between restrainer and animal	Competent animal handlers, proper design and layout of restraint	Cattle, calves, sheep, goats, pigs
	Mechanical - upright	Flat bed/deck Tipped out of containers on to conveyors	Presentation of birds for shackling prior to electrical stunning Gas stunning	Stress and injury due to tipping in dump-module systems height of tipping conscious poultry broken bones and dislocations	Proper design and operation of equipment	Poultry
	Suspension and/or inversion	Poultry shackle	Electrical stunning Slaughter without stunning	Inversion stress; pain from compression on leg bones	Competent animal handlers; proper design and operation of equipment	Poultry
	Suspension and/or inversion	Cone	Electrical – head-only; Captive bolt Slaughter without stunning	Inversion stress	Competent animal handlers; proper design and operation of equipment	Poultry
	Upright restraint	Mechanical leg clamping	Electrical – head-only	Stress of resisting restraint in ostriches	Competent animal handlers; proper equipment design and operation	Ostriches

Appendix XXVI (contd)
Appendix D (contd)
Appendix III (contd)

	Presentation of animals	Specific procedure	Specific purpose	AW concerns/implications	Key AW requirements	Applicable species
Restraining by inversion	Rotating box	Fixed side(s) (e.g. Weinberg)	Slaughter without stunning	Inversion stress; stress of resisting restraint, prolonged restraint. Keep restraint as brief as possible	Proper design and operation of equipment	Cattle
Restraining by inversion		Compressible side(s)	Slaughter without stunning	Inversion stress, stress of resisting restraint, prolonged restraint. Preferable to rotating box with fixed sides; Keep restraint as brief as possible	Proper design and operation of equipment	Cattle
Body restraint	Casting/ hobbling	Manual	Mechanical stunning methods Slaughter without stunning	Stress of resisting restraint; animal temperament; bruising. Keep restraint as short as possible	Competent animal handlers	Sheep, goats, calves, small camelids, pigs
Leg restraints		Rope casting	Mechanical stunning methods Slaughter without stunning	Stress of resisting restraint; prolonged restraint, animal temperament; bruising. Keep restraint as short as possible	Competent animal handlers	Cattle, camelids
		Tying of 3 or 4 legs	Mechanical stunning methods Slaughter without stunning	Stress of resisting restraint; prolonged restraint, animal temperament; bruising. Keep restraint as short as possible	Competent animal handlers	Sheep, goats, small camelids, pigs

Appendix XXVI (contd)

Appendix D (contd)

Appendix III (contd)

Article 7

Stunning methods

Stunning

The competence of the operators, and the appropriateness and effectiveness of the method used for stunning are the responsibility of the management of the slaughterhouse, and should be checked regularly by a competent authority.

Persons carrying out stunning should be properly trained and competent, and should ensure that:

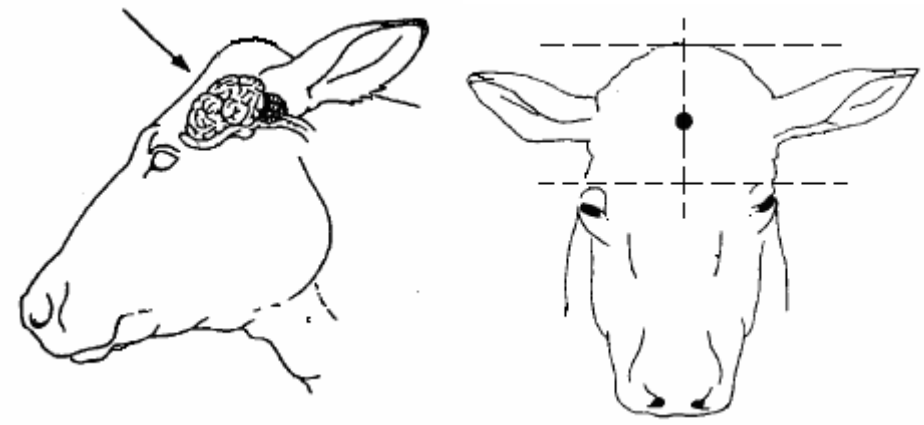
- the animal is adequately restrained,
- animals in restraint are stunned as soon as possible;
- the equipment used for stunning is maintained and operated properly in accordance with the manufacturer's recommendations, in particular with regard to the species and size of the animal;
- the instrument is applied correctly;
- stunned animals are bled out (slaughtered) as soon as possible,
- do not stun animals when slaughter is likely to be delayed.

In addition, such persons should be able to recognise when an animal is not correctly stunned and should take appropriate action.

Mechanical stunning

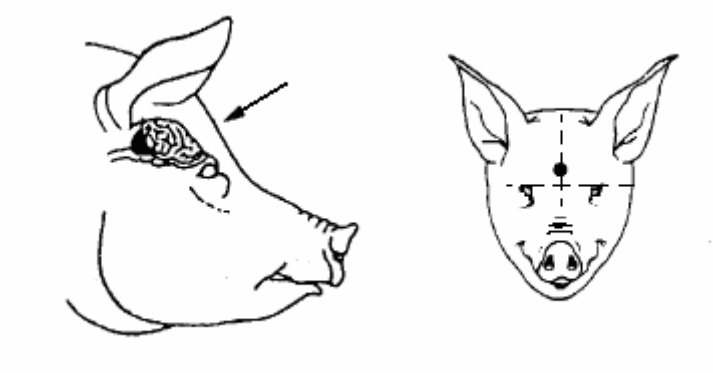
A mechanical device should be applied usually to the front of the head and perpendicular to the bone surface. The following diagrams illustrate the proper application of the device for certain species.

Cattle



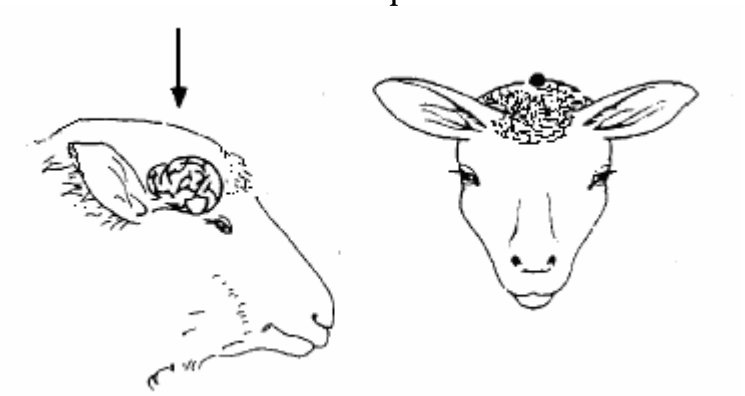
Cattle: aim at the point halfway between the top of the head and the imaginary line between the eyes and place the muzzle at right angles to the frontal surface.

Pigs



Pigs: place the muzzle about 2.5 to 5 cm above the level of the eyes, and at right angles to the frontal surface.

Sheep



In hornless sheep use the highest point of the head and aim towards the angle of the jaw.
For horned sheep place the muzzle just behind the ridge which runs between the horns and aim towards the mouth.

Goats

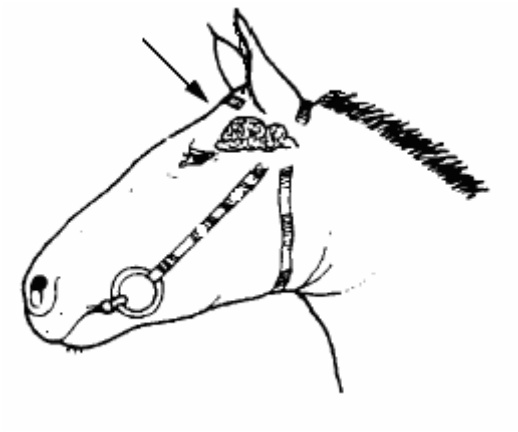
In hornless goats use the highest point of the head and aim towards the angle of the jaw. For horned goats, place the muzzle just behind the ridge which runs between the horns and aim towards the mouth.

Appendix XXVI (contd)

Appendix D (contd)

Appendix III (contd)

Horses



Place the muzzle at right angles to the frontal surface well above the point where imaginary lines from eye to ear cross.

Signs of correct stunning using a mechanical instrument:

i) the animal collapses immediately and does not attempt to stand up;

ii) the body and muscles of the animal become tonic (rigid) immediately after the shot;

iii) normal rhythmic breathing stops; and

iv) the eyelid is open with the eyeball facing straight ahead and is not rotated.

Electrical stunning

b) General

An electrical device should be applied to the animal in accordance with the following guidelines.

Electrodes should be designed, constructed, maintained and cleaned regularly to ensure that the flow of current is optimal and in accordance to manufacturing specification. They should be placed so that they span the brain. The application of electrical currents which bypass the brain are unacceptable unless the animal has been stunned. The use of a single current leg-to-leg is unacceptable as a stunning method.

If, in addition, it is intended to cause cardiac arrest, the electrodes should either span the brain and immediately thereafter the heart, on the condition that it has been ascertained that the animal is adequately stunned, or span brain and heart simultaneously.

Electrical stunning equipment should not applied on animals as a means of guidance, movement, restraint or immobilisation, and shall not deliver any shock to the animal before the actual stunning or killing.

Electrical stunning apparatus should be tested prior to application on animals using appropriate resistors or dummy loads to ensure the power output is adequate to stun animals.

The apparatus should incorporate a device which monitors and displays stunning current delivered to the animals

Appropriate measures, such as removing excess wool or wetting the skin only at the point of contact can be taken to minimise impedance of the skin and facilitate effective stunning.

The stunning apparatus requires for electrical stunning should be provided with adequate power to achieve continuously the minimum current level recommended for stunning as indicate in the table below:

Species	Minimum current levels
Cattle	1.5 amps
Calves	1.0 amps
Pigs	1.25 amps
Sheep & Goats	0.5 amps
Ostriches	0.4 amps

In all cases, the correct current level shall be attained within one second of the initiation of stun and maintained at least for between one and three seconds and in accordance with the manufacturer's instructions.

b) Electrical stunning of birds using a waterbath

In the case of birds suspended on a moving line, measures should be taken to ensure that the birds are not wing flapping at the entrance of the stunner. The birds should be secure in their shackle, but there should not be undue pressure on their shanks.

Waterbaths for poultry should be adequate in size and depth for the type of bird being slaughtered, and their height should be adjustable to allow for the head of each bird to be immersed. The electrode immersed in the bath should extend the full length of the waterbath. Birds should be immersed in the bath up to the base of their wings.

The waterbath should be designed and maintained in such a way that when the shackles pass over the water they are in continuous contact with the earthed rubbing bar.

The control box for the waterbath stunner should incorporate an ammeter which displays the total current flowing through the birds.

The shackle-to-leg contact should be wetted preferably before the birds are inserted in the shackles. In order to improve electrical conductivity of the water it is recommended that salt be added in the waterbath as necessary.

Appendix XXVI (contd)

Appendix D (contd)

Appendix III (contd)

Birds should receive the current for at least 4 seconds.

Using waterbaths, birds are stunned in groups and different birds will have different impedances. The voltage should be adjusted so that the total current is the required current per bird as shown in the table hereafter, multiplied by the number of birds in the waterbath at the same time.

The following values have been found to be satisfactory when employing a 50 Hertz sinusoidal alternating current.

Species	Current (milliamperes per bird)
Broilers	120
Layers (spent hens)	120
Turkeys	150
Ducks and Geese	130

While a lower current may also be satisfactory, the current shall in any case be such as to ensure that unconsciousness occurs immediately and lasts until the bird has been killed by cardiac arrest or by bleeding. When higher electrical frequencies are used, higher currents may be required.

Every effort shall be made to ensure that no conscious or live birds enter the scalding tank.

In the case of automatic systems, until fail-safe systems of stunning and bleeding have been introduced, a manual back-up system is recommended to ensure that any birds which have missed the waterbath stunner and/or the automatic neck-cutter are immediately stunned and/or humanely killed. and they are dead before entering scald tank.

To lessen the number of unstunned birds, reaching neck cutters, steps should be taken to ensure that small birds do not go on the line amongst bigger birds and that these small birds are stunned separately.

Gas stunning

a) Stunning of pigs by exposure to carbon dioxide (CO_2)

The concentration of CO_2 for stunning should be preferably 90% by volume but in any case no less than 80% by volume. After entering the stunning chamber the animals should be conveyed to the point of maximum concentration of the gas and be kept until they are dead or brought into a state of insensibility which lasts until death occur due to bleeding. Ideally, pigs should be exposed to this concentration of CO_2 for three minutes.

In any case, the concentration of the gas should be such that it minimises as far as possible all stress of the animal prior to loss of consciousness.

The chamber in which animals are exposed to CO_2 and the equipment used for conveying them through it shall be designed, constructed and maintained in such a way as to avoid injury or unnecessary stress to the animals. The animal density within the chamber should be such to avoid stacking animals on top of each others.

The conveyor and the chamber shall be adequately lit to allow the animals to see their surroundings and if possible, each other.

It should be possible to inspect the CO_2 chamber whilst it is in use, and to have access to the animals in emergency cases.

The chamber shall be equipped to continuously measure and display register at the point of stunning the CO_2 concentration and the time of exposure, and to give a clearly visible and audible warning if the concentration of CO_2 falls below the required level.

b) Inert gas mixtures for stunning pigs (under development)

Inhalation of high concentration of carbon dioxide is aversive and can be distressing to animals. Therefore, the use of non-aversive gas mixtures is being developed.

Gas mixtures:

a) A maximum of 2% by volume of oxygen in argon, nitrogen or other inert gases, or

b) to a maximum of 30% by volume of carbon dioxide and a maximum of 2% by volume of oxygen in mixtures with carbon dioxide and argon, nitrogen or other inert gases.

Exposure time to the gas mixtures should be sufficient to ensure that no pigs regain consciousness before death supervenes through bleeding or cardiac arrest is induced.

c) Gas stunning of poultry

The main objective of gas stunning is to avoid the pain and suffering associated with shackling conscious poultry under water bath stunning and killing systems. Therefore, gas stunning should be limited to birds contained in crates or on conveyors only. The gas mixture should be non-aversive to poultry.

Gas stunning of poultry in their transport containers will eliminate the need for live bird handling at the processing plant and all the problems associated with the electrical stunning.

Gas stunning poultry on a conveyor eliminates the problems associated with the electrical water bath stunning.

Live poultry shall be conveyed into the gas mixtures either in transport crates or on conveyor belts.

i) Gas mixtures used for stunning poultry

- Minimum of 2 min exposure to 40% carbon dioxide, 30% oxygen and 30% nitrogen, followed by a minimum of 1 min exposure to 80% carbon dioxide in air; or
- Minimum of 2 min exposure to any mixture of argon, nitrogen or other inert gases with atmospheric air and carbon dioxide, provided that the carbon dioxide concentration does not exceed 30% by volume and the residual oxygen concentration does not exceed 2% by volume; or
- Minimum of 2 min exposure to argon, nitrogen, other inert gases or any mixture of these gases in atmospheric air with a maximum of 2% residual oxygen by volume; or
- Minimum of 2 minutes exposure to a minimum of 55% carbon dioxide in air.

Appendix XXVI (contd)

Appendix D (contd)

Appendix III (contd)

ii) Requirements for effective use:

- Compressed gases should be vaporised prior to administration into the chamber.
- Under no circumstances, should solid gases with freezing temperatures enter the chamber.
- Gas mixtures should be humidified.
- Appropriate gas concentrations should be monitored and displayed continuously at the level of the birds inside the chamber.

Under no circumstances should birds exposed to gas mixtures be allowed to regain consciousness. If necessary, the exposure time should be extended.

Bleeding

From the point of view of animal welfare, animals which are stunned with a reversible method should be bled without delay and in any case within the following time limits:

Stunning method	**Maximum delay for bleeding to be started**
Electrical methods and non penetrating bolt	20 seconds
CO_2	60 seconds (after leaving the chamber)

All animals should be bled by incising both carotid arteries, or the vessels from which they arise (e.g. chest stick). However, when the stunning method used causes cardiac arrest, the incision of all of these vessels is not necessary from the point of animal welfare.

It should be possible for staff to observe, inspect and access the animals throughout the bleeding period. Any animal showing signs of recovering consciousness should be restunned.

After incision of the blood vessels, no scalding carcass treatment or dressing procedures should be performed on the animals for at least thirty seconds, or in any case until all brain-stem reflexes have ceased.

Article 8

Summary of acceptable stunning methods and the associated animal welfare issues

Method	Specific method	AW concerns/implications	Key AW requirements applicable	Species	Comment
Mechanical	Free bullet	Inaccurate targeting and inappropriate ballistics	Accuracy; head shots only correct ballistics	Cattle, calves, buffalo, deer, horses, pigs (boars and sows)	Personnel safety
	Captive bolt - penetrating	Inaccurate targeting, velocity and diameter of bolt	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, buffalo, sheep, goats, deer, horses, pigs, camelids, ratites	(Unsuitable for specimen collection from TSE suspects). A back-up gun should be available in the event of an ineffective shot
	Captive bolt - non-penetrating	Inaccurate targeting, velocity of bolt, potentially higher failure rate than penetrating captive bolt	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, sheep, goats, deer, pigs, camelids, ratites	Presently available devices are not recommended for young bulls and animals with thick skull
	Manual percussive blow	Inaccurate targeting; insufficient power; size of instrument	Competent animal handlers; restraint; accuracy. Not recommended for general use	Young and small mammals, ostriches and poultry	Mechanical devices potentially more reliable. Where manual percussive blow is used, unconsciousness should be achieved with single sharp blow delivered to central skull bones
Electrical	Split application: 1. across head then head to chest; 2. across head then across chest	Accidental pre-stun electric shocks; electrode positioning; application of a current to the body while animal conscious; inadequate current and voltage	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, sheep, goats and pigs, ratites and poultry	Systems involving repeated application of head-only or head-to-leg with short current durations (<1 second) in the first application should not be used. Where cardiac arrest occurs, the carcass may not be suitable for Halal

Appendix XXVI (contd)

Appendix D (contd)

Appendix III (contd)

Article 8 (contd)

Summary of acceptable stunning methods and the associated animal welfare issues

Method	Specific method	AW concerns/implications	Key AW requirements applicable	Species	Comment
Electrical	Single application: 1. head only; 2. head to body; 3. head to leg	Accidental pre-stun electric shocks; inadequate current and voltage; wrong electrode positioning; recovery of consciousness	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, sheep, goats, pigs, ratites, poultry	Where cardiac arrest occurs, the carcass may not be suitable for Halal
	Waterbath	Restraint, accidental pre-stun electric shocks; inadequate current and voltage; recovery of consciousness	Competent operation and maintenance of equipment	Poultry only	Where cardiac arrest occurs, the carcass may not be suitable for Halal
Gaseous	CO_2 air/O_2 mixture; CO_2 inert gas mixture	Aversiveness of high CO_2; respiratory distress; inadequate exposure	Concentration; duration of exposure; design, maintenance and operation of equipment; stocking density management	Pigs, poultry	Gaseous methods may not be suitable for Halal
	Inert gases	Recovery of consciousness	Concentration; duration of exposure; design, maintenance and operation of equipment; stocking density management	Pigs, poultry	Gaseous methods may not be suitable for Halal

Appendix XXVI (contd)

Appendix D (contd)

Appendix III (contd)

Article 9
Summary of acceptable slaughter methods, and the associated animal welfare issues

Slaughter methods	Specific method	AW concerns / implications	Key requirements	Species	Comments
Bleeding out by severance of blood vessels in the neck without stunning	Full frontal cutting across the throat	Failure to cut both common carotid arteries; occlusion of cut arteries	A very sharp blade or knife, of sufficient length so that the point of the knife remains outside the incision during the cut; the point of the knife should not be used to make the incision. An incision which does not close over the knife during the throat cut.	Cattle, buffalo, horses, camelids, sheep, goats, poultry, ratites	This method is applicable to Halal and Kosher for relevant species
Bleeding with prior stunning	Neck stab followed by forward cut	Ineffective stunning; failure to cut both common carotid arteries; impaired blood flow; delay in cutting after reversible stunning	Prompt and accurate cutting;	Camelids, sheep, goats, poultry, ratites	
	Neck stab alone	Ineffective stunning; failure to cut both common carotid arteries; impaired blood flow; delay in cutting after reversible stunning	Prompt and accurate cutting	Camelids, sheep, goats, poultry, ratites	
	Chest stick into major arteries or hollow-tube knife into heart	Ineffective stunning; Inadequate size of stick wound inadequate length of sticking knife; delay in sticking after reversible stunning	Prompt and accurate sticking;	Cattle, sheep, goats, pigs,	

Appendix XXVI (contd)
Appendix D (contd)
Appendix III (contd)

Article 9 (contd)
Summary of acceptable slaughter methods, and the associated animal welfare issues

Slaughter methods	Specific method	AW concerns / implications	Key requirements	Species	Comments
	Neck skin cut followed by severance of vessels in the neck	Ineffective stunning; Inadequate size of stick wound; Inadequate length of sticking knife; delay in sticking after reversible stunning	Prompt and accurate cutting of vessels	Cattle	
Bleeding with prior stunning	Automated mechanical cutting	Ineffective stunning; failure to cut and misplaced cuts. Recovery of consciousness following reversible stunning systems	Design, maintenance and operation of equipment; accuracy of cut; manual back-up	Poultry only	
	Manual neck cut on one side	Ineffective stunning; recovery of consciousness following reversible stunning systems	Prior non-reversible stunning	Poultry only	N.B. slow induction of unconsciousness under slaughter without stunning
	Oral cut	Ineffective stunning; recovery of consciousness following reversible stunning systems	Prior non-reversible stunning	Poultry only	N.B. slow induction of unconsciousness in non-stun systems
Other methods without stunning	Decapitation with a sharp knife	Pain due to loss of consciousness not being immediate		Sheep, goats, poultry	This method is only applicable to Jhatka
	Manual neck dislocation and decapitation	Pain due to loss of consciousness not being immediate; difficult to achieve in large birds	Neck dislocation should be performed in one stretch to sever the spinal cord	Poultry only	Slaughter by neck dislocation should be performed in one stretch to sever the spinal cord
Cardiac arrest in a waterbath electric stunner	Bleeding by evisceration		Induction of cardiac arrest	Quail	
	Bleeding by neck cutting			Poultry	

Appendix XXVI (contd)

Appendix D (contd)

Appendix III (contd)

Article 10

Methods, procedures or practices unacceptable on animal welfare grounds

- The restraining methods through immobilisation by injury like 'puntilla' and 'leg tendon cutting', cause severe pain and stress in animals. Those methods are not acceptable in any species.

- The use of electrical stunning method with single application leg to leg is ineffective and unacceptable in any species. The electrocution in this way is likely to be painful. The animal welfare concerns are:

    - accidental pre-stun electric shocks;

    - inadequate current and voltage;

    - wrong electrode positioning;

    - recovery of consciousness.

- The slaughter method of brain stem severance by piercing through the eye socket or skull bone is not acceptable in any species except fish.

Appendix XXVI (contd)

Appendix E

Original: English
September 2004

REPORT OF THE SECOND MEETING OF THE OIE *AD HOC* GROUP ON LAND TRANSPORT OF ANIMALS

Paris, 22-24 September 2004

The OIE *ad hoc* Group on Land Transport of Animals held its second meeting at the OIE Headquarters from 22 to 24 September 2004.

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

The Director General of the OIE, Dr B. Vallat, welcomed the members of the *ad hoc* Group and thanked them for their willingness to continue working on the new mandate of the OIE for animal welfare. He noted that many Member Countries were developing legislation on animal welfare after the OIE Conference of February 2004 and that they would be looking to the OIE for guidance. The Director General advised that the recommendations from the *ad hoc* Group would be put to the Working Group on Animal Welfare for endorsement and then circulated in the report of the OIE Terrestrial Animal Health Standards Commission for Member Country comment. He urged all Member Countries to examine carefully the recommendations with a view to adoption at the 2005 OIE General Session.

The Director General and the Chairman agreed that it was necessary for the guidelines to contain sufficient detail to be useful for Member Countries but that Member Countries should appreciate that refinement would be required as experience in their use was gained. Accordingly, the *ad hoc* Group prepared general guidelines on the principles which should be adopted in order that animal welfare during transport can be good. Further work is in progress in the preparation of detailed guidelines for the major species which are transported.

The *ad hoc* Group noted that the aim of its recommendations was to ensure that the welfare of animals during land transport was as good as possible and to provide standards which will be usable by all OIE Member Countries. This is an important and wide-ranging objective since many billions of animals are transported each year and there are many potential causes of poor welfare in these animals. The major reason for attempting to minimise any poor welfare is our obligation to and concern for the animals which we use but it is also clear that there is a close relationship between welfare and product quality when animals are travelling to slaughter, and between welfare and continuing efficient production in animals travelling to a place of further rearing. In the assessment of welfare during transport, due account has been taken of pain, fear, failure to meet the animals'

needs and disease. Since disease is an important cause of poor welfare, the health of transported animals and of animals potentially affected by those which are transported has been carefully considered.

Appendix XXVI (contd)

Appendix E (contd)

The *ad hoc* Group worked through comments received from two Member Countries, information from several non-governmental organisations, the report of the land transport syndicate group from the animal welfare conference and the report of the recent meeting of the Working Group on Animal Welfare. It also took into account the work of the *ad hoc* Group on Sea Transport. The *ad hoc* Group drafted guidelines addressing the responsibilities of various parties at each stage, the competences and documentation required, preparation for transport, loading and unloading, and journey issues. The proposed definitions are at Appendix III and the draft guidelines at Appendix IV.

…/Appendices

Appendix XXVI (contd)

Appendix E (contd)

Appendix I

SECOND MEETING OF THE OIE *AD HOC* GROUP ON LAND TRANSPORT OF ANIMALS

Paris, 22-24 September 2004

List of participants

MEMBERS OF THE OIE *AD HOC* GROUP

Professor Donald Broom (Chair)
Professor of Animal Welfare
Department of Veterinary Medicine
University of Cambridge
Cambridge CB3 0ES
UNITED KINGDOM
Tel: 44-01 223 337 697
Fax:44-01 223 337 610
E-mail: dmb16@cam.ac.uk

Dr David Adams
Senior Principal Research Scientist
Department of Agriculture, Fisheries and Forestry Australia
GPO Box 858, Canberra City, ACT 2601
AUSTRALIA
Tel: (61 2) 6272-4051
Fax: (61 2) 6272-3150
E-mail: david.adams@daff.gov.au

Dr Carmen Gallo
Médico Veterinario (Ph D)
Instituto de Ciencia Animale y Tecnología de Carnes
Facultad de Ciencias Veterinarias
Universidad Austral de Chile
Casilla 567. Valdivia
CHILE
Tel & Fax:56-63-221212
E-mail: cgallo@uach.cl

Dr Carolyn Stull
Extension Specialist
Animal Welfare Program,
Veterinary Medicine Extension
University of California
Davis, CA 95616
UNITED STATES OF AMERICA
Tel: 1-530-752-0855
Fax: 1-530-752-7563
E-mail: clstull@ucdavis.edu

OTHER PARTICIPANTS

Dr A. Thiermann
(President of the OIE Terrestrial Animal Health Standards Commission)
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: a.thiermann@oie.int

Dr Sira Abdul Rahman
(Member of the OIE Working Group on Animal Welfare)
Retd. Dean Bangalore Veterinary College
No 123, 7th B Main Road
4th Block (West)
Jayanagar, Bangalore 560 011
INDIA
Tel.: (91-80) 26635210
Fax: (91-80) 26635210
E-mail: shireen@blr.vsnl.net.in

OIE CENTRAL BUREAU

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

Dr David Wilson
Head
International Trade Department
OIE
Tel.: 33 (0)1 44.15.18.80
Fax: 33 (0)1 42.67.09.87
E-mail: d.wilson@oie.int

Dr Antonio Petrini
Chargé de mission
International Trade Department
OIE
Tel.: 33 (0)1 44.15.18.89
Fax: 33 (0)1 42.67.09.87
E-mail: a.petrini@oie.int

Appendix XXVI (contd)

Appendix E (contd)

Appendix II

SECOND MEETING OF THE OIE *AD HOC* GROUP ON LAND TRANSPORT OF ANIMALS

Paris, 22 –24 September 2004

Agenda adopted

1. Introduction

1.1. Discussion on the report of the recent meeting of the OIE Working Group on Animal Welfare

1.2. Discussion on the outcomes of the OIE Global Conference on Animal Welfare

1.3. Discussion on the OIE 72nd General Session (Animal Welfare)

1.4. Comments from Member Countries

1.5. Comments from ICFAW

2. Development of specific guiding principles and standards

3. Work programme

4. Conclusions

Article 1

Definitions

Animal

For the purpose of this chapter 'animal' refers to the following live domesticated animals: cattle, buffalo, camels, sheep, goats, pigs, poultry and equines. These guidelines will also be largely applicable to some other animals e.g. deer, other camelids and ratites. Wild, feral and partly domesticated animals may need different conditions.

Animal handler

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

Container

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

Journey

An animal transport journey should be regarded as commencing when the first animal is loaded onto a *vehicle* or into a *container* and as ending when the last animal is unloaded, and includes any stationary resting / holding periods of less than 48 hours.

The same animals should not be regarded as commencing a new journey until a period of over 48 hours sufficient for rest and recuperation of the animals with adequate feed and water provided, has passed since the end of the previous journey.

Loading

Is the procedure of moving animals onto a *vehicle/vessel* or into a *container* from the pre-loading site; **unloading** is the procedure of moving animals off a *vehicle/vessel* or out of a *container*.

Post-journey period

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

Pre-journey period

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

Space allowance

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

Staging point

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

Appendix XXVI (contd)

Appendix E (contd)

Appendix III (contd)

Stocking density

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

Transport

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

Travel

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

Vehicle/vessel

Includes any train, truck, or ship that is used for carrying animal(s).

Appendix XXVI (contd)

Appendix E (contd)

Appendix IV

GUIDELINES FOR THE LAND TRANSPORT OF ANIMALS

Article 1

Responsibilities

The welfare of animals during their *transport* is the joint responsibility of all people involved.

The roles of each of those responsible are defined below:

- Owners and managers of animals are responsible for the general health of the animals and their fitness for the *journey*, and their welfare during the *journey*, regardless of whether duties are subcontracted to other parties during *transport*. They are also responsible for ensuring compliance with any required veterinary or other certification, and for the presence during the *journey* of at least one *animal handler* competent for the species being transported, with the authority to take prompt action. They are also responsible for ensuring that equipment and veterinary assistance are provided as appropriate for the species and *journey*.

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

- *Animal handlers* are responsible for the humane handling and care of the animals, especially during *loading* and *unloading*, and for maintaining a journey log. In the absence of a separate animal handler, the driver is the animal handler.

- Transport companies, *vehicle* owners and drivers are responsible for planning the *journey* to ensure the care of the animals:

  - transport companies and vehicle owners are responsible for choosing appropriate *vehicles* and ensuring that properly trained staff are available for *loading* and caring for animals,

  - transport companies and vehicle owners are responsible for developing and keeping up to date contingency plans to address emergencies and minimise stress during *transport*,

  - transport companies and vehicle owners are responsible for producing a journey plan which includes a loading plan, journey duration and location of resting places,

  - drivers are responsible for *loading* only those animals which are fit to travel, for their correct *loading* into the *vehicle* and their inspection during the *journey*, and for appropriate responses to problems arising.

- Managers of facilities at the start and at the end of the *journey*, and at *staging points* are responsible for:

  - providing suitable premises for *loading*, *unloading* and securely holding the animals in lairage, with water and feed when required, until further *transport*, sale or other use (including rearing or slaughter),

  - providing competent animal handlers to load, unload, drive and hold animals in a manner that causes minimum stress and injury,

Appendix XXVI (contd)

Appendix E (contd)

Appendix IV (contd)

- minimising the opportunities for disease transmission,
- providing appropriate facilities, with water and feed when required,
- providing appropriate facilities for emergencies,
- providing facilities for washing and disinfecting *vehicles* after *unloading*,
- providing facilities and competent staff to allow the humane killing of animals when required,
- ensuring proper rest times and minimal delay during lairage. See Article XXX

- The responsibilities of the *Competent Authority* include:
  - establishing minimum standards for animal welfare, including requirements for inspection of animals before, during and after their *travel*, and appropriate certification and record keeping,
  - approving facilities, *containers* and *vehicles* for the *transport* of animals,
  - ensuring appropriate awareness and training,
  - setting standards for the competence of drivers, *animal handlers* and managers,
  - implementation of the standards, including through accreditation of / interaction with other organisations,
  - monitoring and evaluating the effectiveness of standards of health and other aspects of welfare,
  - monitoring and evaluating the use of veterinary medications.
- All individuals, including veterinarians, involved in transporting animals and the associated handling procedures should receive appropriate training and to be competent to meet their responsibilities.

Article 2

Training and competence

- All people handling animals, or who are otherwise responsible for animals during *journeys*, should be competent according to their responsibilities listed in Article 1. Competence may be gained through formal training or practical experience. Competence in areas other than animal welfare would need to be addressed separately.
- This competence for *animal handlers* should be demonstrated through a current certificate from an independent body, accredited by the *Competent Authority*. The certificate should be in one of the OIE official languages if the international *transport* of animals is involved.
- The training and assessment of the competence of *animal handlers* should at a minimum address knowledge, and ability to apply that knowledge, in the following areas:

- planning a *journey*, including appropriate *space allowance*, and feed, water and ventilation requirements,
- responsibilities for animals during the *journey*, including *loading* and *unloading*,
- sources of advice and assistance,
- animal behaviour, general signs of disease, and indicators of poor animal welfare such as stress, pain and fatigue, and their alleviation,
- relevant authorities and applicable transport regulations, and associated documentation requirements,
- general disease prevention procedures, including cleaning,
- appropriate methods of driving,
- methods of inspecting animals, managing situations frequently encountered during *transport* such as adverse weather conditions, and dealing with emergencies,
- species-specific aspects of animal handling and care, including feeding, watering and inspection,
- maintaining a journey log and other records.

- The above are also important areas of knowledge for owners and managers.

Article 3

Planning the journey

General

- Adequate planning is a key factor affecting the welfare of animals during a *journey*.
- Before the journey starts, plans should be made in relation to:
  - preparation of animals for the *journey*,
  - choice of road or rail,
  - nature and duration of the *journey*,
  - *vehicle* / *container* design and maintenance, including roll-on roll-off vessels,
  - required documentation,
  - *space allowance*,
  - rest, water and feed,
  - observation of animals en route,
  - control of disease, and
  - emergency response procedures.
- Regulations concerning drivers (for example maximum driving periods) should be harmonised with maximum transport journey intervals appropriate for the species.

Appendix XXVI (contd)

Appendix E (contd)

Appendix IV (contd)

Preparation of animals for the journey

- When animals are to be provided with a novel diet or method of water provision during *transport*, an adequate period of adaptation should be planned.

- Animals should be exposed to appropriate contact with humans and handling conditions (including methods of restraint) prior to *transport* to reduce their fearfulness and improve their approachability (see Article 5).

- Behaviour-modifying compounds (such as tranquillisers) should not be used routinely during *transport*. Such compounds should only be administered when a problem exists in an individual animal, and should be administered by a veterinarian or other person who has been instructed in their use by a veterinarian.

Nature and duration of the journey

- The maximum duration of a *journey* should be determined according to:
  - the ability of the animals to cope with the stress of *transport* (such as very young, old or pregnant animals),
  - the animals' previous transport experience,
  - the onset of fatigue,
  - the need for special attention,
  - the need for feed and water,
  - the increased susceptibility to injury and disease,
  - space allowance, vehicle design, road conditions, driving quality,
  - weather conditions.

Vehicle and container design and maintenance

- *Vehicles* and *containers* used for the *transport* of animals should be designed, constructed and fitted as appropriate to the species, size and weight of the animals to be transported; special attention should be paid to the avoidance of injury to animals through the use of secure smooth fittings free from sharp protrusions. The avoidance of injury to drivers and *animal handlers* while carrying out their responsibilities should also be taken into account.

- *Vehicles* and *containers* should be designed with the structures necessary to provide protection from adverse weather conditions and to minimise the opportunity for animals to escape.

- In order to minimise the likelihood of the spread of pathogenic agents during transport, *vehicles* and *containers* should be designed to permit thorough cleaning and disinfection, and the containment of faeces and urine during a *journey*.

- *Vehicles* and *containers* should be maintained in good mechanical and structural condition.

- *Vehicles* should have adequate ventilation which can be adjusted to meet variations in climate and the needs of the animal species being transported.

- *Vehicles* should be designed so that the faeces or urine from animals on upper levels do not soil animals on lower levels.

- When *vehicles* are carried on board ferries, facilities for adequately securing them should be available.

- If feeding or watering while the *vehicle* is moving may be required, adequate facilities on the *vehicle* should be available.

- Suitable bedding should be added to vehicle floors to assist absorption of urine and faeces, to minimise slipping by animals, and protect animals (especially young animals) from hard flooring surfaces and adverse weather conditions.

Special provisions for transport in vehicles (road and rail) on roll-on/roll-off vessels or for containers

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

- *Vehicles* and *containers* should be secured to the ship before the start of the sea journey to prevent them being displaced by the motion of the vessel.

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

Documentation

- Animals should not be loaded until the required documentation is complete.

- The documentation accompanying the consignment should include:

  - journey travel plan,

  - date, time, and place of *loading* and *unloading*,

  - veterinary certification, when required,

  - driver's competencies,

  - identities of the animals transported to allow traceback of individual animals to the premises of departure, and where possible to the premises of origin,

  - details of any animals considered 'at risk' (Article 5),

  - documentation of the period of rest, and access to feed and water, prior to the *journey*,

  - *stocking density* estimate for each load in the consignment,

  - the journey log - daily record of inspection and important events, including records of morbidity and mortality, climatic conditions, rest stops, travel time and distance, feed and water offered and estimates of consumption, medication provided, and mechanical defects.

Appendix XXVI (contd)

Appendix E (contd)

Appendix IV (contd)

- When veterinary certification is required to accompany consignments of animals, it should include:
  - appropriate animal identification (description, number, etc.),
  - health status including test, treatment and vaccination status,
  - factors affecting fitness to travel.

Space allowance

- The number of animals which should be transported on a *vehicle* or in a *container* and their allocation to different compartments should be determined before the *vehicle* or *container* is loaded.
- The space required on a *vehicle* or in a *container* depends upon whether or not the animals need to lie down (for example pigs, camels and poultry), or to stand (horses). Animals which will need to lie down often stand when first loaded or when the *vehicle* is driven with too much lateral movement or sudden braking.
- When animals lie down, they should all be able to adopt a comfortable, normal lying posture which allows necessary thermoregulation.
- When animals are standing, they should have sufficient space to adopt a balanced position without body contact with other animals.
- The amount of headroom necessary depends on the species of animal. Each animal should be able to assume its natural position for *transport* (including during *loading* and *unloading*) without coming into contact with the roof or upper deck of the *vehicle*.
- Calculations according to the *space allowance* permitted for each animal should be carried out, using the figures given in these guidelines (see Appendix XXX) or, in their absence, in a relevant national or international document. The size of already established groups will affect the number and size of the pens, and the distribution of animals in pens on the *vehicle*.
- Other factors which may influence *space allowance* include:
  - *vehicle* / *container* design
  - length of journey
  - quality of roads
  - expected weather conditions.

Rest, water and feed

- There should be planning for the availability of suitable water and feed during the *journey*. Feed should be of appropriate quality and composition for the species, age, condition of the animals, climatic conditions, etc.

- Animals should be rested at *staging points* at appropriate intervals during the *journey*. The type of transport and species being transported should determine the frequency of rest stops and whether the animals are unloaded. There should be planning for water and feed availability during rest stops.

Ability to observe animals en route in relation to journey duration

- Animals should be positioned to enable each animal to be observed regularly during the *journey* to ensure their safety and good welfare.

- If the animals are in crates or on multi-tiered vehicles which do not allow free access for observation, for example where the roof of the tier is too low (i.e. less than 1.3 m), animals cannot be inspected adequately, and serious injury or disease could go undetected. In these circumstances, a shorter journey duration should be allowed, and the maximum duration will vary according to the rate at which problems arise in the species and under the conditions of transport.

Control of disease

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

  - mixing of animals from different sources in a single consignment should be minimised,

  - contact at *staging points* between animals from different sources should be avoided,

  - the use of markets should be minimised,

  - when possible, animals should be vaccinated against diseases to which they are likely to be exposed at their destination,

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

Emergency response procedures

- Appropriate contingency plans to address emergencies should be prepared in advance (see Article 6).

Other considerations

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

- In some circumstances, transportation during the night may reduce thermal stress or the adverse effects of other external stimuli.

Appendix XXVI (contd)

Appendix E (contd)

Appendix IV (contd)

Article 4

Pre-journey period

General

- Pre-journey rest is necessary if the welfare of animals has become poor during the collection period because of major physical or social problems.

- Feed and water should be provided pre-journey if the journey duration is greater than the normal inter-feeding and drinking interval for the animal. Recommendations for specific species are described in detail in Article XXX.

- When animals will be provided with a novel diet or method of water provision during or after *transport*, an adequate period of pre-exposure is necessary.

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

- Where an *animal handler* believes that there is a significant risk of disease among the animals to be loaded, the animals should be inspected by a veterinarian.

Selection of compatible groups

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

  - animals reared together should be maintained as a group; animals with a strong social bond should be transported together,

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

  - young or small animals should be separated from older or larger animals, with the exception that dam and offspring should be transported together,

  - animals with horns or antlers should not be mixed with animals lacking horns or antlers,

  - animals of different species should not be mixed unless they are judged to be compatible.

Shelter in the assembly/holding area

- Assembly/holding areas should be designed to:

  - securely hold the animals,

- maintain a safe environment from hazards, including predators and disease,
- protect animals from exposure to severe weather conditions,
- allow for maintenance of social groups, and
- allow for rest, and appropriate water and feed.

Effect of travel experience, long and short term

- Consideration should be given to an animal's previous transport experience, training and conditioning as these may reduce fear and stress in animals. Animals that are carefully and regularly transported may show less adverse responses to transport.
- Exposure to familiar personnel should reduce the fearfulness of animals and improve their approachability during transport procedures.

Fitness to travel

- Each animal should be inspected by an *animal handler* to assess fitness to travel. Animals found unfit to travel should not be loaded onto a *vehicle*, except for transport to receive veterinary treatment.
- Humane and effective arrangements should be made by the owner or agent for the handling and care of any animal rejected as unfit to travel.
- Animals that are unfit to travel include:
  - those that are sick, injured, weak, disabled or fatigued,
  - those that are unable to stand unaided and bear weight on each leg,
  - those that are blind in both eyes,
  - those that cannot be moved without causing them additional suffering,
  - pregnant animals which are likely to give birth during the *journey*,
  - those whose body condition would result in poor welfare because of the expected climatic conditions.
- Risks during *transport* can be reduced by selecting animals best suited to the conditions of travel and those that are acclimatised to expected weather conditions.
- Animals 'at risk' which require special conditions (such as in the design of facilities and vehicles) and additional attention during *transport*, may include:
  - large or obese individuals,
  - young or old animals,
  - excitable or aggressive animals,
  - animals which have had little contact with humans,

- animal subject to motion sickness,
- females in late pregnancy or heavy lactation; dam and offspring,
- those with a history of exposure to stressors or pathogenic agents prior to *transport*.

Specific species requirements

Transport procedures should be able to take account of variations in the behaviour of the species. Flight zones, social interactions and other behaviour vary significantly among species and even within species. Facilities and handling procedures that are successful with one species are often ineffective or dangerous with another.

- Recommendations for specific species are described in detail in Article XXX.

Article 5
Loading

Experienced supervision

- Since *loading* has been shown to be the procedure most likely to be the cause of poor welfare in transported animals, the methods to be used should be carefully planned.
- *Loading* should be supervised by *animal handlers*. These *animal handlers* should ensure that animals are loaded quietly and without unnecessary noise, harassment or force, and that untrained assistants or spectators do not impede the process.
- When *containers* are loaded onto a *vehicle*, this should be carried out in such a way to avoid poor animal welfare.

Facilities

- The facilities for *loading* including the collecting area, races and loading ramps should be designed and constructed to take into account the needs and abilities of the animals with regard to dimensions, slopes, surfaces, absence of sharp projections, flooring, etc.
- Loading facilities should be properly illuminated to allow the animals to be observed by the *animal handler(s)*, and to allow the animals' ease of movement at all times. Facilities should provide uniform lighting directly over approaches to sorting pens, chutes, loading ramps, with brighter lighting inside *vehicles* / *containers*, in order to minimise baulking. Dim lighting may be advantageous for the catching of poultry and some other animals.
- Ventilation during *loading* and the *journey* should provide for fresh air, the removal of excessive heat, humidity and noxious fumes (such as ammonia and carbon monoxide), and the prevention of accumulations of ammonia and carbon dioxide. Under warm and hot conditions, ventilation should allow for the adequate convective cooling of each animal. In some instances, adequate ventilation can be achieved by increasing the *space allowance* for animals.

Goads and other aids

- The following principles should apply:
    - Animals which have little or no room to move should not be subjected to physical force or goads and other aids which compel movement.
    - Useful and permitted aids include panels, flags, plastic paddles, flappers (a length of cane with a short strap of leather or canvas attached), plastic bags and metallic rattles; they should be used in a manner sufficient to encourage and direct movement of the animals but without physical contact with them.
    - Painful procedures (including whipping, tail twisting, use of nose twitches, pressure on eyes, ears or external genitalia), or the use of unsuitable goads or other aids (including large wooden sticks, sticks with sharp ends, lengths of metal piping, fencing wire or heavy leather belts), should not be used to move animals.
    - The use of goads which administer electric shocks should be discouraged, and restricted to that necessary to assist movement of the animal. Such use should be limited to battery-powered goads on the hindquarters of adult pigs and cattle, and never on sensitive areas such as the eyes, mouth, ears, anogenital region or belly. Such instruments should not be used on other animals.
    - The use of muzzled, well trained dogs to help with the *loading* of some species may be acceptable.
    - The throwing or dropping of animals, or their lifting or dragging by their tail, head, horns, ears, limbs, wool, hair or feathers should not be permitted. The manual lifting of small animals is permissible.

Article 6

Travel

- Drivers and *animal handlers* should check the load immediately before departure to ensure that the animals have been properly loaded. Each load should be checked again early in the trip and adjustments made as appropriate. Periodic checks should be made throughout the trip.
- Drivers should utilise smooth, defensive driving techniques, without sudden turns or stops, to minimise uncontrolled movements of the animals.

Methods of restraining or containing animals

- Methods of restraining animals should be appropriate to the species involved and the training of the individual animal.
- Recommendations for specific species are described in detail in Article XXX.

Regulating the environment within vehicles or containers

- Animals should be protected against harm from hot or cold conditions during *travel*. Effective ventilation procedures for maintaining the animals' environment within *vehicles* or *containers* will vary according to whether conditions are cold, hot and dry or hot and humid, but in all conditions a build-up of noxious gases should be prevented.

Appendix XXVI (contd)

Appendix E (contd)

Appendix IV (contd)

- The animals' environment in hot weather can be regulated by the flow of air produced by the movement of the *vehicle*. In warm and hot weather, the duration of journey stops should be minimised and *vehicles* should be parked under shade, with maximal ventilation.

- To minimise slipping and soiling, and maintain a healthy environment, urine and faeces should be removed from floors when necessary and disposed of in such a way as to prevent the transmission of disease and in compliance with all relevant health and environmental legislation.

Sick, injured and dead animals

- A driver or *animal handler* finding sick, injured or dead animals should act according to a predetermined emergency response plan.

- If possible, sick or injured animals should be segregated.

- Ferries (roll-on roll-off) should have procedures to treat sick or injured animals during the *journey*.

- In order to reduce the likelihood that animal transport will increase the spread of infectious disease, contact between transported animals, or the products of the transported animals, and other farm animals should be minimised.

- During the *journey*, when disposal of a dead animal becomes necessary, this should be carried out in such a way as to prevent the transmission of disease and in compliance with all relevant health and environmental legislation.

- When euthanasia is necessary, the driver or *animal handler* should ensure that it is carried out humanely, and results in immediate death. When necessary, assistance should be sought from a veterinarian or other person(s) competent in euthanasia procedures. Recommendations for specific species are described in the Chapter on humane killing of animals for disease control purposes.

Water and feed requirements

- If journey duration is such that feeding or watering is required or if the species requires feed or water throughout, access to suitable feed and water for all the animals carried in the *vehicle* should be provided. There should be adequate space for all animals to move to the feed and water sources and due account taken of likely competition for feed.

- Recommendations for specific species are described in detail in Article XXX.

Rest periods and conditions including hygiene

- Animals that are being transported should be rested at appropriate intervals during the *journey* and offered feed and water, either on the *vehicle* or, if necessary, unloaded into suitable facilities.

- Suitable facilities should be used en route, when resting requires the *unloading* of the animals. These facilities should meet the needs of the particular animal species and should allow access of all animals to feed and water.

In-transit inspections

- Animals being transported by road should be observed soon after a *journey* is commenced and subsequently at least every 5 hours, in particular whenever the driver has a rest stop. After meal breaks and refuelling stops, the animals should be observed immediately prior to departure.

- Animals being transported by rail should be observed every 5 hours or at the scheduled stop nearest to 5 hours since the last observation. The responsible rail transporter should monitor the progress of trains carrying animals and take all appropriate action to minimise delays.

- During stops, it should be ensured that the animals continue to be properly confined, have appropriate feed and water, and their physical condition is satisfactory.

Article 7
Unloading and post-journey handling

General

- The required facilities and the principles of animal handling detailed in Article 5 (Loading) apply equally to *unloading*, but consideration should be given to the likelihood that the animals will be fatigued.

- *Unloading* should be supervised by *animal handlers* with knowledge and experience of the behavioural and physical characteristics of the species being unloaded. Animals should be unloaded from the *vehicle* into appropriate facilities as soon as possible after arrival at the destination but sufficient time should be allowed for unloading to proceed quietly and without unnecessary noise, harassment or force.

- Facilities should provide all animals with appropriate care and comfort, adequate space and ventilation, access to feed (if appropriate) and water, and shelter from extreme weather conditions.

- For details regarding the *unloading* of animals at a slaughterhouse, see Chapter on slaughter of animal for human consumption.

Sick and injured animals

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

- At the destination, the *animal handler* during transit should ensure that responsibility for the welfare of sick, injured or disabled animals is transferred to a suitable person.

- There should be appropriate facilities and equipment for the humane unloading of animals that are non-ambulatory due to fatigue, injury or sickness. These animals should be unloaded in a manner that causes the least amount of suffering. After *unloading*, separate pens and other appropriate facilities should be available for sick or injured animals.

- Feed, if appropriate, and water should be available for each sick or injured animal.

Addressing disease risks

- The following should be taken into account in addressing the greater risk of disease due to animal transport and the possible need for segregation of transported animals at the destination:
    - increased contact among animals, including those from different sources and with different disease histories,

Appendix XXVI (contd)

Appendix E (contd)

Appendix IV (contd)

- increased shedding of pathogens and increased susceptibility to infection related to stress and impaired defences against disease, including immunosuppression,

- exposure of animals to pathogens which may contaminate *vehicles*, *staging points*, markets etc.

Cleaning and disinfection

- *Vehicles*, crates, *containers*, etc. used to carry the animals should be cleaned before re-use through the physical removal of manure and bedding by scraping, washing and flushing *vehicles* and *containers* with water and detergent. This should be followed by *disinfection* when there are concerns about disease transmission.

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

- When disposal of a dead animal becomes necessary, this should be carried out in such a way as to prevent the transmission of disease and in compliance with all relevant health and environmental legislation.

- Establishments like livestock markets, slaughterhouses, resting sites, railway stations, etc. where animals are unloaded should be provided with appropriate areas for the cleaning and *disinfection* of *vehicles*.

- Where *disinfestation* is necessary, it should be carried out with the minimum stress to the animals.

Article 8

Actions in the event of a refusal to allow the completion of the journey

- The welfare of the animals should be the first consideration in the event of a refusal to allow the completion of the *journey***.**

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

  - the *Competent Authority* of the importing country should provide urgently in writing the reasons for the refusal,

  - in the event of a refusal for animal health reasons, the *Competent Authority* of the importing country should provide urgent access to a veterinarian, where possible an OIE veterinarian(s) appointed by the Director General, to assess the animals' health status with regard to the importing country's concerns, and the necessary facilities and approvals to expedite the required diagnostic testing,

  - the *Competent Authority* of the importing country should provide access to allow continued assessment of the health and other aspects of the welfare of the animals,

  - if the matter cannot be promptly resolved, the *Competent Authorities* of the exporting and importing countries should call on the OIE to mediate.

- In the event that a *Competent Authority* requires the animals to remain on the *vehicle*, the priorities should be:
    - the *Competent Authority* should allow reprovision of the *vehicle* with water and feed as necessary,
    - the *Competent Authority* should provide urgently in writing the reasons for the refusal,
    - in the event of a refusal for animal health reasons, the *Competent Authority* should provide urgent access to an independent veterinarian(s) to assess the animals' health status, and the necessary facilities and approvals to expedite the required diagnostic testing
    - the *Competent Authority* should provide access to allow continued assessment of the health and other aspects of the welfare of the animals.
- The OIE should utilise its dispute settlement mechanism to identify a mutually agreed solution which will address animal health and any other welfare issues in a timely manner.

Article XXX

Species specific issues

(To be developed)

Appendix XXVI (contd)

Appendix F

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

Original: English
September 2004

REPORT OF THE SECOND MEETING OF THE OIE *AD HOC* GROUP ON THE TRANSPORT OF ANIMALS BY SEA

Paris, 15-17 September 2004

The OIE *ad hoc* group on the transport of animals by sea held its second meeting at the OIE Headquarters from 15-17 September 2004.

The members of the OIE *ad hoc* group and other participants are listed in Appendix I. Dr. Kassab advised that he was unable to attend the meeting.

The Agenda adopted is given in Appendix II.

The Director General of the OIE, Dr Bernard Vallat, welcomed the members of the *ad hoc* group and thanked them for their willingness to continue their work within the OIE's new mandate for animal welfare. The Director-General noted the importance of the *ad hoc* Group's work. He indicated that he had discussed with various parties the problems arising from the rejection of a consignment by an importing country and requested the *ad hoc* Group to make recommendations concerning the management of the animal welfare issues arising from a rejected consignment.

The Director-General advised that the recommendations from the *ad hoc* group would be put to the Working Group on Animal Welfare for endorsement and then circulated in the report of the Code Commission for Member Country comment. He urged all Member Countries to examine carefully the recommendations with a view to adoption at the 2005 General Session.

The *ad hoc* group noted with disappointment the paucity of comments from Member Countries (with only New Zealand contributing), but comments had been received from the International Coalition for Farm Animal Welfare and the European Community Shipowners' Association. These were taken into account in its deliberations.

The *ad hoc* group worked through the relevant sections of the report of the Working Group on Animal Welfare to ensure that it addressed all points raised. These included the need for some new or revised definitions, better harmonisation of terms with other relevant *ad hoc* Groups, the importance of competence of animal handlers and the need to consider in more detail roll-on-roll-off transport. The *ad hoc* group next considered the report of the

discussion on sea transport at the OIE Animal Welfare Conference, and at the 2004 General Session, and addressed the points raised.

Appendix XXVI (contd)

Appendix F (contd)

The *ad hoc* group decided that the meeting would be best spent finalising general guidelines for the transport of animals by sea, with some information addressing species-specific issues. Based on the feed-back from Member

Countries, species-specific guidelines addressing *inter alia* accommodation, space requirements, ventilation, and feeding and watering would be the task of future meetings.

With regard to the adopted Guiding Principles, the *ad hoc* group recommended the removal of the word 'entertainment' from the list of uses of animals making a major contribution to the wellbeing of people.

The proposed definitions are at Appendix III and the guidelines at Appendix IV.

.../Appendices

Appendix XXVI (contd)

Appendix F (contd)

Appendix I

SECOND MEETING OF THE OIE *AD HOC* GROUP ON THE TRANSPORT OF ANIMALS BY SEA

Paris, 15-17 September 2004

List of participants

MEMBERS OF THE OIE AD HOC GROUP

Dr Richard Norris (chair)
Department of Agriculture - Western Australia
3 Baron-Hay Court
South Perth WA 6151
AUSTRALIA
Tel: 61 89368 3637
Fax:
E-mail: rnorris@agric.wa.gov.au

Dr Mansour Kassab (absent)
Director of Animal Resources
Ministry of Agricultura
Rue Beydoun
Agrafieh-Beyrouth
LEBANON
Tel: 961 5 455 621 / 631/2/3/4
Fax: 961 5 455 475/455 474
E-mail: minagri_anires@hotmail.com

Dr GB (Ru) Davis
MAF
1216 Howard Street
Hastings
NEW ZEALAND
Tel: 64 6 8789923
Fax: 64 6 8760757
E-mail: walkerra@maf.govt.nz

Mr Tim Harris SDA
AATA European Secretary
[Animal (Air) Transportation Association]
Harris Associates Limited
PO Box 251 REDHILL Surrey
RH1 5FU ENGLAND
Tel: 44 1737 822249
Fax: 44 1737 822954
E-mail harrisassociates@btconnect.com

OTHER PARTICIPANTS

Dr A. Thiermann
President of the OIE Terrestrial Animal Health Standards Commission
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: a.thiermann@oie.int

Dr Andrea Gavinelli
Member of the OIE Working Group on Animal Welfare
European Commission
Rue Froissart 101 - 2/54
1040 Brussels
BELGIUM
Tel : (32-2) 296 64 26
Fax : (32-2) 295 31 44
E-mail: Andrea.Gavinelli@cec.eu.int

OIE HEADQUARTERS

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

Dr David Wilson
Head
International Trade Department
OIE
Tel.: 33 - (0)1 44.15.18.80
Fax: 33 - (0)1 42.67.09.87
E-mail: d.wilson@oie.int

Dr Antonio Petrini
Chargé de mission
International Trade Department
OIE
Tel.: 33 - (0)1 44.15.18.89
Fax: 33 - (0)1 42.67.09.87
E-mail: a.petrini@oie.int

Appendix XXVI (contd)

Appendix F (contd)

Appendix II

SECOND MEETING OF THE OIE *AD HOC* GROUP ON THE TRANSPORT OF ANIMALS BY SEA

Paris, 15-17 September 2004

Agenda adopted

1. **Introduction**
   - Discussion on the report of the recent meeting of the OIE Working Group on Animal Welfare
   - Discussion on outcomes of OIE Global Conference on Animal Welfare
   - Discussion on OIE 72nd General Session (Animal Welfare)
   - Comments from Member Countries
   - Comments from ICFAW
2. **Development of specific guidelines**
3. **Work programme**
4. **Conclusions**

Appendix XXVI (contd)

Appendix F (contd)

Appendix III

INTRODUCTION TO OIE GUIDELINES FOR THE WELFARE OF ANIMALS

Article 1

Definitions

- **Animal**. For the purposes of this chapter, 'animal' refers to the following live domesticated animals: cattle, deer, camelids, buffalo, sheep, goats, pigs and equines. These guidelines may also be applicable to other domesticated animals.
- **Animal handler.** A person with a knowledge of the behaviour and needs of animals which, with appropriate experience and a professional and positive response to an animal's welfare requirements, results in effective management and good welfare. Their competence should be demonstrated through independent assessment and certification.
- **Container.** A non-self-propelled receptacle or other rigid structure for holding animals during a *journey* by one or several means of transport.
- **Exporter**. A person licensed by the *Competent Authority* to export animals by sea. For the purposes of this chapter, the term applies equally to the transport of animals by water within a country
- **Journey**. An animal transport journey commences when the first animal is loaded onto a *vehicle/vessel* or into a *container* and ends when the last animal is unloaded, and includes any stationary resting / holding periods of less than 48 hours.
  The same animals do not commence a new journey until after a period of over 48 hours for rest and recuperation, with adequate feed and water.
- **Loading / unloading**. **Loading** is the procedure of moving animals onto a *vehicle/vessel* or into a *container* from the pre-loading site; **unloading** is the procedure of moving animals off a *vehicle/vessel* or *container*.
- **Pre-journey period**. The period during which animals are identified, and often assembled for the purpose of loading them.
- **Post-journey period**. The period between *unloading* and recovery from the effects of the *journey*.
- **Space allowance** is the measure of the floor area and height on a *vehicle/vessel*, allocated per individual or body weight of animal transported.
- **Stocking density** is the number or body weight of animals per unit area on a *vehicle/vessel*.
- **Staging point.** A place where the journey is interrupted to rest, feed or water the animals; the animals may remain in the *vessel* or be unloaded.
- **Transport**. The procedures associated with the carrying of animals for commercial purposes from one location to another by land, sea or air.
- **Transporter.** The person licensed by the *Competent Authority* to transport animals.
- **Travel**. The movement of a *vehicle/vessel* or *container* carrying animals from one location to another.
- **Vehicle/vessel** includes any train, truck, or ship that is used for carrying an animal(s).

_____

Appendix XXVI (contd)

Appendix F (contd)

Appendix IV

GUIDELINES FOR THE TRANSPORT OF ANIMALS BY SEA

Article 1

Responsibilities

Once the decision to transport animals by sea has been made, the welfare of animals during their transport is paramount and is the joint responsibility of all people involved. These guidelines may also be applied to the transport of animals by water within a country.

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

The roles of each of those responsible are defined below:

- *Exporters*, owners of animals and managers of facilities are jointly responsible for the general health of the animals and their fitness for the *journey*.

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

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

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

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

    - choosing appropriate *vessels* and ensuring that competent *animal handlers* are available for *loading* and caring for animals throughout the *journey*,

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

    - correct *loading* of the ship, regular inspections during the *journey* and for appropriate responses to problems arising

    - disposal of carcases according to international law.

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

Appendix XXVI (contd)

Appendix F (contd)

Appendix IV (contd)

- Managers of facilities during *loading* of the animals are responsible for:
  - providing suitable premises for *loading* the animals,
  - providing competent *animal handlers* to load the animals in a manner that causes minimum stress and injury,
  - providing appropriate facilities for emergencies,
  - providing facilities and veterinarians or competent a*nimal handlers* capable of performing euthanasia or urgent slaughter when required.
- Managers of facilities at the end of the *journey* are responsible for:
  - providing suitable facilities for *unloading* the animals onto transport vehicles for immediate movement or securely holding the animals in lairage, with shelter, water and feed, when required, for transit,
  - providing competent *animal handlers* to unload the animals with minimum stress and injury,
  - minimising the opportunities for disease transmission while the animals are in the facilities,
  - providing appropriate facilities for emergencies,
  - providing facilities and veterinarians or competent *animal handlers* capable of performing euthanasia or urgent slaughter when required.
- The responsibilities of the *Competent Authority* of the exporting country include:
  - establishing minimum standards for animal welfare, including requirements for inspection of animals before and during their travel, and for certification and record keeping,
  - approving facilities, *containers*, *vehicles/vessels* for the holding and transport of animals,
  - setting competence standards for *animal handlers* and managers,
  - ensuring that the *vessel* transporting animals meets the required standards, including those of the importing country,
  - implementation of the standards, including through accreditation of / interaction with other organisations and competent authorities,
  - monitoring and evaluating health and welfare performance, including the use of any veterinary medications.
- The responsibilities of the *Competent Authority* of the importing country include:
  - establishing minimum standards for animal welfare, including requirements for inspection of animals after their travel, and for certification and record keeping,
  - approving facilities, *containers* and vehicles for the *unloading*, holding and transport of animals,
  - setting competence standards for *animal handlers* and managers,

- implementation of the standards, including through accreditation of / interaction with other organisations and competent authorities,
- ensuring that the exporting country is aware of the required standards for the *vessel* transporting the animals,
- monitoring and evaluating health and welfare performance, including the use of any veterinary medications.

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

Article 2

Competence

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

- This competence should be demonstrated through a current certificate in one of the OIE official languages from an independent body.

- Assessment of competence for *animal handlers* should at a minimum address knowledge, and ability to apply that knowledge, in the following areas:
  - responsibilities for animals during the *journey*,
  - sources of advice and assistance,
  - animal behaviour, general signs of disease, and indicators of poor animal welfare such as stress, pain and fatigue, and their alleviation,
  - relevant authorities and applicable transport regulations, and associated documentation requirements,
  - general disease prevention procedures, including cleaning,
  - appropriate methods of animal handling during transport and associated activities such as assembling, *loading*, and *unloading*,
  - methods of inspecting animals, managing situations frequently encountered during transport such as adverse weather conditions, and dealing with emergencies,
  - species-specific aspects of animal handling and care, including feeding, watering and inspection,
  - appropriate record keeping and journey log.

Appendix XXVI (contd)

Appendix F (contd)

Appendix IV (contd)

- Assessment of competence for *exporters* should at a minimum address knowledge, and ability to apply that knowledge, in the following areas:
    - planning a *journey*, including appropriate *space allowances*, and feed, water and ventilation requirements,
    - relevant authorities and applicable transport regulations, and associated documentation requirements,
    - appropriate methods of animal handling during transport and associated activities such as cleaning and disinfection, assembling, *loading*, and *unloading*,
    - species-specific aspects of animal handling and care, including appropriate equipment and medication,
    - sources of advice and assistance,
    - appropriate record keeping and journey log.
    - managing situations frequently encountered during transport such as adverse weather conditions, and dealing with emergencies

Article 3

Documentation

- Animals should not be loaded until the documentation required to that point is complete.
- The documentation accompanying the consignment should include:
    - journey travel plan,
    - time, date and place of *loading*,
    - the journey log – a daily record of inspection and important events which includes records of morbidity and mortality, climatic conditions, food and water consumed, medication provided, mechanical defects,
    - time, date and place of arrival and *unloading*,
    - veterinary certification, when required,
    - animal identification to allow traceback of individual animals to the premises of departure, and where possible to the premises of origin,
    - details of animals at risk,
    - number of *animal handlers* on board, and their competencies,
    - stocking density estimate for each load in the consignment.
- Veterinary certification should accompany consignments of animals and address:
    - cleaning and disinfection of the *vessel*,
    - fitness of the animals to travel,
    - animal identification (description, number, etc.),
    - health status including tests, treatment and vaccinations carried out, if required.

Article 4

Planning the journey

General

- Adequate planning is a key factor affecting the welfare of animals during a *journey*.
- Before the journey starts, plans should be made in relation to:
    - type of transport *vessel* required,
    - route, taking into account distance, expected weather and sea conditions,
    - nature and duration of *journey*,
    - daily care and management of the animals,
    - avoiding the mixing of animals from different sources in a single pen group.
    - provision of appropriate equipment and medication for the numbers and species carried
    - emergency response procedures
- Preconditioning may be required, e.g. for dry food, and unfamiliar methods of supply of feed and water.
- Potential for spread of infectious disease
    - when requested by the *Veterinary Authority* of the importing country, animals should be vaccinated against diseases to which they are likely to be exposed at their destination.
- There should be planning for water and feed availability during the *journey*. Feed should be of appropriate quality and composition for the species, age, condition of the animals, etc.
- Extreme weather conditions are hazards for animals undergoing transport and require appropriate vessel design to minimise risks. Special precautions should be taken for animals that have not been acclimatised or which are unsuited to either hot or cold conditions. In some extreme conditions of heat or cold, animals should not be transported at all.
- Behaviour-modifying or other medication should not be used routinely during transport. Such medicines should only be administered when a problem exists in an individual animal, and should be administered by a veterinarian or other person who has been instructed in their use by a veterinarian. Treated animals should be placed in a dedicated area.
- There should be an emergency management plan that identifies the important adverse events that may be encountered during the *journey*, the procedures for managing each event and the action to be taken in an emergency. For each important event, the plan should document the actions to be undertaken and the responsibilities of all parties involved, including communications and record keeping.

Appendix XXVI (contd)

Appendix F (contd)

Appendix IV (contd)

Vessel and container design and maintenance

- *Vessels* used for the sea transport of animals should be designed, constructed and fitted as appropriate to the species, size and weight of the animals to be transported; special attention should be paid to the avoidance of injury to animals through the use of secure smooth fittings free from sharp protrusions and the provision of non-slip flooring. The avoidance of injury to animal handlers while carrying out their responsibilities should also be taken into account.

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

- *Vessels* should be maintained in good mechanical and structural condition.

- *Vessels* should have adequate ventilation to meet variations in climate and the thermo-regulatory needs of the animal species being transported; the ventilation system should be capable of operating when the *vessel* is stationary and the air flow should be adjustable.

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

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

- Stowage of feed and bedding should be carried out in such a way to ensure protection from the elements and sea water

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

- The above principles apply also to *containers* used for the transport of animals.

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

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

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

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

Space allowance

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

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

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

- The same principles apply when animals are transported in *containers*.

Ability to observe animals en route

- Animals should be positioned to enable them to be observed regularly during the *journey* to ensure their safety and good welfare.

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

Emergency response procedures

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

Article 5

Pre-journey period

General

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

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

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

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

- Pre-journey holding areas should be designed to:

    - securely contain the animals,

    - maintain an environment safe from hazards, including predators and disease,

Appendix XXVI (contd)

Appendix F (contd)

Appendix IV (contd)

- protect animals from exposure to adverse weather conditions, and
- allow for rest, watering and feeding.

Selection of compatible groups

- Compatible groups should be selected before transport to avoid adverse animal welfare consequences. The following guidelines should be applied when assembling groups of animals:
  - animals of different species should not be mixed unless they are judged to be compatible,
  - animals of the same species can be mixed unless there is a significant likelihood of aggression; aggressive individuals should be segregated,
  - young or small animals may need to be separated from older or larger animals, with the exception of nursing mothers with young at foot,
  - animals with horns or antlers should not be mixed with animals lacking horns or antlers,
  - animals reared together should be maintained as a group; animals with a strong social bond, such as a dam and offspring, should be transported together.

Fitness to travel

- Animals should be inspected before travel and those found unfit to travel by farm staff, *animal handlers* or veterinarians should not be loaded onto a *vessel*.
- Humane and effective arrangements should be made by the owner or agent for the handling and care of any animal rejected as unfit to travel.
- Animals that are unfit to travel include:
  - those that are sick, injured, weak, disabled or fatigued,
  - those that are unable to stand unaided and bear weight on each leg,
  - those that are blind in both eyes,
  - those that cannot be moved without causing them additional suffering,
  - newborn with an unhealed navel,
  - females travelling without young which have given birth within the previous 48 hours,
  - pregnant animals which would be in the final 10% of their gestation period at the planned time of unloading.
- Risks during transport can be reduced by selecting animals best suited to the conditions of travel and those that are acclimatised to expected weather conditions.

- Animals at risk, and requiring better conditions and additional attention during transport include:
  - very large or obese individuals,
  - very young or old animals,
  - excitable or aggressive animals,
  - animals which have had little contact with humans,
  - females in the last third of pregnancy or in heavy lactation.
- Hair or wool length needs consideration in relation to the weather conditions expected.

Article 6

Loading

Experienced supervision

- *Loading* should be carefully planned as it has the potential to be the cause of poor welfare in transported animals.
- *Loading* should be supervised by the *Competent Authority* and managed by an *animal handler(s)*. *Animal handlers* should ensure that animals are loaded quietly and without unnecessary noise, harassment or force, and that untrained assistants or spectators do not impede the process.
- Ventilation during *loading* and the *journey* should provide for fresh air, and the removal of excessive heat, humidity and noxious fumes (such as ammonia and carbon monoxide). Under warm and hot conditions, ventilation should allow for the adequate convective cooling of each animal. In some instances, adequate ventilation can be achieved by increasing the *space allowance* for animals.

Facilities

- The facilities for *loading* including the collecting area at the wharf, races and loading ramps should be designed and constructed to take into account of the needs and abilities of the animals with regard to dimensions, slopes, surfaces, absence of sharp projections, flooring, sides etc.
- All loading facilities should be properly illuminated to allow the animals to be easily inspected by the *animal handler(s)*, and to allow the animals' ease of movement at all times.

Goads and other aids

- The following principles should apply:
  - Goads (aids for encouraging animals to move) should not be used on animals that have little or no room to move.
  - Useful and permitted goads include panels, flags, plastic paddles, flappers (a length of cane with a short strap of leather or canvas attached), plastic bags and metallic rattles; they should be used in a manner sufficient to encourage and direct movement of the animals but without physical contact with them.
  - Unsuitable goads such as large wooden sticks, sticks with sharp ends, lengths of metal piping, fencing wire or heavy leather belts should not be used to strike animals.

Appendix XXVI (contd)

Appendix F (contd)

Appendix IV (contd)

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

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

- Manual lifting is permissible for young animals that may have difficulty negotiating ramps, but the lifting of animals by their tail, head, horns, ears, limbs, wool or hair should not be permitted.

Article 7

Travel

Inspections

- Competent *animal handler(s)* should check the consignment immediately before departure to ensure that the animals have been loaded according to the load plan. Each consignment should be checked again within 24 hours.
- Adjustments should be made to the stocking density within 48 hours of departure and as appropriate during the *journey*.
- Each pen of animals should be observed on a daily basis for normal behaviour, health and welfare, and the correct operation of ventilation, watering and feeding systems. There should also be a night patrol. Any necessary corrective action should be undertaken promptly.
- Adequate access to suitable feed and water should be ensured for all animals in each pen.

Sick and injured animals

- Sick or injured animals should be segregated/isolated.
- Sick or injured animals should be treated promptly and appropriately, and veterinary advice should be sought if necessary. All drugs and products should be used in accordance with the manufacturer's recommendations.
- A record of treatments carried out and their outcomes should be kept.
- When euthanasia is necessary, the person responsible for the animals must ensure that it is carried out humanely, and results in immediate death. When necessary, assistance should be sought from a veterinarian or other person(s) competent in euthanasia procedures. Recommendations for specific species are described in the Chapter on humane killing of animals for disease control purposes.

Cleaning and disinfection

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

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

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

Article 8

Unloading and post-journey handling

General

- The required facilities and the principles of animal handling detailed in Article 6 (Loading) apply equally to *unloading*, but consideration should be given to the likelihood that the animals will be fatigued.

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

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

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

- *Unloading* should be supervised by the *Competent Authority* and managed by a competent *animal handler(s)*. The *animal handlers* should ensure that animals are unloaded quietly and without unnecessary noise, harassment or force, and that untrained assistants or spectators do not impede the process.

Facilities

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

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

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

Sick and injured animals

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

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

Appendix XXVI (contd)

Appendix F (contd)

Appendix IV (contd)

Article 9

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

- The welfare of the animals should be the first consideration in the event of a refusal to import.
- When a shipment has been refused import, the *Competent Authority* of that country should make available suitable isolation facilities to allow the *unloading* of animals from a *vessel* and their secure holding, without posing a risk to the health of the national herd, pending resolution of the situation. In this situation, the priorities should be:
    - the *Competent Authority* of the importing country should provide urgently in writing the reasons for the refusal,
    - in the event of a refusal for animal health reasons, the *Competent Authority* of the importing country should provide urgent access to an OIE-appointed veterinarian(s) to assess the animals' health status with regard to the importing country's concerns, and the necessary facilities and approvals to expedite the required diagnostic testing
    - the *Competent Authority* of the importing country should provide access to allow continued assessment of the ongoing health and welfare situation,
    - if the matter cannot be promptly resolved, the *Competent Authority* of the exporting and importing countries should call on the OIE to mediate.
- In the event that the animals are required to remain on the *vessel*, the priorities should be:
    - the *Competent Authority* of the importing country should allow reprovision of the *vessel* with water and feed as necessary,
    - the *Competent Authority* of the importing country should provide urgently in writing the reasons for the refusal,
    - in the event of a refusal for animal health reasons, the *Competent Authority* of the importing country should provide urgent access to an OIE-appointed veterinarian(s) to assess the animals' health status with regard to the importing country's concerns, and the necessary facilities and approvals to expedite the required diagnostic testing,
    - the *Competent Authority* of the importing country should provide access to allow continued assessment of the ongoing health and welfare situation,
    - if the matter cannot be urgently resolved, the *Competent Authorities* of the exporting and importing countries should call on the OIE to mediate.
- The OIE should utilise its dispute settlement mechanism to identify a mutually agreed solution which will address the animal health and welfare issues in a timely manner.

Article 10

Species specific issues

Cattle are sociable animals and may become agitated if they are singled out. Social order is usually established at about two years of age. When groups are mixed, social order has to be re-established and aggression may occur until a new order is established. Crowding of cattle may also increase aggression as the animals try to maintain personal space. Social behaviour varies with age, breed and sex; *Bos indicus* and *Bos indicus*-cross animals are usually more temperamental than European breeds. Young bulls, when moved in groups, show a degree of playfulness (pushing and shoving) but become more aggressive and territorial with age. Adult bulls have a minimum personal space of six square metres. Cows with young calves can be very protective, and handling calves in the presence of their mothers can be dangerous.

Goats should be handled calmly and are more easily led or driven than if they are excited. When goats are moved, their gregarious tendencies should be exploited. Activities which frighten, injure or cause agitation to animals should be avoided. Bullying is particularly serious in goats. Housing strange goats together could result in fatalities, either through physical violence, or subordinate goats being refused access to food and water.

Sheep are sociable animals with good eyesight and tend to "flock together", especially when they are agitated. They should be handled calmly and their tendency to follow each other should be exploited when they are being moved. Sheep may become agitated if they are singled out for attention and will strive to rejoin the group. Activities which frighten, injure or cause agitation to sheep should be avoided. They can negotiate steep ramps.

Pigs have poor eyesight, and may move reluctantly in strange surroundings. They benefit from well lit loading bays. Since they negotiate ramps with difficulty, these should be as level as possible. Ideally a hydraulic lift should be used for greater heights. Pigs also negotiate steps with difficulty. A good 'rule-of-thumb' is that no step should be higher than the pig's front knee.

Horses in this context include all solipeds, donkeys, mules, hinnies and zebra. They have good eyesight and a very wide angle of vision. They may have a history of loading resulting in good or bad experiences. Good training should result in easier loading, but some horses can prove difficult, especially if they are inexperienced or have associated loading with poor transport conditions. In these circumstances two experienced handlers can load an animal by linking arms or using a strop below its rump. Blindfolding may even be considered. Ramps should be as shallow as possible. Steps are not usually a problem when horses mount a ramp, but they tend to jump a step when descending, so steps should be as low as possible. Horses benefit from being individually stalled, but may be transported in compatible groups. When horses are to travel in groups, their shoes should be removed.

Camelids in this context comprise llamas, alpacas, guanaco and vicuna. They have good eyesight and, like sheep, can negotiate steep slopes, though ramps should be as shallow as possible. They load most easily in a bunch as a single animal will strive to rejoin the others. Whilst they are usually docile, they have an unnerving habit of spitting in self-defence. During transport they usually lie down. They frequently extend their front legs forward when lying, so gaps below partitions should be high enough so that their legs are

Appendix XXVI (contd)

Appendix G

Original: English
November 2004

REPORT OF THE SECOND MEETING OF THE OIE *AD HOC* GROUP ON THE HUMANE KILLING OF ANIMALS FOR DISEASE CONTROL PURPOSES

Paris, 2-4 November 2004

The OIE *ad hoc* Group on the Humane Killing of Animals for Disease Control Purposes held its second meeting at the OIE Headquarters from 2 to 4 November 2004.

The members of the OIE *ad hoc* Group and other participants are listed in Appendix I. The Agenda adopted is given in Appendix II. Dr J. Galvin was absent due to a sudden illness.

On behalf of Dr B. Vallat, Director General of the OIE, Dr D. Wilson, Head of the International Trade Department, welcomed the members of the *ad hoc* Group and thanked them for their willingness to continue working on the new mandate of the OIE for animal welfare.

The *ad hoc* Group discussed current international issues in animal welfare as a background to their work. In revising the recommendations from their first meeting, the *ad hoc* Group took into account the outcomes of the OIE Global Animal Welfare Conference and the meeting of the Working Group on Animal Welfare. It also took into account the recommendations of the OIE *ad hoc* Group on the slaughter of animals for human consumption and harmonised its approach to the extent possible. Dr H. Blokhuis noted that the discussion at the Conference would have been improved had the reports of the *ad hoc* Group meetings been circulated more widely and Dr Wilson advised that this was now the OIE policy.

The *ad hoc* Group addressed comments received from Member Countries on the report of its first meeting. It noted the comment on priorities but was of the view that animal welfare standards for the killing of wild and feral animals should be done by a separate *ad hoc* Group, subject to the work being given priority by the Working Group. With regard to a proposal that killing by intrathoracic haemorrhagae be included in its recommendations, the *ad hoc* Group considered that further work was required on this technique, especially regarding time periods before death.

While noting that the animal welfare aspects of disease control procedures needed to be addressed within broader constraints, including those posed by human safety and biosecurity considerations, the *ad hoc* Group advised that its recommendations regarding the advantages and disadvantages of various methods did not take in to account the cost of equipment nor relative human health and safety issues. The *ad hoc* Group confined its

considerations to the procedures that needed to occur from the time that the decision is taken to kill animals for diseases control purposes, until the animals are dead, and to the killing of cattle, sheep, goats, pigs and poultry.

Appendix XXVI (contd)

Appendix G (contd)

The *ad hoc* Group addressed the general principles of humane killing, organisational structure, the responsibilities and competencies of personnel working on affected premises, planning the humane killing of animals, and recommended various killing methods. The recommendations do not contain detailed, specific operating procedures as these are available elsewhere in emergency disease control plans and equipment manufacturer recommendations. The draft guidelines are at Appendix III.

The *ad hoc* Group also recognised that the draft guidelines may also be applicable for the killing of animals following natural disasters and in emergency slaughter situations.

.../Appendices

Appendix XXVI (contd)

Appendix G (contd)

Appendix I

SECOND MEETING OF THE OIE *AD HOC* GROUP ON HUMANE KILLING OF ANIMALS FOR DISEASE CONTROL PURPOSES

Paris, 2-4 November 2004

List of participants

MEMBERS OF THE *AD HOC GROUP*

Dr John Galvin (chair) (absent)
Manager, Animal Health Operations
Department of Primary Industries
Cnr Midland Hwy & Taylor Street
Bendigo, Victoria 3551
AUSTRALIA
Tel: (61) 03 5430 4517
Fax:(61) 03 5431 4520
E-mail:John.Galvin@dpi.vic.gov.au

Dr Micus Chiwasanee Chimbombi
Ministry of Agriculture
Private Bag 003
Gaborone
BOTSWANA
Tel: (267) 3950 658 / 3950 617
Fax:(267) 390 3744
E-mail: mchimbombi@gov.bw

Dr Harry Blokhuis
Manager International Research Networks
Animal Sciences Group
Edelhertweg, 15
P.O. Box 65. NL-8200 AB Lelystad
THE NETHERLANDS
Tel: (31) 320-23-81-95
Fax: (31)320-23-80-94
E-mail: harry.blokhuis@wur.nl

Dr De-shien Jong
Associate Professor of Animal Science
National Taiwan University
#50, Lane 155, Sec. 3, Keelung Rd.,
Taipei
TAIWAN
Tel: (886) 2-23630231-2543-110
E-mai : dsjong@ntu.edu.tw

Mr Steve Wotton
Division of Farm Animal Science
Department of Clinical Veterinary Science
University of Bristol
Langford House
Langford
Bristol BS40 5DU
UNITED KINGDOM
Tel: (44) 117 928 9237
Fax.: (44) 117 928 9324
E-mail: steve.wotton@bris.ac.uk

OTHER PARTICIPANTS

Dr Alex Thiermann
(President of the OIE Terrestrial Animal Health Standards Commission)
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: a.thiermann@oie.int

Dr Andrea Gavinelli
(Member of the OIE Working Group on Animal Welfare)
European Commission
Rue Froissart 101 - 2/54
1040 Brussels
BELGIUM
Tel : (32-2) 296 64 26
Fax : (32-2) 295 31 44
E-mail: Andrea.Gavinelli@cec.eu.int

OIE CENTRAL BUREAU

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

Dr David Wilson
Head
International Trade Department
OIE
Tel.: 33 (0)1 44.15.18.80
Fax: 33 (0)1 42.67.09.87
E-mail: d.wilson@oie.int

Appendix XXVI (contd)

Appendix G (contd)

Appendix II

SECOND MEETING OF THE OIE *AD HOC* GROUP ON HUMANE KILLING OF ANIMALS FOR DISEASE CONTROL PURPOSES

Paris, 2-4 November 2004

Agenda adopted

1. Introduction

1.1. Discussion on the report of the recent meeting of the OIE Working Group on Animal Welfare

1.2. Discussion on the outcomes of the OIE Global Conference on Animal Welfare

1.3. Discussion on the OIE 72nd General Session (Animal Welfare)

1.4. Comments from Member countries

2. Development of specific guiding principles and standards

3. Work programme

4. Conclusions

Appendix XXVI (contd)

Appendix G (contd)

Appendix III

DEFINITIONS

Stockmanship

good stockmanship means a professional and positive response to an animal's welfare requirements.

Animal handler

a person with a knowledge of the behaviour and needs of animals which, with appropriate experience and a professional and positive response to an animal's welfare requirements, results in effective management and good welfare. Their competence should be demonstrated through independent assessment and certification.

Stunning

any mechanical, electrical, chemical or other procedure which causes immediate loss of consciousness which lasts until death;

Death

means irreversible loss of brain activity as demonstrated by loss of brain stem reflexes.

RMS

root mean square – a means of calibrating alternating current to a direct current signal

Neonate

a young animal, from birth to four weeks

Appendix XXVI (contd)

Appendix G (contd)

Appendix III (contd)

GUIDELINES FOR THE HUMANE KILLING OF ANIMALS FOR DISEASE CONTROL PURPOSES

Article 1

General principles of humane killing

1) Disease control contingency plans should be in place at a national level and should contain details of management structure, disease control strategies and operational procedures; animal welfare considerations should be addressed within these disease control contingency plans.

2) Disease control strategies should also address the animal welfare issues that may result from animal movement controls.

3) The following principles apply after a decision to kill the animals has been made.

4) All personnel involved in the humane killing of animals should have the relevant skills and competencies.

5) As necessary, operational procedures should be adapted to the specific circumstances operating on the premises and should address, apart from animal welfare, operator safety and biosecurity.

6) Following the decision to kill the animals, killing should be carried out as quickly as possible and normal husbandry should be maintained until the animals are killed.

7) The handling and movement of animals should be minimised and when done, it should be done in accordance with the guidelines described below.

8) Animal restraint should be sufficient to facilitate effective killing, and in accordance with animal welfare and operator safety requirements; when restraint is required, killing should follow with minimal delay.

9) When animals are killed for disease control purposes, methods used should result in immediate death or immediate loss of consciousness lasting until death; when loss of consciousness is not immediate, induction of unconsciousness should be non-aversive and should not cause anxiety, pain, distress or suffering in the animals.

10) For animal welfare considerations, young animals should be killed before older animals; for biosecurity considerations, infected animals should be killed first, followed by in-contact animals, and then the remaining animals.

11) There should be continuous monitoring of the procedures to ensure they are consistently effective with regard to animal welfare, operator safety and biosecurity.

12) When the operational procedures are concluded, there should be a written report describing the practices adopted and their effect on animal welfare, operator safety and biosecurity.

13) To the extent possible to minimise public distress, killing of animals and carcase disposal should be carried out away from public view.

14) These general principles should also apply when animals need to be killed for other purposes such as after natural disasters.

Article 2

Organisational structure

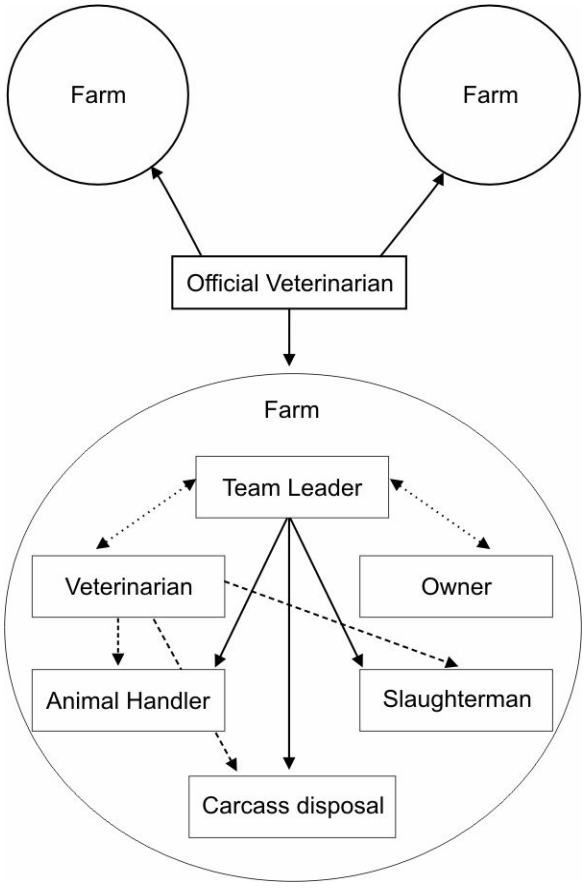
The operational activities should be led by an *official veterinarian* who has the authority to appoint the personnel in the specialist teams and ensure that they adhere to the required animal welfare and biosecurity standards. When appointing the personnel, he/she should ensure that the personnel involved has the required competencies.

The *official veterinarian* should be responsible for all activities across one or more affected premises and should be supported by coordinators for planning (including communications), operations and logistics to facilitate efficient operations.

The *official veterinarian* should provide overall guidance to personnel and logistic support for operations on all affected premises to ensure consistency in adherence to the OIE animal welfare and biosecurity guidelines.

A specialist team, led by a team leader answerable to the *official veterinarian*, should be deployed to work on each affected premises. The team should consist of personnel with the competencies to conduct all required operations; in some situations, personnel may be required to fulfil more than one function. Each team should contain a veterinarian.

In considering the animal welfare issues associated with killing animals, the key personnel, their responsibilities and competencies required are described in Article 3.



Appendix XXVI (contd)

Appendix G (contd)

Appendix III (contd)

Article 3

Responsibilities and competencies of the specialist team

Team leader

- Responsibilities
  - plan overall operations on an affected premises
  - determine and address requirements for animal welfare, operator safety and biosecurity
  - organise, brief and manage team of people to facilitate humane killing of the relevant animals on the premises in accordance with national regulations and these guidelines
  - determine logistics required
  - monitor operations to ensure animal welfare, operator safety and biosecurity requirements are met
  - report upwards on progress and problems
  - provide a written report at the conclusion of the killing, describing the practices adopted and their effect on animal welfare
- Competencies
  - appreciation of animal welfare and the underpinning behavioural, anatomical and physiological processes involved in the killing process
  - skills to manage all activities on premises and deliver outcomes on time
  - awareness of psychological effects on farmer, team members and general public
  - effective communication skills

Veterinarian

- Responsibilities
  - determine and implement the most appropriate killing method to ensure that animals are killed without avoidable pain and distress
  - determine and implement the additional requirements for animal welfare, including the order of killing
  - minimise the risk of disease spread within and from the premises through the supervision of biosecurity procedures
  - continuously monitor animal welfare and biosecurity procedures
  - in cooperation with the leader, prepare a written report at the conclusion of the killing, describing the practices adopted and their effect on animal welfare
- Competencies
  - ability to assess animal welfare, especially the effectiveness of stunning and killing and to correct any deficiencies

- ability to assess biosecurity risks

Animal handlers

- Responsibilities
  - review on-site facilities in terms of their appropriateness
  - design and construct temporary animal handling facilities, when required
  - move and restrain animals
- Competencies
  - good stockmanship
  - awareness of animal behaviour
  - experience of animal handling in emergency situations and in close confinement

Slaughterers

- Responsibilities
  - ensure humane killing of animals through effective stunning and killing
- Competencies
  - when required by regulations, licensed to use necessary equipment or licensed to be slaughterers
  - competent to use and maintain relevant equipment
  - competent to use techniques for the species involved
  - competent to assess effective stunning and killing

Carcase disposal personnel

- Responsibilities
  - ensure efficient carcase disposal to ensure killing operations are not hindered
- Competencies
  - competent to use and maintain available equipment and apply techniques for the species involved

Farmer / owner / manager

- Responsibilities
  - assist when requested
- Competencies
  - specific knowledge of his/her animals and their environment

Appendix XXVI (contd)

Appendix G (contd)

Appendix III (contd)

Article 4

Operational guidelines

Planning the humane killing of animals

Many activities will need to be conducted on affected premises, including the humane killing of animals. The team leader should develop a plan for humanely killing animals on the premises which should include consideration of:

- Minimising handling and movement of animals
- Killing the animals on the affected premises; however, there may be circumstances where the animals may need to be moved to another location for killing; when the killing is conducted at an abattoir, the guidelines in Chapter on slaughter of animals for human consumption should be followed.
- The species, number, age and size of animals to be killed, and the order of killing them
- Methods of killing the animals, and their cost
- Housing and location of the animals
- The availability and effectiveness of equipment needed for killing of the animals
- The facilities available on the premises that will assist with the killing
- Biosecurity issues
- The health and safety of personnel conducting the killing
- Any legal issues that may be involved, for example where restricted veterinary drugs or poisons may be used, or where the process may impact on the environment, and
- The presence of other nearby premises holding animals.

In designing a killing plan, it is essential that the method chosen be consistently reliable to ensure that all animals are humanely and quickly killed.

Article 5

Table summarising killing methods*

Species	Age range	Procedure	Restraint necessary	Animal welfare concerns with inappropriate application	Article reference
cattle	all	free bullet	no	non-lethal wounding	
	all except neonates	captive bolt - penetrating, followed by pithing or bleeding	yes	ineffective stunning	
	adults only	captive bolt - non-penetrating, followed by bleeding	yes	ineffective stunning, regaining of consciousness before killing	
	calves only	electrical, two stage application	yes	pain associated with cardiac arrest after ineffective stunning	
	calves only	electrical, single application (method 1)	yes	ineffective stunning	
	all	injection with barbiturates and others	yes	non-lethal dose, pain associated with injection site	
sheep and goats	all	free bullet	no	non-lethal wounding	
	all except neonates	captive bolt - penetrating, followed by pithing or bleeding	yes	ineffective stunning, regaining of consciousness before killing	
	all except neonates	captive bolt - non-penetrating, followed by bleeding	yes	ineffective stunning, regaining of consciousness before killing	
	neonates	captive bolt - non-penetrating	yes	non-lethal wounding	
	all	electrical, two stage application	yes	pain associated with cardiac arrest after ineffective stunning	
	all	electrical, single application (Method 1)	yes	ineffective stunning	
	neonates only	CO_2 air mixture	yes	slow induction of unconsciousness, aversiveness of induction	
	neonates only	nitrogen/inert gas mixed with CO_2	yes	slow induction of unconsciousness, aversiveness of induction	
	neonates only	Nitrogen/inert gases	yes	slow induction of unconsciousness,	

	all	injection of barbiturates and others	yes	non-lethal dose, pain associated with injection site	

Appendix XXVI (contd)
Appendix G (contd)
Appendix III (contd)

Table summarising killing methods* (contd)

Species	Age range	Procedure	Restraint necessary	Animal welfare concerns with inappropriate application	Article reference
pigs	all	free bullet	no	non-lethal wounding	
	all except neonates	captive bolt - penetrating, followed by pithing or bleeding	yes	ineffective stunning,	
	neonates only	captive bolt - non-penetrating	yes	non-lethal wounding	
	All §	electrical, two stage application	yes	pain associated with cardiac arrest after ineffective stunning	
	all	electrical, single application (Method 1)	yes	ineffective stunning	
	neonates only	CO_2 air mixture	yes	slow induction of unconsciousness, aversiveness of induction	
	neonates only	nitrogen/inert gas mixed with CO_2	yes	slow induction of unconsciousness, aversiveness of induction	
	neonates only	Nitrogen/inert gases	yes	slow induction of unconsciousness,	
	all	injection with barbiturates and others	yes	non-lethal dose, pain associated with injection site	
poultry	adults only	captive bolt - non-penetrating	yes	ineffective stunning	
	neonates and eggs only	Maceration	no	non-lethal wounding, non-immediacy;	
	adults only	electrical single application (Method 2)	yes	ineffective stunning	
	adults only	electrical single application, followed by killing (Method 3)	yes	ineffective stunning; regaining of consciousness before killing	
	all	CO_2 air mixture Method 1 Method 2	 yes no	slow induction of unconsciousness, aversiveness of induction	
	all	nitrogen/inert gas mixed with CO_2	yes	slow induction of unconsciousness, aversiveness of induction	
	all	Nitrogen/inert gases	yes	slow induction of unconsciousness	

Table summarising killing methods* (contd)

Species	Age range	Procedure	Restraint necessary	Animal welfare concerns with inappropriate application	Article reference
	all	injection of barbiturates and others	yes	non-lethal dose, pain associated with injection site	
	adults only	addition of anaesthetics to feed or water, followed by an appropriate killing method	no	ineffective or slow induction of unconsciousness	

* the methods are described in the order of mechanical, electrical and gaseous, not in an order of desirability from an animal welfare viewpoint

§ the only preclusion against the use of this method for neonates is the design of the stunning tongs that may not facilitate their application across such a small-sized head/body.

Article 6

Free bullet

Introduction

A free bullet is a projectile fired from a shotgun, rifle, handgun or purpose-made humane killer.

The most commonly used firearms for close range use are:

- humane killers (specially manufactured/adapted single-shot weapons)
- shotguns (12, 16, 20, 28 bore and .410)
- rifles (.22 rimfire)
- handguns (various calibres from .32 to .45)

The most commonly used firearms for long range use are:

- rifles (.22, .243, .270 and .308)

A free bullet used from long range should be aimed to penetrate the skull or soft tissue at the top of the neck of the animal, to cause irreversible concussion and death and should only be used by properly trained and licensed marksmen.

Requirements for effective use

- The marksman should take account of human safety in the area in which he/she is operating
- The marksman should ensure that the animal is not moving and in the correct position to enable accurate targeting and the range should be as short as possible (5 –50 cm for a shotgun) but the barrel should not be in contact with the animal's head

Appendix XXVI (contd)

Appendix G (contd)

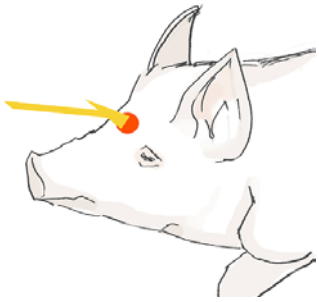
Appendix III (contd)

Figure 1. The optimum shooting position for cattle is at the intersection of two imaginary lines drawn from the rear of the eyes to the opposite horn buds.

Figure 2. The optimum shooting position for hornless sheep and goats is on the midline, just above the eyes and directing the shot down the line of the spinal chord.

Figure 3. The optimum shooting position for heavily horned sheep and horned goats is behind the poll.

Figure 4. The optimum shooting position for pigs is just above the eyes and directing the shot down the line of the spinal chord.



- The correct cartridge, calibre and type of bullet for the different species age and size should be used. Ideally the ammunition should expand upon impact and dissipate its energy within the cranium
- Shot animals should be checked to ensure the absence of brain stem reflexes

Advantages

- Used properly, it provides a quick and effective method for killing
- It requires minimal or no restraint and can be use to kill from a distance
- It is suitable for killing agitated animals in open spaces

Disadvantages

- Potentially dangerous to humans and other animals in the area
- Potential for non-lethal wounding
- Destruction of brain tissue may preclude diagnosis of some diseases
- Leakage of bodily fluids may present a biosecurity risk
- Legal requirements may preclude or restrict use
- Limited availability of competent personnel

Conclusions

- A suitable method for cattle, sheep and goats, pigs and poultry, including large animals in open spaces

Appendix XXVI (contd)

Appendix G (contd)

Appendix III (contd)

Article 7

Penetrating captive bolt

Introduction

A penetrating captive bolt is fired from a gun powered by either compressed air or a blank cartridge. There is no free projectile.

The captive bolt should be aimed on the skull in a position to penetrate the cortex and mid-brain of the animal. The impact of the bolt on the skull produces unconsciousness. Physical damage to the brain caused by penetration of the bolt may result in death, however pithing or bleeding should be performed as soon as possible after the shot to ensure the death of the animal.

Requirements for effective use

- For cartridge powered and compressed air guns, the bolt velocity and the length of the bolt should be appropriate to the species and type of animal, in accordance with the manufacturer's recommendations
- Captive bolt guns should be frequently cleaned and maintained in good working condition
- More than one gun may be necessary to avoid overheating and a back-up gun should be available in the event of an ineffective shot
- Animals should be restrained; at a minimum they should be penned for cartridge powered guns and in a race for compressed air guns
- The operator should ensure that the animal's head is accessible
- The operator should fire the captive bolt at right angles to the skull in the optimal position (see figures 1, 3 & 4. The optimum shooting position for hornless sheep is on the highest point of the head, on the midline and aim towards the angle of the jaw)
- To ensure the death of the animal, pithing or bleeding should be performed as soon as possible after stunning
- Animals should be monitored continuously after stunning until death to ensure the absence of brain stem reflexes

Advantages

- Mobility of cartridge powered equipment reduces the need to move animals
- Immediate onset of a sustained period of unconsciousness

Disadvantages

- Poor gun maintenance and misfiring, and inaccurate gun positioning and orientation may result in poor animal welfare

- Post stun convulsions may make pithing difficult and hazardous
- Difficult to apply in agitated animals
- Repeated use of a cartridge powered gun may result in over-heating
- Leakage of bodily fluids may present a biosecurity risk
- Destruction of brain tissue may preclude diagnosis of some diseases

Conclusion

A suitable method for cattle, sheep, goats and pigs (except neonates), when followed by pithing.

Article 8

Captive bolt - non-penetrating

Introduction

A non-penetrating captive bolt is fired from a gun powered by either compressed air or a blank cartridge. There is no free projectile.

The gun should be placed on the front of the skull to deliver a percussive blow which produces unconsciousness in cattle (adults only), sheep, goats and pigs, and death in poultry and neonate sheep, goats and pigs. In mammals, bleeding should be performed as soon as possible after the blow to ensure the death of the animal.

Requirements for effective use

- For cartridge powered and compressed air guns, the bolt velocity should be appropriate to the species and type of animal, in accordance with the manufacturer's recommendations
- Captive bolt guns should be frequently cleaned and maintained in good working condition
- More than one gun may be necessary to avoid overheating and a back-up gun should be available in the event of an ineffective shot
- Animals should be restrained; at a minimum mammals should be penned for cartridge powered guns and in a race for compressed air guns; birds should be restrained in cones, shackles, crushes or by hand.
- The operator should ensure that the animal's head is accessible
- The operator should fire the captive bolt at right angles to the skull in the optimal position

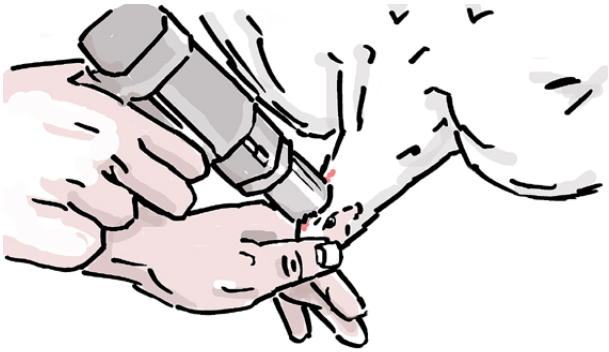


Figure 5 The optimum shooting position for

- To ensure death in non-neonate mammals, bleeding should be performed as soon as possible after stunning

- Animals should be monitored continuously after stunning until death to ensure the absence of brain stem reflexes

Advantages

- Immediate onset of unconsciousness, and death in birds and neonates
- Mobility of equipment reduces the need to move animals

Disadvantages

- As consciousness can be regained quickly in non-neonate mammals, they should be bled as soon as possible after stunning
- Laying hens in cages have to be removed from their cages and most birds have to be restrained
- Poor gun maintenance and misfiring, and inaccurate gun positioning and orientation may result in poor animal welfare
- Post stun convulsions may make bleeding difficult and hazardous
- Difficult to apply in agitated animals
- Repeated use of a cartridge powered gun may result in over-heating
- Bleeding may present a biosecurity risk

Conclusions

- A suitable method for poultry, and neonate sheep, goats and pigs.
- If bleeding does not present a biosecurity issue, this is a suitable method for cattle (adults only), and non-neonate sheep, goats and pigs.

Article 9

Maceration

Introduction

Maceration, utilising a mechanical apparatus with rotating blades or projections, causes immediate fragmentation and death in neonate poultry and embryonated eggs

Requirements

- Maceration requires specialised equipment which should be kept in excellent working order
- The rate of introducing the birds should not allow the equipment to jam, birds to rebound from the blades or the birds to suffocate before they are macerated

Advantages

- Procedure results in immediate death
- Large numbers can be killed quickly

Disadvantages

- Specialised equipment is required
- Macerated tissues may present a biosecurity issue

Conclusion

A suitable method for killing neonatal poultry and embryonated eggs.

Article 10

Electrical – two stage application

Introduction

A two stage application of electric current comprises firstly an application of current to the head by scissor-type tongs, immediately followed by an application of the tongs across the chest in a position that spans the heart.

The application of sufficient electric current to the head will induce 'tonic/clonic' epilepsy and unconsciousness. Once the animal is unconscious, the second stage will induce ventricular fibrillation (cardiac arrest) resulting in death. The second stage (the application of low frequency current across the chest) should only be applied to unconscious animals to prevent unacceptable levels of pain.

Figure 6. Scissor-type stunning tongs.

Requirements for effective use

- The stunner control device should generate a low frequency (30 – 60 Hz) current with a minimum voltage of 250 volts true RMS under load
- Appropriate protective clothing (including rubber gloves and boots) should be worn
- Animals should be restrained, at a minimum free-standing in a pen, close to an electrical supply
- Two team members are required, the first to apply the electrodes and the second to manipulate the position of the animal to allow the second application to be made
- A stunning current should be applied via scissor-type stunning tongs in a position that spans the brain for a minimum of 3 seconds; immediately following the application to the head, the electrodes should be transferred to a position that spans the heart and the electrodes applied for a minimum of 3 seconds
- Electrodes should be cleaned regularly and after use, to enable optimum electrical contact to be maintained
- Animals should be monitored continuously after stunning until death to ensure the absence of brain stem reflexes

Appendix XXVI (contd)

Appendix G (contd)

Appendix III (contd)

Advantages

- The application of the second stage minimises post-stun convulsions and therefore the method is particularly effective with pigs
- Non-invasive technique minimises biosecurity risk

Disadvantages

- Requires a reliable supply of electricity
- The electrodes must be applied and maintained in the correct positions to produce an effective stun and kill
- Most stunner control devices utilise low voltage impedance sensing as an electronic switch prior to the application of high voltages; in unshorn sheep, contact impedance may be too high to switch on the required high voltage (especially during stage two)
- The procedure may be physically demanding, leading to operator fatigue and poor electrode placement

Conclusion

- A suitable method for calves, sheep and goats, and especially for pigs (over one week of age, see table footnote)

Article 11

Electrical – single application

Introduction

Method 1 comprises the single application of sufficient electrical current to the head and back, to simultaneously stun the animal and fibrillate the heart. Provided sufficient current is applied in a position that spans both the brain and heart, the animal will not recover consciousness.

Method 2 stuns and kills by drawing inverted and shackled poultry through an electrified waterbath stunner. Electrical contact is made between the 'live' water and earthed shackle and, when sufficient current is applied, poultry will be simultaneously stunned and killed.

Method 3 comprises the single application of sufficient electrical current to the head of poultry in a position that spans the brain, causing unconsciousness; this is followed by a killing method (Article 17).

Method 1

Requirements for effective use

- The stunner control device should generate a low frequency (30 – 60 Hz) current with a minimum voltage of 250 volts true RMS under load
- Appropriate protective clothing (including rubber gloves and boots) should be worn

- Animals should be individually and mechanically restrained close to an electrical supply as the maintenance of physical contact between the stunning electrodes and the animal is necessary for effective use
- The rear electrode should be applied to the back, above or behind the heart, and then the front electrode in a position that is forward of the eyes, with current applied for a minimum of 3 seconds
- Electrodes should be cleaned regularly between animals and after use, to enable optimum electrical contact to be maintained
- Water or saline may be necessary to improve electrical contact with sheep
- An effective stun and kill should be verified by the absence of brain stem reflexes

Advantages

- Stuns and kills simultaneously
- Minimises post-stun convulsions and therefore is particularly effective with pigs
- A single team member only is required for the application
- Non-invasive technique minimises biosecurity risk

Disadvantages

- Requires individual mechanical animal restraint
- The electrodes must be applied and maintained in the correct positions to produce an effective stun and kill
- Requires a reliable supply of electricity

Conclusions

- A suitable method for calves, sheep, goats, and pigs (over 1 week of age)

Method 2

Requirements for effective use

- A mobile waterbath stunner and a short loop of processing line are required
- A low frequency (30-60 Hz) current applied for a minimum of 3 seconds is necessary to stun and kill the birds
- Poultry need to be manually removed from their cage, house or yard, inverted and shackled onto a line which conveys them through a waterbath stunner with their heads fully immersed
- Required minimum currents to stun and kill dry birds are:
  - Quail - 100 mA/bird
  - Chickens – 160 mA/bird
  - Ducks & Geese – 200 mA/bird

- Turkeys – 250 mA/bird

Appendix XXVI (contd)

Appendix G (contd)

Appendix III (contd)

A higher current is required for wet birds

- An effective stun and kill should be verified by the absence of brain stem reflexes

Advantages

- Stuns and kills simultaneously
- Capable of processing large numbers of birds reliably and effectively
- Non-invasive technique minimises biosecurity risk

Disadvantages

- Requires a reliable supply of electricity
- Handling, inversion and shackling of birds are required

Conclusion

A suitable method for large numbers of poultry.

Method 3

Requirements for effective use

- The stunner control device should generate sufficient current (more than 300 mA/bird) to stun
- Appropriate protective clothing (including rubber gloves and boots) should be worn
- Birds should be restrained, at a minimum manually, close to an electrical supply
- A stunning current should be applied in a position that spans the brain for a minimum of 3 seconds; immediately following this application, the birds should be killed (Article 17)
- Electrodes should be cleaned regularly and after use, to enable optimum electrical contact to be maintained
- Birds should be monitored continuously after stunning until death to ensure the absence of brain stem reflexes

Advantages

- Non-invasive technique (when combined with neck dislocation) minimises biosecurity risk

Disadvantages

- Requires a reliable supply of electricity
- The electrodes must be applied and maintained in the correct position to produce an effective stun

Conclusion

Suitable for small numbers of birds

Article 12

CO_2 / air mixture

Introduction

Controlled atmosphere killing is performed by exposing animals to a predetermined gas mixture, either by placing them in a gas-filled container or apparatus (Method 1) or by the gas being introduced into a poultry house (Method 2).

Inhalation of carbon dioxide (CO_2) induces respiratory and metabolic acidosis and hence reduces the pH of cerebrospinal fluid (CSF) and neurones thereby causing unconsciousness and, after prolonged exposure, death.

Method 1

Requirements for effective use in a container or apparatus

- Containers or apparatus should allow the required gas concentration to be maintained and accurately measured
- When animals are exposed to the gas individually or in small groups in a container or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the animals and allow them to be observed
- Animals should be introduced into the container or apparatus after it has been filled with the required CO_2 concentration, and held in this atmosphere until death is confirmed
- Team members should ensure that there is sufficient time allowed for each batch of animals to die before subsequent ones are introduced into the container or apparatus
- Containers or apparatus should not be overcrowded and measures are needed to avoid animals suffocating by climbing on top of each other

Advantages

- CO_2 is readily available
- Application methods are simple

Disadvantages

- The need for special equipment
- The aversive nature of high CO_2 concentrations

- No immediate loss of consciousness
- The risk of suffocation due to overcrowding

- Difficulty in verifying death while the animals are in the container or apparatus.

Conclusion

Suitable for use in poultry and neonatal sheep, goats and pigs

Method 2

Requirements for effective use in a poultry house

- Prior to introduction of the CO_2, the poultry house should be appropriately sealed to allow control over the gas concentration
- The house should be gradually filled with CO_2 so that all birds are exposed to a concentration of >40% until they are dead; a vaporiser may be required to prevent freezing
- Devices should be used to accurately measure the gas concentration at the highest level of birds

Advantages

- Applying gas to birds *in situ* eliminates the need to manually remove live birds
- CO_2 is readily available
- Gradual raising of CO_2 concentration minimises the aversiveness of the induction of unconsciousness

Disadvantages

- Difficulty in determining volume of gas required to achieve adequate concentrations of CO_2 in some poultry houses
- Difficulty in verifying death while the birds are in the poultry house.

Conclusion

Suitable for use in poultry in closed-environment sheds

Article 13

Nitrogen/inert gas mixed with CO_2

Introduction

CO_2 may be mixed in various proportions with nitrogen or an inert gas eg argon, and the inhalation of such mixtures leads to hypercapnic-hypoxia and death when the oxygen concentration by volume is ≤2%. This method involves the introduction of animals into a container or apparatus containing the gases. Such mixtures do not induce immediate loss of consciousness, therefore the aversiveness of various gas mixtures containing high concentrations of CO_2 and the respiratory distress occurring during the induction phase, are important animal welfare considerations.

Pigs and poultry appear not to find low concentrations of CO_2 strongly aversive, and a mixture of nitrogen or argon with ≤30% CO_2 by volume and ≤2% O_2 by volume can be used for killing poultry and neonatal sheep, goats and pigs.

Requirements for effective use

- Containers or apparatus should allow the required gas concentrations to be maintained, and the O_2 and CO_2 concentrations accurately measured
- When animals are exposed to the gases individually or in small groups in a container or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the animals and allow them to be observed
- Animals should be introduced into the container or apparatus after it has been filled with the required gas concentrations (with ≤2% O_2), and held in this atmosphere until death is confirmed
- Team members should ensure that there is sufficient time allowed for each batch of animals to die before subsequent ones are introduced into the container or apparatus
- Containers or apparatus should not be overcrowded and measures are needed to avoid animals suffocating by climbing on top of each other

Advantages

- Low concentrations of CO_2 cause little aversiveness and, in combination with nitrogen or an inert gas, produces a fast induction of unconsciousness

Disadvantages

- Need for a properly designed container or apparatus
- Difficulty in verifying death while the animals are in the container or apparatus
- No immediate loss of consciousness
- Exposure times required to kill are considerable

Conclusion

A suitable method for poultry and neonatal sheep, goats and pigs.

Article 14

Nitrogen and/or inert gasses

Introduction

This method involves the introduction of animals into a container or apparatus containing nitrogen or an inert gas such as argon. The controlled atmosphere produced leads to unconsciousness and death from hypoxia.

Research has shown that hypoxia is not aversive to pigs and poultry, as it doesn't induce any signs of respiratory distress prior to loss of consciousness.

Appendix XXVI (contd)

Appendix G (contd)

Appendix III (contd)

Requirements for effective use

- Containers or apparatus should allow the required gas concentrations to be maintained, and the O_2 concentration accurately measured
- When animals are exposed to the gases individually or in small groups in a container or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the animals and allow them to be observed
- Animals should be introduced into the container or apparatus after it has been filled with the required gas concentrations (with ≤2% O_2), and held in this atmosphere until death is confirmed
- Team members should ensure that there is sufficient time allowed for each batch of animals to die before subsequent ones are introduced into the container or apparatus
- Containers or apparatus should not be overcrowded and measures are needed to avoid animals suffocating by climbing on top of each other

Advantages

- Animals are unable to detect nitrogen or inert gases, and the induction of hypoxia by this method is not aversive to animals

Disadvantages

- Need for a properly designed container or apparatus
- Difficulty in verifying death while the animals are in the container or apparatus
- No immediate loss of consciousness
- Exposure times required to kill are considerable

Conclusion

A suitable method for poultry and neonatal sheep, goats and pigs.

Article 15

Lethal injection

Introduction

A lethal injection using high doses of anaesthetic and sedative drugs causes CNS depression, unconsciousness and death. In practice, barbiturates in combination with other drugs are commonly used.

Requirements for effective use

- Doses and routes of administration that cause rapid loss of consciousness followed by death should be used.

- Prior sedation may be necessary for some animals
- Intravenous administration is preferred, but intraperitoneal or intramuscular administration may be appropriate, especially if the agent is non-irritating
- Animals should be restrained to allow effective administration
- Animals should be monitored to ensure the absence of brain stem reflexes

Advantages

- The method can be used in all species
- Death can be induced smoothly

Disadvantages

- Restraint and/or sedation may be necessary prior to injection
- Some combinations of drug type and route of administration may be painful, and should only be used in unconscious animals
- Legal requirements may restrict use to veterinarians

Conclusion

A suitable method for killing small numbers of cattle, sheep, goats, pigs and poultry

Article 16

Addition of anaesthetics to feed or water

Introduction

An anaesthetic agent which can be mixed with poultry feed or water may be used to kill poultry in houses. Poultry which are only anaesthetised need to be killed by another method such as cervical dislocation

Requirements for effective use

- Sufficient quantities of anaesthetic need to be ingested rapidly for effective response
- Intake of sufficient quantities is facilitated if the birds are fasted or water is withheld
- Must be followed by killing (Article 17) if birds are anaesthetised only

Advantages

- Handling is not required until birds are anaesthetised
- May be biosecurity advantages in the case of large numbers of diseased birds

Disadvantages

- Non-target animals may accidentally access the medicated feed or water when provided in an open environment

Appendix XXVI (contd)

Appendix G (contd)

Appendix III (contd)

- Dose taken is unable to be regulated and variable results may be obtained
- Animals may reject adulterated feed or water due to illness or adverse flavour
- May need to be followed by killing
- Care is essential in the preparation and provision of treated feed or water, and in the disposal of uneaten treated feed/water and contaminated carcasses

Conclusion

A suitable method for killing large numbers of poultry in houses.

Article 17

Killing methods in unconscious animals

Method 1 Cervical dislocation (manual and mechanical)

Introduction

Poultry may be killed by either manual cervical dislocation (stretching) or mechanical neck crushing with a pair of pliers. Both methods result in death from asphyxiation and/or cerebral anoxia.

Requirements for effective use

- Killing should be performed either by manually or mechanically stretching the neck to sever the spinal cord or by using mechanical pliers to crush the cervical vertebrae with consequent major damage to the spinal cord
- Consistent results require strength and skill so team members should be rested regularly to ensure consistently reliable results
- Birds should be monitored continuously until death to ensure the absence of brain stem reflexes

Advantages

- It is a non-invasive killing method
- Can be performed manually on small birds.

Disadvantages

- Operator fatigue
- The method is more difficult in larger birds

Conclusion

This method is suitable for killing unconscious poultry.

Method 2 Decapitation

Introduction

Decapitation results in death by cerebral ischaemia using a guillotine or knife.

Requirements for effective use

- The required equipment should be kept in good working order

Advantages

- The technique is effective and does not require monitoring

Disadvantages

- Contamination of the working area with body fluids

Conclusion

This method is suitable for killing unconscious poultry.

Method 3 Pithing

Introduction

Pithing is a method of killing animals which have been stunned by a penetrating captive bolt. Pithing results in the physical destruction of the brain and upper regions of the spinal cord, through the insertion of a rod or cane through the bolt hole.

Requirements for effective use

- Pithing cane or rod
- Access to the head of the animal and to the brain through the skull
- Animals should be monitored continuously until death to ensure the absence of brain stem reflexes

Advantages

- The technique is effective in producing immediate death

Disadvantages

- Delayed and/or ineffective pithing due to convulsions
- Contamination of the working area with body fluids

Conclusion

This method is suitable for killing unconscious animals which have been stunned by a penetrating captive bolt.

Appendix XXVI (contd)

Appendix G (contd)

Appendix III (contd)

Method 4 Bleeding

Introduction

Bleeding is a method of killing animals through the severance of the major blood vessels in the neck or chest that results in a rapid fall in blood pressure, leading to cerebral ischaemia and death.

Requirements for effective use

- Sharp knife
- Access to the neck or chest of the animal
- Animals should be monitored continuously until death to ensure the absence of brain stem reflexes

Advantages

- The technique is effective in producing death after an effective stunning method which does not permit pithing

Disadvantages

- Delayed and/or ineffective bleeding due to convulsions
- Contamination of the working area with body fluids

Conclusion

This method is suitable for killing unconscious animals.

BSE FINAL 3/5/05

Explanatory memorandum[1]

In February 2005 OIE presented, for comments, a detailed draft proposal to simplify the current criteria for the categorisation of countries according to their BSE risk. Based on the comments received OIE will present a final proposal for discussion and possible adoption at the OIE General session in May 2005.

The proposal includes three key topics:

(1) a **list of tradeable products** which can be traded without any BSE restrictions (including boneless beef, blood and blood products);

(2) a simplified categorisation procedure which foresees **three categories**:

- Category 1: Countries with a negligible BSE risk without the application of any mitigating measures - imports allowed without restrictions);
- Category 2: Countries with a negligible BSE risk when mitigating measures are applied – imports allowed when SRM (30 months) removed;
- Category 3: Countries with an undetermined BSE risk. The country will be allowed to export only a list of tradeable products or meat and meat products under very strict conditions and when SRM (12 months) has been removed.

(3) A new Appendix on **surveillance** proposing;

- Category 1: only passive surveillance (based on the notification by the farmer or the veterinary practitioner);
- Category 2: passive and active surveillance (using the rapid tests) on a certain number of cattle;
- Category 3: no surveillance (this category is designed for developing countries with no adequate lab facilities or resources for testing)

The attached document includes the draft comments of the Community to the OIE proposal. The main points are:

(1) list of tradeable products; EU propose to include boneless beef under the condition that all necessary steps have been taken during the slaughter and deboning process to avoid any contamination with Specified Risk Material;

(2) a simplified categorisation procedure which foresees three categories:

- Category 1: no major comments
- Category 2: no major comments ;

[1] To be deleted in the final draft forwarded to OIE

- Category 3: EU propose that the country will be allowed to export only a limited list of tradeable products (no offal).

(3) A new Appendix on surveillance proposing;

- Category 1: EU propose to include an active surveillance to prove a design prevalence of 1 per 50 000 adult cattle;
- Category 2: EU propose to include an active surveillance to prove a design prevalence of 1 per 100 000 adult cattle;
- Category 3: no surveillance (this category is designed for developing countries with no adequate lab facilities or countries not willing to carry out active surveillance).

In addition;

- The maintenance surveillance after categorising the countries should be defined (under study)

PROPOSED THREE CATEGORY VERSION

BOVINE SPONGIFORM ENCEPHALOPATHY

Community position:

The Community welcomes the action taken by the OIE Terrestrial Animal Health Standards Commission to draft a new text reflecting a simplified categorisation system for BSE but would like the detailed comments made in the Appendices taken on board.

Article 1

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

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

   a) *milk* and *milk products*;

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

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

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

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

Community position

The Community would like to reserve its position pending the outcome of the Quantitative risk assessment and the subsequent update of the European Food Safety Authority (EFSA) of the scientific opinions on tallow, gelatin and collagen.

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

   g) deboned skeletal muscle *meat* (excluding mechanically separated meat) from cattle which were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process;

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

Community position

The Community can support the inclusion of deboned skeletal muscle meat to the list of tradeable products but only under certain conditions (i.e. avoid cross contamination during the slaughter and deboning process). In addition the definition of deboned boneless beef should be clearly defined.

The Commission propose the following:

" g) deboned skeletal muscle meat (excluding mechanically separated meat and head meat) from cattle under 30 months of age which were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, the slaughter process has been carried out under good hygiene conditions and the necessary steps have been taken during slaughter and deboning process to avoid any cross-contamination with the tissues listed in Article 13 (SRM). A system to allow Veterinary Administrations to certify the age of the animals from which the meat is derived from must be in place. "

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

~~a) cattle;~~

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

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

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

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

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

Article 2

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

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

Community position:

The requirement is that the risk assessment should be annually reviewed. In principle the Community supports the idea for a regular review but considering how time consuming the process of conducting a risk assessment can be it might be difficult to achieve annually. Furthermore the Community recommends that the risk assessment should be carried out by an international expert panel.

a) Release assessment

Release assessment consists of assessing the likelihood that a transmissible spongiform encephalopathy (TSE) agent has been introduced into the cattle population from a pre-existing

TSE in the indigenous ruminant population or via ~~the following~~ commodities potentially contaminated with a TSE agent, through a consideration of the following:

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

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

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

iv) imported live animals;

v) imported animal feed and feed ingredients;

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

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

Surveillance and other epidemiological investigations (especially surveillance for BSE conducted on the cattle population) relevant to the above should be taken into account in carrying out the assessment.

Community position

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

On point vi), products from the indigenous ruminant population should also be included under point v), if there is a pre-existing TSE in that population.

b) Exposure assessment

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

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

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

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

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

Community position

The Community strongly support the inclusion of the feed ban in the risk assessment which is considered as one of the most important risk mitigating measures. The assessment should take into account different factors like raw materials as feed ingredients, cross-contamination within the whole production chain, enforcement: Inspections and testing and time period of the measures in place.

In addition on point b) ii), it is very important to assess the system for collecting fallen stock in the country or compartment.

The Community proposes the following wording:

"the use and disposal of ruminant carcasses (including fallen stock, and the system to collect fallen stock) …"

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

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

4~~5~~) the examination in an approved laboratory of brain or other tissues collected within the framework of the aforementioned surveillance and monitoring system.

~~5) 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;~~

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

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

Community position

The EU supports the inclusion of the surveillance as integrated part of the risk assessment, rather than being assessed only independently according to certain rigid standards. Even if the risk assessment points to a certain risk, this could be compensated by an intensive surveillance allowing quantification of the incidence level in the relevant age cohorts.

The Community is aware and acknowledge that not the same surveillance criteria might apply to countries with or without a BSE risk. However the Community opposes to the proposal to limit the surveillance activity in a country with a negligible BSE risk without mitigation measures to the examination of animals showing clinical signs compatible with BSE (type B - passive surveillance).

Any surveillance activity should at least include the different risk animals i.e. clinical suspects, fallen stock and emergency slaughtered animals or animals with observations at the ante mortem inspection. Since often many of these animals show clinical signs not recognised as being compatible with BSE this target group should be included in any surveillance.

Article 3

Negligible BSE risk without commodity-specific risk mitigation ~~mitigating~~ measures

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

1) a risk assessment, as described in point 1) of Article 2, has been conducted in order to identify the historical and existing risk factors and the country ~~it~~ has been demonstrated that appropriate generic measures have been taken for the relevant period of time defined below to manage ~~any~~ all risk identified;

2) the country has demonstrated that Type B ~~a level of~~ surveillance ~~and monitoring which complies with the requirements of~~ in accordance with Appendix 3.8.4. is in place, ~~and~~

3) EITHER:

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

i) the criteria in points 2) to ~~5~~4) of Article 2 have been complied with for at least 7 years; and

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

Community position

The experience in EU regarding the implementation of the feed ban has clearly demonstrated the risk of cross contamination. Therefore the control and audit of the feed ban should also include the risk of cross-contamination.

The situation in case of female imported animals the Community proposes to include a new point 3) a) iii) as follows:

"iii) all BSE *cases*, as well as all the progeny of female *cases*, born within 2 years prior to or after clinical onset of the disease, and if alive in the country, *zone* or *compartment*, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed.

OR

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

i) the criteria in points 2) to ~~5~~4) of Article 2 have been complied with for at least 7 years; and

ii) it has been demonstrated, thorough an appropriate level of control and audit, that for at least 8 years ~~the feeding of ruminants with~~ *meat-and-bone meal* and *greaves* derived from ruminants has not been fed to ruminants; ~~banned and the ban has been effectively enforced for at least 8 years;~~ and

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

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

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

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

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

Article 4

Negligible BSE risk with commodity-specific risk mitigation ~~mitigating~~ measures

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

1) a risk assessment, as described in point 1) of Article 2, has been conducted in order to identify the historical and existing risk factors, and ~~it~~ the country has ~~been~~ not demonstrated that appropriate generic measures have been taken for the relevant period of time defined below to manage ~~any~~ all risks identified;

2) the country has demonstrated that ~~level of~~ Type A surveillance ~~and monitoring which complies with the requirements of~~ in accordance with Appendix 3.8.4. is in place; ~~and~~

3) EITHER

a) there has been no *case* of BSE or any *case* of BSE has been demonstrated to have been imported and has been completely destroyed, the criteria in points 2) to 4) of Article 2 are complied with, and it can be demonstrated, through an appropriate level of control and audit, that *meat-and-bone meal* and *greaves* derived from ruminants has not been fed to ruminants, but~~; and either~~ at least one of the following two conditions applies:

i) the criteria in points 2) to ~~5~~4) of Article 2 ~~are complied with, but~~ have not been complied with for 7 years; ~~or~~

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

Community position

The situation in case of female imported animals the Community proposes to include a new point 3) a) iii) as follows:

"iii) all BSE *cases*, as well as all the progeny of female *cases*, born within 2 years prior to or after clinical onset of the disease, and if alive in the country, *zone* or *compartment*, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed.

OR

b) there has been an ~~the last~~ indigenous *case* of BSE ~~was~~ reported ~~more than 7 years ago~~, the criteria in points 2) to ~~4~~5) of Article 2 are complied with, and it can be demonstrated, through an appropriate level of control and audit that ~~a ban on feeding ruminants~~ *meat-and-bone meal* and

greaves derived from ruminants ~~is~~ have not been fed to ruminants ~~effectively enforced~~, but ~~either~~ at least one of the following two conditions applies:

i) the criteria in points 2) to ~~5~~4) of Article 2 have not been complied with for 7 years; ~~or~~

ii) ~~the ban on feeding ruminants with~~ it cannot be demonstrated that controls over the feeding of *meat-and-bone meal* and *greaves* derived from ruminants to ruminants have been in place ~~has not been effectively enforced~~ for 8 years;

Community position

In case where indigenous cases are detected the current wording foresee that one of the conditions should comply listed under point b) i) or ii) although the actual wording foresee the two conditions. The Community proposes to delete the points (i) and (ii) and to reword point b) as follows:

"b) there has been an indigenous case of BSE reported, the criteria in points 2) to 4) of Article 2 are complied with, and it can be demonstrated, through an appropriate level of control and audit that a ban on feeding ruminants meat-and-bone meal and greaves derived from ruminants is effectively enforced."

AND

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

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

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

~~OR~~

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

~~i) the criteria in points 2) to 5~~4) ~~of Article 2 have been complied with for at least 7 years;~~

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

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

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

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

Article 5

Undetermined BSE risk

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

Article 6

When importing from a country, *zone* or *compartment* posing a negligible BSE risk without commodity-specific risk mitigation measures ~~mitigating measures~~, *Veterinary Administrations* should require:

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

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

Article 7

When importing from a country, *zone* or *compartment* posing a negligible BSE risk with commodity-specific risk mitigation measures ~~mitigating measures~~, *Veterinary Administrations* should require:

for cattle

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

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

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

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

Community position

Taking into account the modification proposed to Article 4 and an evaluation of the feed ban in the risk assessment, the Community propose to reword point 2) of Article 7. In addition the current wording in point 3) referring to indigenous cases could be misinterpreted that only countries with indigenous cases should comply with point 3) as follows:

"2) cattle selected for export are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin, and are not exposed cattle as described in point 3) b) iii) of Article 4

3) in the case of a country or zone/compartment , cattle selected for export were born after the date when the BSE risk is considered negligible."

Article 8

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

for cattle

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

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

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

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

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

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

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

3) cattle selected for export:

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

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

Article 9

When importing from a country, *zone* or *compartment* posing a negligible BSE risk without commodity-specific risk mitigation measures ~~mitigating measures~~, *Veterinary Administrations* should require:

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

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

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

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

Article 10

When importing from a country, *zone* or *compartment* posing a negligible BSE risk with commodity-specific risk mitigation measures ~~mitigating measures~~, *Veterinary Administrations* should require:

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

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

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

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

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

~~elongated rod-shaped instrument introduced into the cranial cavity)~~;

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

   a) the tissues listed in Article 13,

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

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

Community position

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

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

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

Article 11

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

Community position

Taken into account that the risk of these countries is unknown these countries should <u>only</u> trade the commodities listed in Article 1. 1) i.e. commodities which do not require any BSE related conditions.

<u>for *fresh meat* and *meat products* from cattle (other than those listed in point 1) of Article 1)</u>

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

1) the cattle from which the *fresh meat* and *meat products* originate:

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

   b) have not been fed *meat-and-bone meal* or *greaves* ~~for at least 8 years~~;

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

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

2) the *fresh* meat and *meat products* ~~are derived from deboned meat and~~ do not contain:

   a) the tissues listed in Article 13,

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

   c) mechanically separated meat from the skull and vertebral column <u>from cattle over 12 months of age ,</u>

   all of which have been completely removed in a manner to avoid contamination of <u>the *fresh meat* and *meat products*</u> ~~these tissues~~.

Article 12

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

Article 13

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

Community position

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

The Community proposes to amend Article 13, point 1) as follows:

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

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

Community position

The Community would like to reserve its position on the age limit for the removal of SRM as defined in Article 13, point 2) pending scientific updates of the EFSA based on the results of a quantitative risk assessment and new evolving scientific knowledge.

3) From cattle that were at the time of slaughter over 12 months of age originating from a country, *zone* or *compartment* defined in Article 5, the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, skull, vertebral column and derived protein products. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

Article 14

Veterinary Administrations of *importing countries* should require:

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

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

1) a country, *zone* or *compartment* posing a negligible BSE risk without commodity-specific risk mitigation ~~mitigating~~ measures; or

2) a country, *zone* or *compartment* posing a negligible BSE risk with commodity-specific risk mitigation ~~mitigating~~ measures; and

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

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

      i) pressure washing (degreasing),

      ii) acid demineralisation,

      iii) prolonged alkaline treatment,

      iv) filtration,

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

      or to an equivalent process in terms of infectivity reduction.

Community position

Regarding the point using the hides and skins from the head, the Community would like to reserve its position pending the outcome of the Quantitative risk assessment and the subsequent update of the European Food Safety Authority (EFSA) of the scientific opinions on tallow and stunning.

Article 15

Veterinary Administrations of *importing countries* should require:

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

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

1) a country, *zone* or *compartment* posing a negligible BSE risk without commodity-specific risk mitigation ~~mitigating~~ measures, or

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

Community position

Since SRM should not be used for the production of tallow or dicalcium phosphate and it is not excluded that intestines or tonsils may be used for this purpose, point 2 of article 15 should also exclude to these tissues. The Community proposes to amend point 2 of Article 15 as follows:

"2) a country or zone/compartment posing a negligible BSE risk with commodity-specific risk mitigation measures, and it originates from cattle which have been subjected to ante-mortem and post-mortem inspections and has not been prepared using the tissues listed in point 1 and 2 of Article 13."

Article 16

Veterinary Administrations of *importing countries* should require:

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

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

1) they originate from a country, *zone* or *compartment* posing a negligible BSE risk without commodity-specific risk mitigation ~~mitigating~~ measures; or

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

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

— text deleted

APPENDIX 3.8.4.

SURVEILLANCE FOR BOVINE SPONGIFORM ENCEPHALOPATHY

Article 3.8.4.1.

Community position

The Community welcomes the work done by OIE to amend the Appendix on surveillance for BSE which is based on the BSurvE model which was developed by the OIE and Community Reference laboratory for TSEs, Weybridge, United Kingdom (CRL) and proposed by the Community to OIE.

However based on the points allocated to the different age groups within the four surveillance streams and on the data of the EU surveillance programme the proposed design prevalence of 1 per million adult cattle is overambitious and can not be proven within a acceptable time period. This becomes even clearer for countries with a small cattle population. The Community propose to define a design prevalence of 1 in 100 000 adult cattle.

In order to provide the necessary guidance for a Member Country to design the appropriate surveillance programme taken into account the structure and dynamics of the cattle population, OIE should establish a Reference Laboratory as centre of excellence in the field of epidemiology.

Introduction

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

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

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

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

   d) supporting a claimed BSE status;

   e) gaining or regaining a higher BSE status.

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

   a) cattle not exposed to the infective agent;

   b) cattle exposed but not infected;

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

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

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

iii) the smallest number will show clinical signs.

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

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

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

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

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

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

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

Article 3.8.4.2.

Description of cattle subpopulations

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

Cattle affected by illnesses that are refractory to treatment, and displaying progressive behavioural changes such as excitability, persistent kicking when milked, changes in herd hierarchical status, hesitation at doors, gates and barriers, as well as those displaying progressive neurological signs without signs of infectious illness are candidates for examination. These behavioural changes, being very subtle, are best identified by those who handle animals on a daily basis. Since BSE causes no pathognomonic clinical signs, all countries with cattle populations will observe individual animals displaying clinical signs consistent with BSE. It should be recognised that cases may display only some of these signs, which may also vary in severity, and such animals should still be investigated as potential BSE affected animals. The rate at which such suspicious cases are likely to occur will differ among epidemiological situations and cannot therefore be predicted reliably.

This subpopulation, particularly cattle over 30 months of age, is the one exhibiting the highest prevalence. The recognition greatly depends on the owner's awareness and observation of suspect animals. The reporting of these suspect animals when at the farm will depend on the owner's motivation based on cost and socio-economic repercussions.

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

These cattle may have exhibited some of the clinical signs listed above which were not recognised as

being consistent with BSE. Experience in countries where BSE has been identified indicates that this subpopulation is the one demonstrating the second highest prevalence. For that reason, it is the second most appropriate population to target in order to detect BSE.

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

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

4) Cattle over 36 months of age at routine slaughter

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

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

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

Article 3.8.4.3.

1) Implementation of type A surveillance

In order to implement efficiently a surveillance strategy for BSE, a country must use good quality data (or reliable estimates) concerning the age distribution of its adult cattle population and the number of cattle tested for BSE stratified by age and by subpopulation. Depending on the country's choice, the application of the following procedure will allow the detection of BSE prevalence of either at least one case per million in the adult cattle population, or at least one case per 100,000 in the adult cattle population, at a confidence level of 95% in the country, *zone* or *compartment* of concern. This Appendix utilises Tables 1 and 2 to determine a desired surveillance point target and the point values of surveillance samples collected.

Community position

The Community proposes to define only one design prevalence in the cattle population within the country. Therefore the second sentence in the first paragraph of point 1 of Article 3.8.4.3.. is amended as follows:

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

The approach assigns 'point values' to each sample, based on the subpopulation from which it was collected and the likelihood of detecting infected cattle in that subpopulation. The number of points a sample is assigned is determined by the subpopulation from which the sample is collected and the

age of the animal sampled. The total points accumulation is then periodically compared to the target number of points for a country, *zone* or *compartment*.

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

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

a) a prevalence of either at least one case per million or one case per 100,000 of the adult cattle population;

b) a confidence level of 95%;

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

   i) sensitivity of diagnostic methods used;

   ii) relative frequency of expression by age;

   iii) relative frequency of expression within each subpopulation;

   iv) interval between clinical pathological change and clinical expression;

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

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

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

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

g) cattle population numbers stratified by age;

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

2) Maintenance (type B) surveillance (under study)

For countries which have demonstrated through risk assessment (including surveillance) that they meet the requirements for 'negligible risk without commodity-specific risk mitigation measures', surveillance should continue at a reduced, maintenance level.

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

Community position

The Community is aware and acknowledge that not the same surveillance criteria might apply to countries with or without a BSE risk. However the Community opposes to the proposal to limit the

surveillance activity in a country with a negligible BSE risk without mitigation measures to the examination of animals showing clinical signs compatible with BSE (type B - passive surveillance).

Therefore an active surveillance with a design prevalence of one case per 50 000 is proposed for those countries listed in Article 3. A maintenance surveillance should be defined when countries are categorised in one of the three categories as defined in the simplified categorisation system.

The Community propose to re-word point 2) as follows;

2) Implementation of type B surveillance

For countries which have demonstrated through risk assessment that they meet the requirements for 'negligible risk without commodity-specific risk mitigation measures', an active surveillance programme should be in place at a reduced level.

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

And add a third point to this Article 3.8.4.3.

" 3) Maintenance (type B) surveillance (under study)

Following categorisation based on a risk assessment and an adequate surveillance programme, surveillance should continue at a reduced, maintenance level, including a level of an active surveillance for a certain period of time submitted to review.

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

Article 3.8.4.4.

1) Selecting the points target

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

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

Target points for country, zone or compartment with 0 cases, 95% confidence		
Adult Cattle Population Size (24 months and older)	***DP 1/1,000,000**	***DP 1/100,000**
≥ 1,000,000	3,000,000	300,000
800,000 – 1,000,000	2,400,000	240,000
600,000 – 800,000	1,800,000	180,000
400,000 – 600,000	1,200,000	120,000
200,000 – 400,000	600,000	60,000
100,000 – 200,000	300,000	30,000
50,000 – 100,000	150,000	15,000

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

Community position

The current wording in the Chapter referring to the Appendix does not mention the design prevalence for the type A or B surveillance. The Community proposes to define one specific design prevalence for the type A and one for type B surveillance within the current Appendix as was described in our initial comments to this Appendix.

2) Determining the point values of samples collected

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

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

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

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

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

* Article 3.8.4.2 4
** Article 3.8.4.2 3
*** Article 3.8.4.2 2
**** Article 3.8.4.2 1

Community position

The Community proposes to include the supporting documents which lead to the proposal for the points allocated between the surveillance streams and age groups.

The points allocated using the simplified BSurvE model are a mean value based on the surveillance data of different countries. If a country can show that the points allocated do not correspond to the findings within the country, a country should be allowed to apply the full BSurvE model using the own cattle data.

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

Article 3.8.4.5.

To monitor the evolution of BSE in a country, zone or compartment once it is detected

To monitor the evolution of BSE in a country, *zone* or *compartment* once it is detected, a more intensive sampling method needs to be used to determine disease prevalence. For countries that have determined that BSE exists within their cattle population, the goal of surveillance shifts from one of detection to one of monitoring the extent and evolution of the disease, and monitoring the effectiveness of control measures such as feed bans and SRM removal policies.

Appendix XIII

APPENDIX 3.6.3.

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

Article 3.6.3.1.

Meat-and-bone meal

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

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

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

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

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

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

Paris, 15-16 April 2004

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

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

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

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

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

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

Appendix I

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

Paris, 15-16 April 2004

List of Participants

MEMBERS OF THE AD HOC GROUP

Dr Dagmar Heim
Co-ordination TSE
Office vétérinaire fédéral
Schwarzenburgstrasse 161
Case Postale 3003
Bern
SWITZERLAND
Tel: (41-31) 324 9993
Fax: (41-31) 323 8594
E-mail: dagmar.heim@bvet.admin.ch

Dr Robert Biddle
Deputy Chief Veterinary Officer
Product Integrity, Animal and Plant Health
Agriculture, Fisheries
and Forestry Australia (AFFA)
GPO BOX 858
Canberra ACT 2601
AUSTRALIA
E-mail: bob.biddle@affa.gov.au

Dr Danny Matthews
TSE Programme Manager
Veterinary Laboratories Agency
Woodham Lane
New Haw, Addlestone
Surrey KT15 3NB
UNITED KINGDOM
Tel: (44.1932) 35 95 12
Fax: (44.1932) 35 49 29
E-mail: d.matthews@vla.maff.gsi.gov.uk

Dr John A. Kellar
Disease Surveillance
Science Advisory and Management Division
Canadian Food Inspection Agency
3851 Fallowfield Road
Room C305
Nepean, Ontario K1A OY9
CANADA
Tel: (1.613) 228 66 98
Fax: (1.613) 991 69 88 & 228 66 75
E-mail: jkellar@inspection.gc.ca

Dr Kajsa Hakulin
European Commission
DG Health and Consumer Protection
Directorate D Unit D 2: Biological risks
Brussels
BELGIUM
E-mail: kajsa.HAKULIN@cec.eu.int

Dr Tsutsui Toshiyuki
Applied National Epidemiology Section
National Institute of Animal Health 3-1-5, Kannondai
305-0856 Tsukuba-city,
JAPAN
Tel: (81) (0)298-38-7769
Fax: (81)(0)298-
E-mail: tsutsui@affrc.go.jp

OTHER PARTICIPANTS

Dr Alex Thiermann
President of the Terrestrial Animal Health Standards Commission
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: a.thiermann@oie.int

Dr Kenichi Sakamoto
Vice-President of the Scientific Commission of Animal diseases
Chief of Diagnostic Laboratory
Department of Exotic Diseases
Research National Institute of Animal Health
6-20-1 Josui-honcho 187-0022
KodairaTokyo
JAPAN
Tel: (81-423) 21 14 41
Fax: (81-423) 25 51 22
E-mail: skenichi@affrc.go.jp

OIE HEADQUARTERS

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

Dr David Wilson
Head
International Trade Department
OIE
Tel.: 33 (0)1 44.15.18.80
Fax: 33 (0)1 42.67.09.87
E-mail: d.wilson@oie.int

Dr Hiroyuki Kamakawa
Chargé de mission
International Trade Department
OIE
Tel.: 33 (0)1 44.15.18.92
Fax: 33 (0)1 42.67.09.87
E-mail: h.kamakawa@oie.int

Appendix II

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

Paris, 15-16 April 2004

Adopted Agenda

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

Appendix III

PROPOSED BOVINE SPONGIFORM ENCEPHALOPATHY CATEGORISATION SYSTEM

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

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

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

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

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

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

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

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

c) Category 3 - *undetermined BSE risk*

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

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

– an effective ruminant to ruminant feed ban;

– routine ante-mortem and post-mortem veterinary inspection;

– SRM removal and destruction to reinforce the effectiveness of the feed ban;

– completion and regular review of a risk assessment in accordance with Article 2.3.13.2;

– implementation of a surveillance programme (in accordance with Appendix 3.8.4) to supplement data provided by the risk assessment;

– routine examination and notification of clinical cases;

– access to adequate laboratory capacity;

– implementation of an awareness programme in accordance with Article 2.3.13.2.

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

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

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

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

"*Veterinary Administrations* should authorise trade:

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

   a) *milk* and *milk products*;

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

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

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

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

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

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

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

hygienic manner;

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

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

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

a) cattle;

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

c) gelatin and collagen prepared from bones;

d) tallow and tallow derivatives, and dicalcium phosphate.

Appendix IV

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

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

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

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

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

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

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

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

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

have been separated adequately in feed manufacturing premises and over the presence of ruminant-derived *meat-and-bone meal* in the intestines of pigs and poultry at slaughter.

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

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

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

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

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

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

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

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

- sample more than one sub-population;
- recognise that BSE is not unilaterally present in the first sub-population;
- propose a relative distribution of BSE among sub-populations;
- recognise that Table 1 is a highly optimistic interpretation based on the following (as described in Article 3.8.4.2)
    - concentration of all BSE within that sub-population,
    - an adult cattle mortality rate of 1%,
    - prevalence of central nervous system (CNS) signs of 1% within dying adult cattle.

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

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

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

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

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

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

CHAPTER 2.3.13.

BOVINE SPONGIFORM ENCEPHALOPATHY

. . .

Article 2.3.13.2.

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

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

   a) Release assessment

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

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

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

      ii) imported live animals;

      iii) imported animal feed and feed ingredients;

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

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

   b) Exposure assessment

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

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

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

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

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

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

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

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

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

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

. . .

Original: English
January 2005

REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON BSE SURVEILLANCE

Paris, 12-14 January 2005

The OIE *ad hoc* group on surveillance for bovine spongiform encephalopathy (BSE) met at the OIE Headquarters from 12 to 14 January 2005. The members of the *ad hoc* group and other participants are listed in Appendix I. The Agenda adopted is given in Appendix II.

Dr B. Vallat, Director General of the OIE, welcomed the participants and thanked them for their willingness to work on improving the guidelines in the OIE *Terrestrial Animal Health Code* (hereafter referred to as the *Terrestrial Code)* on conducting surveillance for BSE. He recalled the discussions on BSE at the 2004 General Session regarding the Appendix, and noted the comments from OIE invited experts, Member Countries (the USA, Japan, New Zealand, Chile, the Southern Cone countries of South America, Australia, Norway and the EU) all of which should form the basis of the *ad hoc* Group's discussions.

Working on the basis of a three category BSE-risk system, the *ad hoc* Group first clarified the reasons for conducting surveillance for BSE, which included:

. detecting BSE, to a pre-determined design prevalence, on a country or zone/compartment basis;

. monitoring the evolution of BSE in a country or zone/compartment;

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

. supporting a claimed BSE risk status (in conjunction with a risk assessment and the evaluation of other factors);

. gaining or regaining a higher BSE status.

Based on Member Countries' comments, the *ad hoc* Group recommended the division of the cattle population into four subpopulations for surveillance purposes, instead of the current three subpopulations. Based on the latest scientific information, the *ad hoc* Group also recommended a cut off age of 36 months when sampling healthy cattle at slaughter, and a cut off age of 30 month for the other three subpopulations.

The *ad hoc* Group recalled that the International Committee had accepted the gradient concept, and the approach used assigns 'point values' to each sample based on the likelihood of detecting infection according to the subpopulation from which it was collected and the age of the animal sampled. This approach takes into account the general principles of surveillance described in Chapter 3.8.7 and the epidemiology of BSE.

The approach taken by the *ad hoc* Group assigns 'point values' to each sample collected based on the age of the animal sampled, the subpopulation from which it was collected and the likelihood of detecting infected cattle in that subpopulation. For example, a sample from the highest risk animal (a 5-year old cow that is a clinical suspect for BSE) is assigned more points than a sample from a healthy animal of any age because the 5-year old clinical suspect is much more likely to test positive if BSE is present, and therefore provides more valuable information. The number of points a sample is assigned is determined by the subpopulation from which the sample is collected and the age of the animal sampled. The previous appendix did not take age into account.

Because precise aging of animals that are sampled may not be available, the appendix combines point values into five age categories. The point estimates for each category were determined as an average over each of the ages comprising the group. The age groups were selected on their relative likelihoods of expressing BSE according to scientific knowledge of the incubation of the disease, its clinical and pathological diagnosis and the world BSE experience. While samples may be collected from any combination of subpopulations and ages, the *ad hoc* Group believed that they should reflect the demographics of the cattle herd of the country, zone or compartment.

The total points for samples may be accumulated over an interval of a maximum of seven consecutive years to achieve the target number of points.

The epidemiological model referred to above as being the basis for the *ad hoc* Group's recommendations is the *BSurvE* model developed by the EU. The *ad hoc* Group could not recommend that this model be used directly by Member Countries, at this stage, because of its intense informational requirements, its complexity, and the fact that few Member Countries have had the opportunity to attend the explanatory seminars. In addition, the *ad hoc* group understood that the model would soon be subjected to a process of international peer review. Nevertheless, extensive use was made of a model derived from *BSurvE* by experts from the USA.

In the time available, the *ad hoc* Group was not able to develop detailed recommendations on maintenance surveillance, and proposed to continue work on this subject after the 2005 General Session. However, it was acknowledged that the level of surveillance needed for maintenance in countries which had demonstrated negligible BSE risk through risk assessment (taking into account results from historical BSE surveillance) should be significantly lower than the level needed to demonstrate freedom from disease or to determine the prevalence of disease. The *ad hoc* Group recommended that the Code Commission examine this approach. (Dr Poudelet was not present during the discussion on maintenance surveillance.)

The *ad hoc* Group's proposed new appendix is at Appendix III.

.../Appendices

Appendix I

MEETING OF THE OIE *AD HOC* GROUP ON BSE SURVEILLANCE

Paris, 12-14 January 2005

List of Participants

MEMBERS OF THE *AD HOC* GROUP

Dr Stuart C. MacDiarmid
New Zealand Food Safety Authority
Principal Adviser
Zoonoses and Animal Health
P.O. Box 2835
South Tower, 68-86 Jervois Quay
WELLINGTON
NEW ZEALAND
Tel : (64)4-463-2648
Fax (64) 4-463-25-30
E-mail: stuart.macdiarmid@nzfsa.govt

Dr John A. Kellar
Disease Surveillance
Science Advisory and Management Division
Canadian Food Inspection Agency
3851 Fallowfield Road
Room C305
Nepean, Ontario K1A OY9
CANADA
Tel: (1.613) 228 66 98
Fax: (1.613) 991 69 88 & 228 66 75
E-mail: jkellar@inspection.gc.ca

Dr Victoria Bridges
Veterinary Epidemiologist
Center for Emerging Issues, CEAH
US Department of Agriculture
Ft. Collins, Colorado
UNITED STATES OF AMERICA
Tel: (1) 970 494 73 22
Fax: (1) 970 494 73 19
E-mail:
victoria.e.bridges@aphis.usda.gov

Dr Eric Poudelet
Chef d'Unité
SANCO D.2.
Risques biologiques
Commission Européenne
Rue Froissart 101/3-72
B-1049 Bruxelles
BELGIQUE
Tel: (32-2) 2955207
Fax: (32-2) 2969062
E-mail: eric.poudelet@cec.eu.int

Dr Dagmar Heim (absent)
Co-ordination TSE
Office vétérinaire fédéral
Schwarzenburgstrasse 161
Case Postale 3003
Bern
SWITZERLAND
Tel: (41-31) 324 9993
Fax: (41-31) 323 8594
E-mail: dagmar.heim@bvet.admin.ch

OTHER PARTICIPANTS

Dr Alex Thiermann
President of the Terrestrial Animal Health Standards Commission
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: a.thiermann@oie.int

OIE HEADQUARTERS

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

Dr David Wilson
Head
International Trade Department
OIE
Tel.: 33 (0)1 44.15.18.80
Fax: 33 (0)1 42.67.09.87
E-mail: d.wilson@oie.int

Dr Tomoko Ishibashi
Chargée de mission
International Trade Department
OIE
Tel.: 33 (0)1 44.15.18.92
Fax: 33 (0)1 42.67.09.87
E-mail: t.ishibashi@oie.int

Appendix II

MEETING OF THE OIE AD HOC GROUP ON BSE SURVEILLANCE

Paris, 12-14 January 2005

Adopted Agenda

1. Update on research on BSE surveillance
2. Update on discussions at the General Session and the meeting of the Bureau of the Code Commission
3. Proposed Appendix on BSE surveillance
4. Other issues
5. Further work programme

APPENDIX 3.8.4.

SURVEILLANCE AND MONITORING FOR BOVINE SPONGIFORM ENCEPHALOPATHY

Article 3.8.4.1.

Introduction

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

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

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

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

4) supporting a claimed BSE risk status;

5) gaining or regaining a higher BSE status.

The cattle population of a country or zone not known to be free from BSE, will comprise the following sectors in order of decreasing size:

1) cattle not exposed to the infective agent;

2) cattle exposed but not infected;

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

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

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

   c) the smallest number will show clinical signs.

A surveillance programme cannot be the sole determinant of the BSE status of a country, *zone* or *compartment*, which should be determined in accordance with Article 2.3.13.2. The surveillance programme should take into account the diagnostic limitations associated with the above sectors and the relative distributions of infected cattle among them.

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

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

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

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

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

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

Article 3.8.4.2.

Description of cattle subpopulations

A cattle over 30 months of age displaying clinical signs consistent with BSE

Cattle affected by illnesses that are refractory to treatment, and displaying progressive behavioural changes such as excitability, persistent kicking when milked, changes in herd hierarchical status, hesitation at doors, gates and barriers, as well as those displaying progressive neurological signs without signs of infectious illness are candidates for examination. These behavioural changes, being very subtle, are best identified by those who handle animals on a daily basis. Since BSE causes no pathognomonic clinical signs, all countries with cattle populations will observe individual animals displaying clinical signs consistent with BSE. It should be recognised that cases may display only some of these signs, which may also vary in severity, and such animals should still be investigated as potential BSE affected animals. The rate at which such suspicious cases are likely to occur will differ among epidemiological situations and cannot therefore be predicted reliably.

This subpopulation, particularly cattle over 30 months of age, is the one exhibiting the highest prevalence. The recognition greatly depends on the owner's awareness and observation of suspect animals. The reporting of these suspect animals when at the farm will depend on the owner's motivation based on cost and socio-economic repercussions.

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

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

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

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

D cattle over 36 months of age at routine slaughter

Experience in countries where BSE has been identified indicates that this subpopulation is the one demonstrating the lowest prevalence. For that reason, it is the least appropriate population to target in

order to detect BSE. However, sampling in this subpopulation may be an aide in monitoring the progress of the epizootic and the efficacy of control measures applied, because it offers continuous access to a cattle population of known class, age structure and geographical origin.

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

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

Article 3.8.4.3.

Application of the procedure

In order to implement efficiently a national surveillance strategy for BSE, a country must use good quality data (or reliable estimates) concerning the age distribution of its adult cattle population and the number of cattle tested for BSE stratified by age and by subpopulation. Depending on the country's choice, the application of the following procedure will allow the detection of BSE prevalence of either at least one case per million in the adult cattle population, or at least one case per 100,000 in the adult cattle population, at a confidence level of 95% in the country, *zone* or *compartment* of concern. This Appendix utilises Tables 1 and 2 to determine a desired surveillance point target and the point values of surveillance samples collected.

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

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

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

- a prevalence of either at least one case per million or one case per 100,000 of the adult cattle population;
- a confidence level of 95%;
- the pathogenesis, and pathological and clinical expression of BSE
    - sensitivity of diagnostic methods used
    - relative frequency of expression by age
    - relative frequency of expression within each subpopulation

. interval between clinical pathological change and clinical expression;

. demographics of the cattle population, including age distribution;

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

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

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

. cattle population numbers stratified by age;

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

Article 3.8.4.4.

Selecting the points target

The desired surveillance points target is selected from Table 1, which shows target points for populations of different sizes. A country's adult cattle population size may be estimated or may be set at one million because, for statistical reasons, one million is the point beyond which sample size does not further increase with population size. The choice of target depends on the degree of certainty with which a country wishes to demonstrate its BSE prevalence.

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

Target points for country, zone or compartment with 0 cases, 95% confidence		
Adult Cattle Population Size (24 months and older)	***DP 1/1,000,000**	***DP 1/100,000**
≥ 1,000,000	3,000,000	300,000
800,000 – 1,000,000	2,400,000	240,000
600,000 – 800,000	1,800,000	180,000
400,000 – 600,000	1,200,000	120,000
200,000 – 400,000	600,000	60,000
100,000 – 200,000	300,000	30,000
50,000 – 100,000	150,000	15,000

*DP is the maximum possible prevalence or "design prevalence"

Determining the point values of samples collected

Table 2 can be used to determine the point values of the surveillance samples collected. The approach assigns point values to each sample according to the likelihood of detecting infection based on the

subpopulation from which it was collected and the age of the animal sampled. This approach takes into account the general principles described in Appendix 3.8.1 and the epidemiology of BSE.

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

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

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

Surveillance subpopulation			
routine slaughter	**fallen stock ***	**casualty slaughter ****	**clinical suspect**
age ≥ 1 year and < 2 years			
0.01	0.2	0.4	N/A
Age ≥ 2 years and < 4 years (young adult)			
0.1	0.2	0.4	260
Age ≥ 4 years and < 7 years (middle adult)			
0.2	0.9	1.6	750
Age ≥ 7 years and < 9 years (older adult)			
0.1	0.4	0.7	220
Age ≥ 9 years (aged)			
0.0	0.1	0.2	45

* Article 3.8.4.2 C
** Article 3.8.4.2 B

Surveillance points remain valid for seven years (the incubation period that encompasses 95% of cases).

Maintenance surveillance (under study)

For countries which have demonstrated that they meet the requirements for 'negligible risk without commodity-specific risk mitigation measures', surveillance should continue at a maintenance level. Maintenance surveillance should focus on clinical suspects, and the number of clinical suspect samples taken annually should approximate the number of samples taken annually from clinical suspect cases during the time taken to reach the country, zone or compartment's BSE status (to a maximum of seven years).

To monitor the evolution of BSE in a country, zone or compartment once it is detected

To monitor the evolution of BSE in a country, zone or compartment once it is detected, a more intensive sampling method needs to be used to determine disease prevalence. For countries that have determined that BSE exists within their cattle population, the goal of surveillance shifts from one of detection to one of monitoring the extent and evolution of the disease, and monitoring the effectiveness of control measures such as feed bans and SRM removal policies.

Appendix XXIII

APPENDIX 3.6.5

GENERAL GUIDELINES FOR THE DISPOSAL OF CARCASSES

Community position:

The Community can agree with this draft but would like the comments below taken on board.

Introduction

The mass destruction and disposal of animals in the event of an animal disease outbreak are always subject to intense public and media scrutiny thereby obligating the *Veterinary Administration* of a Member Country to not only conduct carcass disposal operations within acceptable scientific principles to destroy the causative pathogen of disease but also to satisfy animal welfare, public and environmental concerns.

The guidelines in this Appendix are general and generic in nature. They are recommended for adoption after consideration of the application best suited to prevailing circumstances of a specific disease outbreak. The choice of one or more of the recommended technologies should be in compliance with the mandates provided for within relevant local and national legislation and be attainable with the resources available within the Member Country. The guidelines should also be read and applied in conjunction with the procedures described for the humane killing of animals in Appendix XXX of the *Code*.

The chapter aims to briefly describe the definitions applicable to the disposal of carcasses, outline the regulatory and jurisprudence requirements that should be considered, identify the most important risk factors associated with the disposal of carcasses, list the social factors and practical considerations relevant to carcass disposal, give guidelines on appropriate technologies that could be applied and give guidance on the decision-making process in electing the most appropriate technology for the disposal of carcasses under specific circumstances.

Where indicated within the relevant chapters of the *Code,* the vaccination of animals in combination with or without a stamping-out policy to contain a disease outbreak could be the preferred choice above mass destruction. The eventual decision to embark on the mass destruction and disposal of animals to contain a disease outbreak should be carefully evaluated against available alternatives, environmental, socio-political and socio-economical concerns, trade implications as well as prevailing ethical and ethnic beliefs and preferences.

Definitions

For the purpose of this Appendix the following definitions relevant to the disposal of carcasses shall apply:

- **Carcass -** means the body of an animal subsequent to euthanasia or death that requires safe destruction.

- **Disposal -** means the inactivation of the pathogen with reduction of the carcass and related materials to constituent components.

- **Technology -** means the process by which disposal is achieved.

- **Transport -** means the bio-secure removal of animals or carcasses or material from the site of infection to the site of disposal.

- **Bio-security -** means the absolute containment of infection.

- **Human safety -** means elimination of risks to the health and well-being of the persons involved in animal disposal procedures.

- **Animal welfare -** means reference to guidelines established for humane killing as defined in Appendix XXX.

- **Mass destruction -** means an emergency destruction and disposal of a large number of animals for disease control purposes

Community position:

The Community proposes the following wording as one does not dispose of animals but their carcasses *"means an emergency/mass culling of animals and disposal of the carcasses for disease control purposes".* This problem occurs in other parts of the text.

Regulations and jurisdiction

The laws regulating animal health, prevention and eradication of animal diseases, and the organisation of the *Veterinary Administration* should give the *Veterinary Services* the authority and the legal powers to carry out the necessary activities for an efficient and effective disposal of carcasses. For most of the disposal options, legislation of other governmental bodies at national or local level is in force and should be respected. Therefore close co-operation between the *Veterinary Service* and these authorities is indispensable to develop a coherent set of legal measures for carcass disposal in peace time in order to apply these undisturbed where and when it is necessary. In this context the following aspects should be clearly regulated:

- Right of entry on a farm and its premises for personnel of the *Veterinary Service* and of contractors working for the *Veterinary Service.*

- Total movement ban to be applied on an infected or suspected farm and the authority to make exemptions under certain bio-security conditions - for instance for transport of carcasses to another location for disposal..

Community position

In order to make a more general exception based on legislation addressing other considerations of public interest, the Community proposes to include:

" and for certain purposes not related to the disposal of carcasses as may be foreseen under legislation into force."

- The obligation for the involved farmer, his relatives and his personnel to co-operate with and to apply all the measures ordered by the *Veterinary Service.*

Community position

In order to avoid unjustified burdens, while guaranteeing sufficient powers under the right of entry, the Community proposes to include:

" The obligation of the involved farmer and any person working on the farm under his direction to co-operate with and to apply all the measures orders by the Veterinary Service."

As regard to infected and suspected animals and their products:

- the transfer of the ownership of these to the competent authority (for instance through confiscation or buying up with compensation of the farmer) and

Community position

In order to take into account different national systems regulating civil obligations, which may not require the transfer of ownership while guaranteeing sufficiently the right to intervene for the competent authority, the Community proposes to add under this bullet point:

"if necessary, under the applicable legislation regulating civil obligations, the transfer of the ownership of these to the competent authority (for instance through confiscation or buying up with compensation of the farmer) and ."

- the right to kill these animals on the farm or wherever the *Veterinary Service* determines.

If burning of the carcasses is the option of choice:

- the Veterinary Service should have the authority to determine the place where the pyre is situated,
- national and local governmental organisations competent for the protection of the environment should have given their approval for this solution in advance and should have adopted the necessary legal framework to allow this and

Community position

In order to take into account different distributions of competences within national systems, while safeguarding the defence of interests of the Veterinary Service, the Community proposes the following amendment:

" the Veterinary Service should have the authority to determine the place where the pyre is situated, in cooperation with national and local governmental organisations competent for the protection of the environment and under the necessary legal framework to allow this adopted in advance and"

- all involved authorities should have determined on the conditions for removal of the ashes.

If mass burial, mounding or open farm burial is the preferred option:

- the Veterinary Service should have the authority to determine the place of burial in accordance with other involved authorities,

- national and local governmental organisations competent for the protection of the environment and subsoil water reserves should have agreed with this solution and should have adopted the necessary legislation and

Community position

In order to take into account different distributions of competences within national systems, while safeguarding the defence of interests of the Veterinary Service, the Community proposes the following amendment:

"the Veterinary Service should have the authority to determine the place of burial in accordance with other involved authorities in cooperation with national and local governmental organisations competent for the protection of the environment and subsoil water reserves and under the necessary legal framework to allow this adopted in advance and"

- all involved authorities should have determined together the regime applicable to the site after the burial.

If rendering or any other centralised processing is the preferred option:

- the Veterinary Service should have the authority to require the necessary capacity at the processing company and to determine priorities,

- national and local governmental organisations regulating these types of processing should have agreed with the increased production volumes and other related consequences beforehand and should have covered the legal aspects and

Community position

In order to take into account different distributions of competences within national systems, while safeguarding the defence of interests of the Veterinary Service, the Community proposes the following amendment: "the Veterinary Service shall have the authority to require the necessary capacity at the processing company and to determine priorities, in cooperation with national and local governmental organisations competent for these types of processing interalia as regards the necessity to increase production volumes, and under the necessary legal framework (as provided under Community legislation : article 3(3) of Regulation (EC) N;1774/2002) to allow this adopted in advance and"

- all involved authorities should have determined on the conditions applicable to the products from these carcasses.

It might happen that the chosen option for carcass disposal has to be applied near the border of a neighbouring country. In such cases the competent authorities of this country should be consulted and common legal solutions should be found in order to prevent misunderstanding and conflict.

If there is insufficient capacity in the country for processing of carcasses and if other options for carcass disposal are also limited, a solution could be the processing in another country. However, when an outbreak of an infectious animal disease occurs in a country, governments take preventive measures against import of potentially infected animals and products from the infected region. Those measures will also prevent the importation and transport of carcasses to a processing plant. If the export option is the choice, the conditions should be well established between the two involved countries and all legal aspects cleared beforehand. It should be realised that strong opposition can be expected from the farming

community in the importing country against such transports. An agreement and preparation of the necessary legal aspects in peace time will help to apply this solution rapidly when it is needed. Clear communication about the process to be followed will help to elicit public support.

Pre-outbreak activities

The decision to embark on the mass destruction and disposal of animals in the event of a major disease outbreak or the mass disposal of animals in the event of natural disasters such as floods, and the implementation of the decision, need often to be taken in a short limit of time and activities to execute the decision, must similarly proceed with the minimum delay. The success or failure however, is primarily determined by the structures, policies and infrastructure that were established and agreed upon well in advance of such an event within contingency plans and working relationships and responsibilities established in preparation with other supportive structures.

- *Technical preparedness* – implies a predetermined decision process enunciated in a document, training of staff in the technical aspects of applicable technologies and the development of instructional manuals such as standing operating procedures (SOP's) for events of disposal. The sensitivity and public scrutiny on the process of carcass disposal requires that a trained and competent official must be available on site. Such an official must be familiar with procedures to conduct the chosen technologies for carcass disposal.

Community position

In order to allow for sufficient flexibility on the presentation of the decision process to be put in place, the Community proposes the following amendment of the first sentence under this bullet point:

"Technical preparedness – implies a predetermined decision process , training of staff in the technical aspects of applicable technologies, where necessary by case simulations and the development of instructional manuals such as standing operating procedures (SOP's) for events of disposal"

- *Financial preparedness* - the factors of a compensation mechanism to assist affected producers; access to emergency funding permitting rapid and effective action; and access to an expanded human resource through agreements with private veterinarians, are considered critical to the success of the program. To be effective, these factors must be considered, resolved and in place prior to a disease occurrence. Transparency on the criteria for compensation and the minimum delay in the execution of payments are critical factors to ensure cooperation from affected farmers.

- *Pre-established partnerships* - a relationship with industry is essential to obtain compliance with animal health policies. Partnerships should not only include farmer associations or commodity representatives but also animal welfare organisations, supportive structures such as security services, disaster management units within government structures, the media and consumer representative groupings. This relationship is encouraged and essential to enhance the receptivity to future risk communications. In some countries tourism is a very significant contributor to the national economy and can be adversely affected by animal disposal and emergency operations.

- *Communication plan* - the *Veterinary Administration* must accept that the information on any event of mass culling and disposal of animals cannot and should not be withheld from public scrutiny. Sharing the information based on scientific facts on an ongoing basis is essential. Information sharing with politicians and the media is especially important but information sharing with officials involved in the outbreak, affected farmers and professional organizations is equally essential but often neglected or forgotten. A well informed and knowledgeable spokesman should be available at all times to answer questions from the media and the public. Consistency in the

information given is essential and should be guided by an available set of pre-empted well debated questions and answers that should be daily updated. An essential pre-requisite is to ensure ownership by politicians for the policies applied for the mass destruction and disposal of animals to contain a disease outbreak. The support by politicians should already be established in policy formulation and budgetary processes by the *Veterinary Administration* of the Member Country.

Community position

In order to allow for sufficient flexibility on the presentation of the information, the Community proposes the following amendment to the third and second last sentence under this bullet point:

"Consistency in the information given is essential and should be daily updated. An essential pre-requisite is to ensure support by politicians for the policies applied for the mass destruction and disposal of animals to contain a disease outbreak. the development of instructional manuals such as standing operating procedures (SOP's) for events of disposal"

- *Equipment* – a supply of essential emergency equipment should be available immediately while contracts with rendering plants should be established as a default standing arrangement. The management of equipment should include provisions for expansion, temporary storing facilities, transport, and transport on farm, drivers, disinfection, mobile handling facilities for animals such as mobile crush-pens, protective and disposable material and logistical support. Procurement procedures should be simplified and special authorizations provided for the operation to enable the minimum delay in obtaining essential equipment and to supplement or replace existing equipment. Equipment would also include the type of burning material used for pyre burning of carcasses. In some countries sufficient wood would still be available but usage thereof is subject to environmental legislation and environmental concerns. Old vehicle tyres are a cheap and readily accessible alternative to wood but could be a source of environmental pollution and should only be used if sanctioned by applicable local or national legislation. The prior identification of sources of burning material are therefore essential so that it could be obtained with the minimum loss of time and effort when needed.

- *Transport arrangements* – The transport needed during mass disposal of animals are generally not included in the normal stock of vehicles of a *Veterinary Administration.* Heavy trucks, tractors, bulldozers, front-end loaders and the like, are all types of vehicles needed for transport of animals, collection of burning material, filling and closure of disposal sites and transport from the farm to a disposal site. It is important to ensure that the vehicles used do not pose a source for dissemination of the infection.

Risk factors

The list of risk factors has not the pretension to be complete. Other risk factors may influence the choice of a technique for carcass disposal as well.

- ***Speed*** - early detection of new infections, immediate killing of infected animals and rapid removal of the carcasses with inactivation of the pathogen are of utmost importance for the eradication of infectious diseases. Viral pathogens will not further multiply after the host is killed, but active and passive spread of the pathogen from the carcasses and their surroundings should be blocked as soon and as effectively as possible.

- ***Occupational health safety*** - carcasses in decomposition soon become a health risk for the persons who have to handle them during the process of disposal. Disposal should be organised in such a way that the workers are safeguarded against the risks of handling decomposed dead bodies. However special attention should be given to zoonotic aspects of certain pathogens as for instance avian influenza. Workers should be sufficiently protected against infection with a

zoonotic pathogen (protective clothing, gloves, face masks, spectacles, vaccination, anti viral medicines, regular health checks).

- ***Pathogen inactivation*** - the chosen disposal procedure must give optimal safety as regards to the inactivation of the pathogen. If this cannot be achieved instantly, the spreading of the pathogen from the process should be blocked. Scientific information about the reduction of the pathogenic agent over time under the expected climatological conditions for any of the technologies should be the basis for the lifting of restrictions for the products or sites

- ***Environmental concerns*** - the different technologies for carcass disposal have different effects on the environment. For instance pyre burning will produce smoke and smells; burial might lead to gas production; escape of these gases and as a result smell; but also risk of contamination of air, soil, surface and sub surface water. Increased operating hours or increased throughput in a rendering plant may lead to increased smell or disturbances in the normal functioning of the waste water treatment and other protective facilities of the plant.

- ***Availability of capacity*** - practically all the technologies for carcass disposal have limitations on capacity. When the number of carcasses to be disposed of is high, the capacity of the acceptable technologies will soon be the bottle neck. An assessment of possibilities and capacities in peace time is very important to be able to take quick decisions in case of emergency. Temporary storage of carcasses in cold stores could sometimes relieve the lack of processing capacity.

Community position

In order to take into account possible risks from using cold stores which might not normally dedicated for that purpose, the Community proposes the following amendment to the last sentence under this bullet point:

"Temporary storage of carcasses in cold stores, under conditions preventing cross-contamination, could sometimes relieve the lack of processing capacity"

- ***Cost*** - technologies for carcass disposal and specially those using sophisticated equipment are very costly. Budgetary provisions should be made for emergencies. When the Veterinary Service during a disease outbreak seeks the cooperation of private companies offering the needed capacity, the costs might escalate tremendously. Therefore it is necessary to negotiate a contract in peace time with those suppliers about capacities and costs when preparing a strategy for eradication.

- ***Public reaction*** - carcass disposal can easily lead to adverse reactions from the public when pictures of half burned or hoisted carcasses are shown on TV or in press. Urbanised populations estranged from rural practices will react often very emotionally on these images. In poorer countries the destruction of valuable meat of not yet sick animals may provoke public misunderstanding.

- ***Acceptance by farmers*** - the owners of an infected farm will in general prefer technologies at a distance and not on their own farm. Farmers outside an infected zone will prefer disposal within the infected area. All farmers will be very sensitive with regard to the safety measures taken to prevent spread of the disease by the used technology and the transport of the carcasses to the processing plant or disposal site. Proper compensation of owners for the loss of their animals or for the disposition of burial or burning sites will improve acceptability.

- ***Transport*** - for the application of all technologies for disposal, cranes, shovels and trucks must be used to transport the carcasses. This equipment can transfer the infection to other farms. Cleaning and disinfection of the outside surfaces of these vehicles when leaving an infected premise should receive special attention. The hygiene of the driver, his cabin, his lockers and his clothing and footwear should also be part of this process. The trucks transporting carcasses

should be leak proof and be completely covered in order to prevent spread of the pathogen from the truck. The Veterinary Service should supervise the departure of the vehicle from the farm, the route the transport passes and the arrival at the disposal plant or site.

- ***Wildlife*** - many infectious diseases can affect wild animals as well as domesticated animals. Sometimes farm animals become infected through contact with game, but the population of wild animals might also become infected from an outbreak of a disease on a farm. When disposing of carcasses full attention should be given to the prevention of contamination of wildlife. Predators could try to get access to dead carcasses which might cause active or passive spread of the infection to other wild or domesticated animals.

Social factors related to carcass disposal

Culling and destroying of animals for the eradication of infectious disease often produce vehement reactions from the public. Reactions can be expected from the owners of animals which have to be culled, from farmers who are scared that their animals might contract the disease, animal welfare advocates who try to protect the lives of animals, people who abhor pictures of the culling of animals and the transport, burning and burial of carcasses, organisations who fight for environmental protection, culling perceived as a waste of edible food, etc.

In general a stamping out policy is applied to defend the export interests of the animal husbandry industry and is economically motivated. However, in some countries the general public and politicians express their doubts or their opposition against economical reasons as the leading argument to apply this strategy.

Even not all farmers will support the economic necessity of stamping out. For many farmers the rapid regaining of export markets is of no interest. Animals often represent a much more important and differentiated value than pure economics. For an animal breeder his animals represent a professional achievement based on the skills of himself and his ancestors. Many hobby farmers consider their animals as personal companions. In traditional communities animals are kept not for production but for a variety of reasons like a beast of draught or burden, for ceremonial reasons or as a symbol of wealth. For some religions the killing of certain animals is not acceptable. The export related economic argument will fail to convince such owners of the need for culling especially when animals, not showing any symptoms of disease but identified as carriers or serological positive, are included in the culling operation. Loss of certain animals cannot be compensated financially.

Practical considerations

In addition to the risk factors and pre-outbreak activities identified above, several practical issues, often not considered or often accepted as obvious but not attended to, need to be noted. The list is not exhaustive but gives an indication of some of the easily forgotten but essential considerations:

- ***Selection of disposal site*** – sufficient top soil to cover the site; water drainage; prevailing wind conditions; easy access to transport; availability of meteorological data; separation from sensitive public sites.
- ***Selection of contractors for transport –*** availability; can they supply in all the needs; exclusive use of vehicles or would they also be used for other purposes (risk of disease transmission); access to available roads; suitable for the purpose to be used.
- ***Logistical preparedness for the appropriate technology*** – availability of burning material (wood, old tyres); sufficient manual labour available; sites and availability of disinfection tents for personnel; storage and disposal of protective clothing; housing for personnel to prevent them from going back to home and spread infection; facilities for entry and exit control; availability of electricity for night operations; personal facilities for personnel such as toilets, drinking water; availability of communication – mobile phone reception; protection (eg vaccination) of personnel; rendering capacity at rendering plants; additional cold storage and holding facilities at rendering plants and abattoirs; availability of freezing facilities before rendering.

- ***Procedures and policies for disposal of other products*** – manure, eggs; milk; non-animal products; animal feed.
- ***Wildlife*** – do they pose a risk in the immediate environment; expertise availability for culling of wildlife; availability of capture teams?

Recommended technologies for the disposal of carcasses

These technologies are presented as a hierarchy based on their reliability for pathogen inactivation.

- ***Rendering -*** This is a closed system for mechanical and thermal treatment of animal tissues leading to stable, sterilized products, e.g. animal fat and dried animal protein. It grinds the tissue and sterilizes it by heat under pressure. The technology exists in fixed facilities and is in normal usage. It produces an effective inactivation of all pathogens with the exception of prions where infectivity is reduced. A medium sized rendering plant could process 12 tonnes per hour of operations. The availability of the capacity should be determined in advance. Such a plant can operate within environmental standards.
- ***Incineration -*** This technology can be applied as:
    - Fixed, whole-carcass incineration,
    - Mobile air curtain whole carcass incineration,
    - Municipal incinerators,
    - Co-incineration

  Fixed whole carcass incineration occurs in an established facility in which whole carcasses or carcass portions can be completely burned and reduced to ash. Effective inactivation of pathogens is produced. Without additional technology, the exhaust emissions are not subjected to environmental control. However these emissions can be subjected to air scrubbing procedures to meet environmental standards. Fixed facility incineration has been used to dispose of BSE infected carcasses, as well as rendered meat-and-bone meal (MBM) and tallow from cattle carcasses considered to be at risk of BSE. Fixed facility incineration is wholly contained and usually highly controlled. It is typically fuelled by diesel, natural gas, or propane. The exhausts may be fitted with afterburner chambers to completely burn hydrocarbon gases and particulate matter from the main combustion chamber. Whole carcass disposal can be problematic given the batch-feed requirements at most biological waste incineration plants. Many waste incineration facilities refuse whole animals which are 70% water, but prefer waste of 25% water. Therefore, combining rendering and incineration is a promising approach. The resultant ash is less problematic and is considered safe. Although this is a more controlled procedure, there is still a potential fire hazard.

  Municipal incinerators are pre-established facilities which are normally used for the burning of household or industrial waste. They may not be currently licensed to burn carcasses.

Community position

In order to recall the necessity to remove practical as well as legal obstacles well before the necessity to use such facilities becomes evident, the Community proposes the following amendment to the last sentence under this bullet point:

"They may not be currently able and/or licensed to burn carcasses"

Co-incineration is a process in which meat and bone meal, carcasses or parts of carcasses are burned in conjunction with other substances such as hazardous waste incineration, clinical waste incineration, and other industrial incinerations such as power plants, cement kilns, blast furnaces and coke ovens. In practice meat and bone meal has been used as a secondary fuel on a large scale in cement kilns and power plants.

Air curtain incineration - air curtain incineration involves a machine that fan-forces a mass of

air through a manifold, thereby creating a turbulent environment in which incineration is accelerated up to six times faster than open-air burning. The equipment for this process can be made mobile which can be taken on-site but the potential fire hazard must be considered. Because it can be used on site, there is no requirement for transportation of the animal material. It also produces effective inactivation of pathogens and may actually achieve higher temperatures (1000 ^{0}C). Fuelled by diesel engines, high velocity air is blown into either a metal refractory box or burn pit. The materials required are wood (in a wood:carcass ratio of from 1:1 to 2:1), diesel fuel for both the fire and the air-curtain fan, and properly trained personnel. For incineration of 500 adult swine, the requirements are 30 cords of dry wood and 200 gallons of diesel fuel. The product is ash. Since the procedure is not wholly contained, it is subject to variable factors such as human operation, weather, and local community preferences.

Pyre burning - this is an open system of burning carcasses either on-farm or in collective sites fuelled by additional materials of high energy content. This is a well established procedure that can be conducted on site with no requirement for transportation of the input material. However, this process could be contrary to environmental standards for air, water and soil. It takes an extended period of time and has no verification of pathogen inactivation. In fact, there is a possibility of particulate transmission from incomplete combustion. Further, because the process is open to view, there is a negative reaction and lack of acceptance by the public.

Comparison of incineration methods

With all three incineration methods described above, the greater the percentage of animal fat, the more efficiently a carcass will burn. (Swine have a higher fat content than other species). For fixed facility incinerators, the capacity depends on the chamber's size and can range from 50 kg / hour up to 10 tonnes of poultry carcasses / day. Preprocessed, relatively homogeneous carcass material is more easily handled than large numbers of whole animal carcasses. Depending on the design and on-site management, air-curtain incinerators can burn 4 - 6 tons of carcasses / hour.

- ***Open-air burning*** can be relatively inexpensive, but it is not suitable for TSE infected carcasses. It is labour and fuel intensive, and dependent on favourable weather. It has environmental problems and a poor public perception. It is generally accepted that open-air burning pollutes. Although this is dependent on a number of factors. This may be more perception than established fact. Open air burning can also pose significant public perception, psychological, and economic problems

- ***Fixed facility incineration*** destroys TSE infected carcasses and is highly biosecure. However it is expensive and difficult to operate and manage from a regulatory perspective. Properly operated fixed facility incineration pose fewer pollution concerns.

- ***Air-curtain incineration*** is mobile, usually environmentally sound, and suitable for combination with debris removal. However it is fuel intensive, logistically challenging, and is not validated to dispose of TSE infected carcasses. Air curtain technology in general has been shown to cause little pollution with fire boxes burning cleaner than trench burners. It has higher combustion efficiencies with less carbon monoxide and particulate matter emissions.

- ***Composting -*** carcass composting is a natural biological decomposition process that takes place in the presence of oxygen. In the first phase, the temperature of the compost pile increases, organic materials break down into relatively small compounds, soft tissue decomposes, and bones soften partially. In the second phase, the remaining materials, mainly bones, break down fully to a dark brown or black humus containing primarily non-pathogenic bacteria and plant nutrients.

  Composting systems require a variety of ingredients including carbon sources, bulking agents and biofilter layers. Carbon sources can include materials such as sawdust, straw, cured cornstalks, poultry litter, ground corn cobs, wheat straw, hay, shavings, paper,

leaves, vermiculite, and matured compost. A 50:50 mixture of separated solids from manure and a carbon source can be used as a base material for carcass composting. The finished compost retains nearly 50% of the original carbon source which can be recycled in the compost process. A carbon:nitrogen (C:N) ratio in the range of 25:1 - 40:1 generates enough energy and produces little odour during the composting process. As a general rule the weight of carbon source materials to mortalities is approximately 1:1 for high C:N materials such as sawdust, 2:1 for medium C:N materials such as litter and 4:1 for low CN materials such as straw.

Bulking agents have bigger particle sizes than carbon sources and maintain adequate air spaces (around 25-35% porosity) within that compost pile by preventing packing of materials. Bulking agents include spent horse bedding, wood chips, rotting hay bales, peanut shells, and tree trimmings. The ratio of bulking agents to carcasses should result in a bulk density of the final compost mixture that does not exceed 600 Kg/m^3. The weight of the compost mixture in a 19 litre bucket should not be more than 11.4 kg.

A biofilter is a layer of carbon source or bulking material that enhances microbial activity with proper moisture, pH, nutrients, and temperature. It deodorizes gases released at ground level and prevents access by insects and birds thus minimizing transmission of disease agents.

The site selection criteria include a well drained area at 90 cm above the high water table level, at least 90 metres from sensitive water resources, and an adequate slope (1-3%) to allow proper drainage and prevent pooling of water. Runoff should be collected and treated. The location should be downwind of nearby residences. The site should have full accessibility but have minimal interference with other operations and traffic. Storage time of mortalities should be minimized. Co-composting materials should be ground to 2.5 - 5.0 cm and mixed. Compost materials should be lifted and dropped rather than be pushed into place. Compost piles should be covered by a biofilter layer during both phases of composting. The moisture content of the carcass compost pile should be 40-60% (wet basis).

A temperature probe should be inserted straight down into each quadrant of the pile and internal temperatures should be monitored daily and weekly during both phases of composting. During the first phase, the temperature at the core of the pile should rise to at least 55-60 ^oC within 10 days and remain there for several weeks. A temperature of 65^oC at the core, maintained for 1 - 2 days, will reduce pathogenic bacterial activity and weed seed germination. However spore formers such as *Bacillus anthracis* and other pathogens such as *Mycobacterium tuberculosis* will survive. Proper aeration is important in maintaining uniform temperature and moisture content throughout the pile. After the first phase of composting, the volume and weight of the pile may be reduced by 50-75%. Following the first phase, the entire compost pile should be mixed, displaced and reconstituted for the secondary phase. If necessary, moisture can be added.

The end of the second phase is marked by an internal temperature of 25-35^oC, a reduction in bulk density of approximately 25%, a colour of dark brown to black and the lack of an unpleasant odour. Although heat generated during carcass composting results in some microbial destruction, it is not sufficient to completely sterilize the end product. Pathogenic bacterial activity is reduced when the temperature in the middle of the pile reaches 65 ^oC within one to two days. An average temperature of 55-60 ^oC for a day or two reduces pathogenic viruses, bacteria, protozoa (including cysts) and helminth ova to an acceptably low level, but endospores produced by spore-forming bacteria would not be inactivated.

- ***Trench burial and mass burial -*** this is a system to deposit whole carcasses below ground level and to be covered by soil, with no additional inactivation of pathogens. It is an established procedure which if conducted on site does not require transportation and is used to control the spread of disease. It does however require an environmental assessment because of the potential contamination of groundwater, or of aquifers if leachate is not controlled. Further, it does not inactivate all pathogenic agents.

- ***Licensed commercial landfill -*** this process involves deposition of carcasses in predetermined and environmentally licensed commercial sites. Because the site has been previously licensed, all environmental impacts such as leachate management, gas management, engineered containment, flooding and aquifers have already been considered. However, the area is open and uncovered for extended periods, there is a potential emission of aerosols, and there is resistance from the public to such an approach.

- ***Mounding -*** this process is one of mass burial above ground and it has similar considerations to those of mass burial and composting.

- ***Fermentation -*** this process is a closed system of anaerobic microbiological decompositions which requires prior mechanical and thermal treatment and which results in the production of biogas. This process does not inactivate pathogens, but typically uses non-dried rendered product as the input material.

- ***Alkaline hydrolysis -*** alkaline hydrolysis uses sodium hydroxide or potassium hydroxide to catalyse the hydrolysis of biological material into a sterile aqueous solution consisting of small peptides, amino acids, sugars, and soaps. Heat is applied (150^{o}C) to accelerate the process. The only solid byproducts are the mineral constituents of the bones and teeth of vertebrates. This residue (2% of the original weight of the carcass) is sterile and easily crushed into a powder. The temperature and alkali conditions of the process destroy the protein coats of viruses and the peptide bonds of prions. Both lipids and nucleic acids are degraded. Significantly large carbohydrate molecules, such as cellulose, although sterilized by the process, are not digestible by alkaline hydrolysis eg paper, string, undigested plant fibres, and wood shavings.

  The process is carried out in an insulated steam-jacketed, stainless steel pressure vessel with a sealed lid. The vessel operates at 70psig to achieve 150^{o}C. The process does not release any emissions into the atmosphere and only causes minor odour production. The end product solution can be released into the sanitary sewer with proper monitoring of pH and temperature according to guidelines. The total process time for alkaline hydrolysis digestion of carcass material is 3-8 hours depending on the disease agent eg bacterial and viral contaminated waste (4 hours), transmissible spongiform encephalopathy waste (6 hours). A mobile trailer unit has a capacity of digesting 4000 pounds of carcasses every 8 hours.

- ***Lactic acid fermentation*** - lactic acid fermentation is a means to preserve carcasses up to 25 weeks until they can be rendered. Fermentation is an anaerobic process. Carcasses are ground to fine particles, mixed with a fermentable carbohydrate source and a culture inoculant, and added to a fermentation container. For lactic acid fermentation, lactose, glucose, sucrose, whey, whey permeates, and molasses are suitable carbohydrate sources. The carbohydrate source is fermented to lactic acid by *Lactobacillus acidophilus*.

  Under optimum conditions with a temperature of about 35 ^{o}C, the pH of fresh carcasses is reduced to less than 4.5 within two days. Some microorganisms are destroyed by the acid pH while the remainder will be destroyed by heat during rendering.

- ***Anaerobic digestion*** - this process is suited for large-scale operations. It reduces odours and reduces pollution by greenhouse gases due to the combustion of methane. It can eliminate carcasses and at the same time produce energy but may require size reduction and sterilization of carcasses on-site before applying anaerobic technology. Anaerobic digestion transforms waste into fertilizer. Although anaerobic digestion is less expensive with mesophilic organisms at 35^{o}C, the use of thermophilic organisms at 55 ^{o}C is preferred because the additional heat destroys some pathogens. It is necessary to use additional heat treatment at the end of the process to fully inactivate pathogens however, even with this, prions are not inactivated. Carcasses have a higher nitrogen content than most other wastes and therefore result in a high ammonia concentration which can inhibit anaerobic digestion. This limits the loading rate for anaerobic digesters that are treating carcass wastes.

- ***Non-traditional and novel technologies***

  - ***Pre-processing*** - this involves on farm pre-processing prior to transportation of carcasses to central facilities because of the complexity and cost (eg rendering or incineration). Preprocessing could include the grinding of carcasses. (A large portable grinder can grind up to 15 tons of animal carcasses per hour). This could then be transported in sealed containers, or be subjected to fermentation or freezing. The primary objectives are to minimize on-site contamination risks and to maximize the number of options for disposal.

  - ***Carcass disposal at sea -*** disposal in a coastal sea or on a continental plateau cannot occur without the authorization of the coastal State which must make a regulation on the dumping and which must consult with other neighbouring States. International Conventions express a fundamental principle which countries should be obliged to respect even if they are not signatories. These Conventions do not directly prohibit disposal of carcasses at sea, but do define the conditions to be met. It is possible for this disposal if it is technically and scientifically proven that the products to be disposed are not harmful, and if the State has authorised this disposal with a permit.

  - ***Bio-refining*** - this is a high pressure, high temperature hydrolytic process, conducted in a sealed pressurized vessel. The waste material is treated at 180 ^{o}C at 12 bar pressure for 40 minutes, heated by indirect steam application to the biolytic reactor. The process can accommodate whole animal carcasses, MBM, food processing wastes, other compostable material, paper and comparable materials, and cereal straws either alone or in combination. In the dehydration cycle, the steam water is condensed and either used for other purposes or discarded. Each cycle lasts four hours. The capacity of each reactor is 20,000 tonnes of raw material per year. The process inactivates all microbiological agents. It is currently under evaluation for its efficiency in inactivating the prions of transmissible spongiform encephalopathies.

Special considerations for prion diseases

One of the problems in demonstrating the effectiveness of the inactivation of prions is the lack of a simple, rapid and inexpensive test for the presence of the infective agent, especially at low concentrations. The ultimate test is bioassay in a sensitive detector species by an efficient route, but usually this is only relevant in research. Typically this is done using panels of mice bred to be susceptible to particular types of transmissible spongiform encephalopathies (TSEs). However it must be recognized that the mouse to cattle species barrier has been demonstrated to be 500, therefore affecting sensitivity.

Although rendering at 133^{0}C and three bars of pressure for 20 minutes is a defined standard, reductions of infectivity by this technology are in the order of 1:200 – 1:1000. Commercial incinerators have an inactivation rate of one million fold, while burning on pyres has a reduction rate of 90 %. (It should be noted that pyres are not suitable for sheep because of the wool and fat.) Alkaline hydrolysis produces a 3-4 log reduction in infectivity over a three hour period. Landfill and deep burial are suggested to have a reduction in infectivity of 98 – 99.8 % over three years. Based on this information, rendering, incineration, and alkaline hydrolysis are the most reliable technologies at this time. The significance of small amounts of infectivity become evident when you consider that experimentally it has been shown that exposure of sensitive species to as little as 1.0, 0.1 or even 0.01 grams of infected nervous tissue can induce infection.

Given all of the above (except complete burning in closed furnaces), it must be recognized that no process has been demonstrated to be 100 % effective in removing TSE infectivity and there will be some residual levels of infectivity remaining after treatment.

Guidelines for decision-making for the disposal of carcasses

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

The disposal of large numbers of carcasses will be expensive. As well, fixed and variable costs will vary with the choice of the disposal method. Each method used will result in indirect costs on the environment, local economies, producers, and the livestock industry. Decision makers need to understand the economic impact of various disposal technologies.

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

- ***Process for decision- making***:

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

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

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

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

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

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

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

Table 1: **Decision Making Process**

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

DISEASES ANIMAL HEALTH Part 2

3/5/2005

Appendix X

CHAPTER 2.3.3.

BOVINE TUBERCULOSIS

Community position:
The Community can support this Chapter provided the comments given in the text below taken on board. The Community asks the OIE to reflect on expanding the scope of this chapter or proposing a new Chapter concerning tuberculosis in other species including wildlife.

Article 2.3.3.1.

The recommendations in this Chapter are intended to manage the human and animal health risks associated with *Mycobacterium bovis* (*M. bovis*) infection in cattle (*Bos taurus*, *Bos indicus* and *Bos grunniens*) and buffalo (*Bubalus bubalus*).

Community position:
The Community proposes that Bison are included above so "Bison bison" should be included in the above sentence.

When authorising import or transit of the following *commodities*, *Veterinary Administrations* should comply with the requirements prescribed in this Chapter relevant to the status of bovine tuberculosis in the *exporting country*, *zone* or *compartment*:

1) live animals;

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

3) *meat* and *meat products*;

4) *milk* and *milk products*.

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

Article 2.3.3.2.

Country, ~~or~~ zone ~~officially~~ or compartment free from bovine tuberculosis

To qualify as ~~officially~~ free from bovine tuberculosis, a country, ~~or~~ *zone* ~~shall~~ or *compartment* should satisfy the following requirements:

1) bovine tuberculosis is a *notifiable disease* in the country;

~~2) 99.8% of the herds in the considered geographical area have been officially free from bovine tuberculosis for at least the past 3 years as disclosed by periodic testing of all cattle in the area to~~

~~determine the absence of bovine tuberculosis (periodic testing of all cattle is not required in an area where a surveillance programme as described in point 4) below reveals that at least 99.9% of the cattle have been in herds officially free from tuberculosis for at least 6 years);~~

3) regular and periodic testing of all cattle herds has shown that at least 99.8% of the herds and 99.9% of the animals in the country, *zone* or *compartment* have been found free from bovine tuberculosis for 3 consecutive years;

Community position:
The Community could support the change from 6 consecutive years with 99.9% to 3 consecutive years with 99.8% of herds and 99.9% of animals free from tuberculosis if scientific evidence exists ensuring that 3 years with 99.8% herds and 99.9% animals free provides for equivalent level of guarantee than the former obligation of 6 years with 99.9% herds free.
The Community consider that the guarantees on absence of disease should be given by the combination of:
- Very high percentage of free herds at the end of the year for several consecutive years (note that a herd can be infected and re-qualified as free in six months) and
- Very low percentage of herd confirmed infected during the year for several consecutive years

The Community proposes the following wording:

"regular and periodic testing of all herds have shown that at least 99.8% of the herds and 99.9% of the animals in the country, *zone* or *compartment* have been found free from bovine tuberculosis and the percentage of herds confirmed infected with tuberculosis has not exceeded 0.1% per year for 3 consecutive years,"

4) a surveillance programme should be in place to ensure the discovery of bovine tuberculosis in the country, *zone* or *compartment*, through monitoring at slaughter based on the inspection described in Article 2.3.3.9. In addition, a prescribed test can also be used for surveillance purposes. The *Veterinary Administration* should be able to trace and test the herd of origin of any reactor to a prescribed test or of any animal which discloses gross pathological lesions of tuberculosis in an abattoir or elsewhere disclosed after removal from the considered territory;

Community position:
The wording "prescribed test" instead "tuberculin test" should be used through the whole text of this chapter in case tuberculin test is the prescribe test or one of the prescribed tests

~~3.~~5) cattle introduced into a country, ~~or~~ *zone* ~~officially~~ or *compartment* free from bovine tuberculosis ~~must~~ should be accompanied by a certificate from an *Official Veterinarian* attesting that they come from ~~herd of cattle officially free from bovine tuberculosis or from~~ a country, ~~or~~ *zone*, *compartment* or herd ~~officially~~ free from bovine tuberculosis.;

~~4. a country or zone officially free from bovine tuberculosis must have a *Veterinary Administration* which should be able to trace and test the herd of origin of any reactor to a tuberculin test disclosed after removal from the considered territory. Also animals which disclosed gross pathological lesions of tuberculosis in an abattoir or elsewhere. In addition, such a country or zone must have in place a surveillance programme to ensure the discovery of bovine tuberculosis should the disease be present in the country or zone, through slaughter monitoring and/or tuberculin testing.~~

Article 2.3.3.3.

Herd ~~officially~~ free from bovine tuberculosis

To qualify as ~~officially~~ free from bovine tuberculosis, a herd of cattle ~~shall~~ should satisfy the following requirements:

1) the herd is in a country, ~~or~~ *zone* ~~officially~~ or *compartment* free from bovine tuberculosis and is certified free by the *Veterinary Administration*; or

2) all cattle in the herd:

   a) show no clinical sign of bovine tuberculosis;

   b) over 6 weeks of age, have shown a negative result to at least two tuberculin tests carried out at an interval of 6 months, the first test being performed at 6 months following the slaughter of the last affected animal;

   c) showed a negative result to an annual tuberculin test to ensure the continuing absence of bovine tuberculosis;

Community position:
The Community could support an "annual prescribed test" to ensure the continuing absence of diseases as a general rule. However it should be allowed to reduce the frequency of routine tests to maintain the certification of free herd under special circumstances of very low prevalence:
- Frequency to be reduced to one test every two years if the annual percentage of herds confirmed as infected with tuberculosis is not more than 1% of all herds in the country during the last two years.
- Frequency to be reduced to one test every three years if the annual percentage of herds confirmed as infected with tuberculosis is not more than 0.2% of all herds in the country during the last four years.
- Frequency to be reduced to one test every four years if the annual percentage of herds confirmed as infected with tuberculosis is not more than 0.1% of all herds in the country during the last six years.

The Community proposes the following wording:
"c) showed a negative result to an annual tuberculin test to ensure the continuing absence of bovine tuberculosis; or
d) showed a negative result to a tuberculin test every two years to ensure the continuing absence of bovine tuberculosis if the annual percentage of herds confirmed as infected with tuberculosis is not more than 1% of all herds in the country during the last two years, or
e) showed a negative result to a tuberculin test every three years to ensure the continuing absence of bovine tuberculosis if the annual percentage of herds confirmed as infected with tuberculosis is not more than 0.2% of all herds in the country during the last four years, or
f) showed a negative result to a tuberculin test every four years to ensure the continuing absence of bovine tuberculosis if the annual percentage of herds confirmed as infected with tuberculosis is not more than 0.1% of all herds in the country during the last six years."

3) all cattle introduced into the herd come from ~~a) must be accompanied by a certificate from an *Official Veterinarian* attesting that they were subjected to a tuberculin test during the 30 days prior to entry into the herd, with negative result; or~~ a herd free from bovine tuberculosis. This condition may be waived for animals which have been isolated and which, prior to entry into the herd, were subjected to at least two tuberculin tests carried out at a 6-month interval with negative results.

Community position:

The Community consider that the requirements animals from non free herds should be the same for the purpose of maintenance of the free status of the free herds (2.3.3.3.3) and for the import of animals (2.3.3.4.4.)

The Community proposes the following wording:
"3)all cattle introduced into the herd come from ~~a) must be accompanied by a certificate from an *Official Veterinarian* attesting that they were subjected to a tuberculin test during the 30 days prior to entry into the herd, with negative result; or~~ a herd free from bovine tuberculosis. This condition may be waived for animals which were isolated for the 3 months prior to entry into the herd and were subjected to the tuberculin test for bovine tuberculosis with negative results on two occasions, with an interval of not less than 60 days between each test."

~~b) were kept in a herd officially free from bovine tuberculosis.~~

Article 2.3.3.4.

Veterinary Administrations of *importing countries* should require:

for cattle for breeding or rearing

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

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

2) originate from a herd free from bovine tuberculosis that is in a country, *zone* or *compartment* free from bovine tuberculosis; or

3) were subjected to the tuberculin test for bovine tuberculosis with negative results during the 30 days prior to shipment and come from a herd ~~officially~~ free from bovine tuberculosis; or

~~2~~4) were isolated for the 3 months prior to shipment and were subjected to the tuberculin test for bovine tuberculosis with negative results on two occasions, with an interval of not less than 60 days between each test. ~~; or.~~

~~4. were subjected to the tuberculin test for bovine tuberculosis with negative results during the 30 days prior to shipment and come from a country or zone officially free from bovine tuberculosis.~~

Article 2.3.3.5.

Veterinary Administrations of *importing countries* should require:

for cattle for slaughter

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

1) originated from a free herd or were subjected to a tuberculin test for bovine tuberculosis with negative results during the 30 days prior to shipment;

2) were not being eliminated as part of an eradication programme against bovine tuberculosis. ~~kept in a herd officially free from bovine tuberculosis; or~~

~~3. were kept in a country or zone officially free from bovine tuberculosis.~~

~~This certificate may be complemented in paragraphs 2) and 3) by:~~

~~4. are not being eliminated as part of an eradication programme against bovine tuberculosis.~~

~~Article 2.3.3.6.~~

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

~~for wild bovines destined for zoological gardens~~

~~the presentation of an *international veterinary certificate* attesting that the animals were subjected to a tuberculin test for bovine tuberculosis with negative results during the 30 days prior to shipment.~~

~~Article 2.3.3.7.~~

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

~~for pigs for breeding or rearing~~

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

~~1) showed no clinical sign of bovine tuberculosis on the day of shipment; and/or~~

~~2) were subjected to a tuberculin test for bovine tuberculosis with negative results, the test being performed on the posterior aspect of the base of the ear (the result should be read after 48 hours); and/or~~

~~3) were kept in a country, zone or herd officially free from bovine tuberculosis.~~

~~Article 2.3.3.8.~~

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

~~for pigs for slaughter~~

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

~~1) were kept in a country, zone or herd officially free from bovine tuberculosis;~~

~~2) are not being eliminated as part of an eradication programme against bovine tuberculosis.~~

Article 2.3.3.~~9.~~6.

Veterinary Administrations of *importing countries* should require:

for semen of cattle ~~and pigs~~

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

1) the donor animals:

   a) showed no clinical sign of bovine tuberculosis on the day of collection of the semen;

~~b) were isolated in the *establishment* of origin during the 3 months prior to collection and were subjected to a tuberculin test for bovine tuberculosis with negative results on two occasions, with an interval of not less than 60 days between each test; or~~

~~c) were kept in the *exporting country* for the 30 days prior to collection, in an *establishment* or *artificial insemination centre* where all animals are officially free from bovine tuberculosis;~~

b) were kept in an *artificial insemination centre* free from bovine tuberculosis in a country, *zone* or *compartment* free from bovine tuberculosis and which only accepts animals from free herds in a free country, *zone* or *compartment*; or

c) showed negative results to tuberculin tests carried out at an interval of 6 months and were kept in an *artificial insemination centre* free from bovine tuberculosis;

Community position:
The Community considers that the requirements should be the same as the requirements laid down in Appendix 3.2.1.5. (Conditions applicable to testing of bulls and teaser animals) where the requirements for the testing programme for bovines resident in the semen collection facilities (all bovines resident in the semen collection facilities should be tested at least annually for Bovine tuberculosis).

The Community proposes the following wording:
"c)showed negative results to tuberculin tests carried out annually and were kept in an *artificial insemination centre* free from bovine tuberculosis;"

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 2.3.3.~~10.~~7.
~~(under study)~~

Veterinary Administrations of *importing countries* should require:

for embryos/ova of cattle ~~and pigs~~

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

1) the donor females:

a) and all other susceptible animals in the herd of origin showed no clinical sign of bovine tuberculosis during the 24 hours prior to departure to the *collection centre*;

Community position:
Taking into account that not all donor females are moved to a collection centre, it should also include an option where it says "… or 24 hours prior to the embryo collection"

~~2) were kept in a herd officially free from bovine tuberculosis;~~

b) originated from a herd free from bovine tuberculosis in a country, *zone* or *compartment* free from bovine tuberculosis; or

c) were kept in a herd ~~officially~~ free from bovine tuberculosis, were isolated in the *establishment* of origin for the 30 days prior to departure to the *collection centre* and were subjected to a tuberculin test for bovine tuberculosis with negative results;

2) the embryos/ova were collected, processed and stored in conformity with the provisions of Appendix 3.3.1., Appendix 3.3.2. or Appendix 3.3.3.

Article 2.3.3.~~11.~~8.

Veterinary Administrations of *importing countries* should require:

for *fresh meat* of cattle ~~and pigs~~

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat comes from animals which have been subjected to ante-mortem and post-mortem inspections for bovine tuberculosis carried out by the *Veterinary Services* in an *approved abattoir* with favourable results.

Article 2.3.3.9.

Veterinary Administrations of *importing countries* should require:

for *meat products*

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

1) the meat is derived from animals satisfying conditions mentioned in Article 2.3.3.8.;

2) the necessary precautions were taken after processing to avoid contact of the entire *meat products* with any potential source of *M. bovis*.

Article 2.3.3.10.

Veterinary Administrations of *importing countries* should require:

for *milk* and *milk products*

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

1) has been derived from animals in a herd free from bovine tuberculosis; or

2) was subjected to pasteurisation or a combination of control measures with equivalent performance in reducing *Mycobacterium bovis* in raw milk as described in the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products.

Community position:
Milk should comply with the requirements laid down by Codex Alimentarius therefore the Community proposes the following wording:
"2)was subjected to pasteurisation or a combination of control measures with equivalent performance as described in the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products."

Article 2.3.3.11.

Veterinary Administrations of *importing countries* should require:

for hides and skins from cattle

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

1) the entire consignment comes from animals which have been subjected to ante-mortem and post-mortem inspections for bovine tuberculosis carried out by the *Veterinary Services* in an *approved abattoir* with favourable results;

2) the necessary precautions were taken after processing to avoid contact of the products with any potential source of *M. bovis*.

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

— text deleted

Appendix XIV

CHAPTER 2.6.7.

CLASSICAL SWINE FEVER

Community position:
The Community can only support the proposal if the points noted below are taken on board. The Community has on a number of previous occasions stated it believes that identification, the control of waste food feeding and movement controls etc are key elements in the granting and maintenance of free status.

Article 2.6.7.1.

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 *Terrestrial Manual*.

Article 2.6.7.2.

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 2.6.7.3.

For the purposes of the *Terrestrial Code*:

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

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

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

Article 2.6.7.4.

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 2.6.7.2. 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.

Community position:

The Community maintains its position that paragraphs 2b-d below must be not only be retained but must apply to this paragraph as well..

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 the conduct of a risk assessment as referred to in Article 2.6.7.2. and when:

a) it is a notifiable disease;

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

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

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

Community position:

The Community maintains its position that these 3 paragraphs must be retained.

AND EITHER

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

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

~~g)~~ where a vaccination strategy has been adopted, with or without a *stamping-out policy*, vaccination against CSF ~~should have~~ has been banned ~~for~~ in all domestic pigs in the country or zone for at

least one year, unless there are validated means of distinguishing between vaccinated and infected pigs; if vaccination has occurred in the past 5 years, ~~a serological monitoring system should have~~ surveillance in accordance with Appendix XXX has 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 2.6.7.5.

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

Requirements in point 2) of Article 2.6.7.4., 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)~~ surveillance in accordance with Appendix XXX is carried out in the domestic pig population, with negative results.

Article 2.6.7.6.

Recovery of free status

Should a CSF *outbreak* occur in an *establishment* of a free country or zone (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-kilometre radius and an outer surveillance area of at least 10-kilometre radius) should be delineated around the *outbreak*, taking into account the control measures applied, the presence of natural and administrative boundaries, and an assessment of the risk of disease spread;

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

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

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

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

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

5) ~~an epidemiological examination including clinical examination, and/or serological and/or virological testing~~ surveillance in accordance with Appendix XXX 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 2.6.7.7.

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)~~ surveillance in accordance with Appendix XXX 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~~ past 12 months;

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

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

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

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

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

Article 2.6.7.8.

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, unless there are validated means of distinguishing between vaccinated and infected pigs.

Article 2.6.7.9.

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

for domestic pigs

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

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

2) have not been vaccinated against CSF, nor are they the progeny of vaccinated sows, unless there are validated means of distinguishing between vaccinated and infected pigs;

3) come from an *establishment* which is not located in a CSF wild pig control area as defined in Article 2.6.7.5., and has been regularly monitored to verify absence of CSF in accordance with Appendix XXX;

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

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

Article 2.6.7.10.

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

for domestic pigs

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

1) have not been vaccinated against CSF nor are they the progeny of vaccinated sows, unless there are validated means of distinguishing between vaccinated and infected pigs;

2) were kept since birth, or for the past 3 months, in an *establishment* not situated in a CSF domestic or wild pig control area as defined in Article 2.6.7.5. and in Article 2.6.7.6.;

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

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

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

Article 2.6.7.11.

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

for wild pigs

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

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

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

3) have not been vaccinated against CSF, unless there are validated means of distinguishing between vaccinated and infected pigs;

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

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

Article 2.6.7.12.

When importing from countries or zones 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 2.6.7.13.

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

for semen of domestic pigs

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

1) the donor animals:

   a) 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 2.6.7.14.

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

for semen of domestic pigs

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

1) the donor animals:

   a) 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 2.6.7.15.

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 3.3.1.

Article 2.6.7.16.

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

for *in vivo* derived embryos of pigs

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

1) the donor females:

   a) were kept 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 3.3.1.

Article 2.6.7.17.

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 in accordance with Appendix XXX;

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 3.3.1.

Article 2.6.7.18.

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 2.6.7.19.

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

for *fresh meat* of domestic pigs

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

1) were kept in a country or zone 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 in accordance with Appendix XXX;

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

Article 2.6.7.20.

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

for *fresh meat* of wild pigs

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

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

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

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

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

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

Article 2.6.7.21.

Veterinary Administrations of *importing countries* should require:

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

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

1) have been prepared:

a) exclusively from *fresh meat* meeting the conditions laid down in Articles 2.6.7.18., 2.6.7.19. or 2.6.7.20., as relevant;

b) in a processing establishment:

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

ii) regularly inspected by the *Veterinary Authority*;

iii) not situated in a CSF control area;

iv) processing only meat meeting the conditions laid down in Articles 2.6.7.18., 2.6.7.19. or 2.6.7.20., as relevant;

OR

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

Article 2.6.7.22.

Veterinary Administrations of *importing countries* should require:

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

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

1) have been prepared:

a) exclusively from products meeting the conditions laid down for *fresh meat* in Articles 2.6.7.18., 2.6.7.19. or 2.6.7.20., as relevant;

b) in a processing establishment:

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

ii) regularly inspected by the *Veterinary Authority*;

iii) not situated in a CSF control area;

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

OR

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

Article 2.6.7.23.

Veterinary Administrations of *importing countries* should require:

for bristles (from pigs)

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

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

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

Article 2.6.7.24.

Veterinary Administrations of *importing countries* should require:

for litter and manure (from pigs)

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

1) come from a country or zone 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.

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

— text deleted

Appendix XV

APPENDIX X.X.X

GUIDELINES FOR THE SURVEILLANCE OF CLASSICAL SWINE FEVER

Community position:
The Community. can support the amendments proposed below. However this Chapter could be a little further developed in particular by the addition of surveillance examples.

Article X.X.X.1.

Introduction

This document defines the principles and provides a guide for the surveillance of classical swine fever (CSF) in accordance with Appendix 3.8.1., applicable to countries seeking recognition of freedom from CSF. This may be for the entire country or a zone within the country. Guidance for countries seeking reestablishment of freedom from CSF for the whole country or a zone, following an *outbreak*, as well as guidelines for demonstrating the maintenance of CSF free status are also provided. This Appendix complements Chapter 2.6.7.

The impact and epidemiology of CSF differ widely in different regions of the world and therefore it is impossible to provide specific guidelines for all situations. It is axiomatic that the surveillance strategies employed for demonstrating freedom from CSF at an acceptable level of confidence will need to be adapted to the local situation. For example, the approach must be tailored in order to prove freedom from CSF for a country or zone where wild pigs provide a potential reservoir of infection, or where CSF is present in adjacent countries. The method must examine the epidemiology of CSF in the region concerned and adapt to the specific risk factors encountered. This should include provision of scientifically based supporting data. There is therefore latitude available to Member Countries to provide a well-reasoned argument to prove that absence of CSFV infection is assured at an acceptable level of confidence.

Surveillance for CSF should be in the form of a continuing programme designed to establish that the whole country or zone is free from CSFV infection. Consideration should be given to the specific characteristics of CSF epidemiology which include: the role of swill feeding and the impact of different production systems on disease spread, the role of semen in transmission of the virus, the lack of pathognomonic gross lesions and clinical signs, the frequency of clinically inapparent infections, the occurrence of persistent and chronic infections, and the genotypic, antigenic, and virulence variability exhibited by different strains of CSFV. Serological cross-reactivity with other pestiviruses has to be taken into consideration when interpreting data from serological surveys. A common route by which ruminant pestiviruses can infect pigs is the use of vaccines contaminated with bovine viral diarrhoea virus (BVDV).

For the purpose of this Appendix virus infection means presence of CSFV as demonstrated directly by virus isolation, the detection of virus antigen or virus nucleic acid, or indirectly by seroconversion which is not the result of vaccination.

Article X.X.X.2.

General conditions and methods

1) A surveillance system in accordance with Appendix 3.8.1. should be under the responsibility of the *Veterinary Administration*. A procedure should be in place for the rapid collection and transport of samples to an accredited laboratory as described in the *Terrestrial Manual*.

2) The CSF surveillance programme should:

   a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers, who have day-to-day contact with livestock, as well as diagnosticians, should report promptly any suspicion of CSF to the *Veterinary Authority*. They should be supported directly or indirectly (e.g. through private veterinarians or *veterinary para-professionals*) by government information programmes and the *Veterinary Administration*. Since many strains of CSFV do not induce pathognomonic gross lesions or clinical signs, cases in which CSF cannot be ruled out should be immediately investigated employing clinical, pathological, and laboratory diagnosis. This requires that sampling kits and other equipment are available to those responsible for surveillance. Personnel responsible for surveillance should be able to call for assistance from a team with expertise in CSF diagnosis, epidemiological evaluation, and control;

   b) implement, when relevant, regular and frequent clinical inspections and serological testing of high-risk groups of animals (for example, where swill feeding is practised), or those adjacent to a CSF infected country or zone (for example, bordering areas where infected wild pigs are present).

   An effective surveillance system will periodically identify suspicious cases that require follow up and investigation to confirm or exclude that the cause of the condition is CSFV. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be reliably predicted. Recognitions for freedom from CSFV infection should, as a consequence, provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of laboratory testing and the control measures to which the animals concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

Article X.X.X.3.

Surveillance strategies

The target population for surveillance aimed at identification of *disease* and *infection* should include domestic and wild pig populations within the country or zone to be recognised as free from CSFV infection. Such surveillance may involve opportunistic testing of samples submitted for other purposes, but a more efficient and effective strategy is one which includes targeted surveillance.

Depending on the local epidemiological situation, targeted surveillance could be considered as more effective than a randomized surveillance strategy. Surveillance is targeted to the pig population which presents the highest risk of *infection* (for example, swill fed farms, pigs reared outdoors, farms in proximity to infected wild pigs). Each country will need to identify its individual risk factors. These may include: temporal and spatial distribution of past *outbreaks*, pig movements and demographics, etc.

For reasons of cost, the longevity of antibody levels, as well as the existence of clinically inapparent infections and difficulties associated with differential diagnosis of other diseases, serology is often the most effective and efficient surveillance methodology. In some circumstances, which will be discussed later, clinical and virological surveillance may also have value.

The country should justify the surveillance strategy chosen as adequate to detect the presence of CSFV infection in accordance with Appendix 3.8.1. and the epidemiological situation. Cumulative survey results in combination with the results of passive surveillance, over time, will increase the level of confidence in the surveillance strategy. If a Member Country wishes to apply for recognition by other Member Countries of a specific zone within the country as being free from CSFV infection, the design of the surveillance strategy and the basis for any sampling process would need to be aimed at the population within the zone.

For random surveys, the design of the sampling strategy will need to incorporate epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect infection if it were to occur at a predetermined minimum rate. The sample size and expected disease prevalence determine the level of confidence in the results of the survey. The country must justify the choice of design prevalence and confidence level based on the objectives of surveillance and the epidemiological situation, in accordance with Appendix 3.8.1. Selection of the design prevalence in particular clearly needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the survey design selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the vaccination/infection history and production class of animals in the target population.

Irrespective of the testing system employed, the surveillance system design should anticipate the occurrence of false positive reactions. This is especially true of the serological diagnosis of CSF because of the recognized cross-reactivity with ruminant pestiviruses. There needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether or not they are indicative of CSFV infection. This should involve confirmatory and differential tests for pestiviruses, as well as further investigations concerning the original sampling unit as well as animals which may be epidemiologically linked.

1) Clinical and virological surveillance

Beyond their role in targeted surveillance, clinical and virological surveillance for CSF have two aims: a) to shorten the period between introduction of CSF virus into a disease free country or zone and its detection, and b) to confirm that no unnoticed *outbreaks* have occurred.

One element of clinical surveillance involves the detection of clinical signs of CSF by close physical examination of susceptible animals. The spectrum of disease signs and gross pathology seen in CSF infections, along with the plethora of other agents that can mimic CSF, renders the value of clinical examination alone somewhat inefficient as a surveillance tool. Nevertheless, clinical presentation should not be ignored as a tool for early detection; in particular, any cases where clinical signs or lesions consistent with CSF are accompanied by high morbidity and/or mortality should be investigated without delay. In CSFV infections involving low virulence strains, high mortality may only be seen in young animals.

In the past, clinical identification of cases was the cornerstone of early detection of CSF. However, emergence of low virulence strains of CSF, as well as new diseases - in particular post-weaning multisystemic wasting syndrome and porcine dermatitis and nephropathy syndrome have made such reliance less effective, and, in countries where such diseases are common, can add significant risk of masking the presence of CSF. In zones or countries where such diseases exist, careful clinical and virological surveillance of such cases should be applied.

Clinical signs and pathology of CSF infection will also vary considerably, depending on the strain of virus as well as host factors, such as age, nutrition and health status. These factors, along with the compounding effects of concurrent infections and disease caused by ruminant pestiviruses, dictate the need for laboratory testing in order to clarify the status of CSF suspects detected by clinical monitoring. The difficulties in detecting chronic disease manifested by non-specific clinical signs and delayed seroconversion and seronegativity, in persistently infected piglets, both of which may be clinically normal, makes virological investigation essential. As part of a herd investigation, such animals are likely to be in a minority and would not confound a diagnosis based on serology. However, individually, or as part of recently mixed batches, such animals may escape detection by this method. A holistic approach to investigation, taking note of herd history, pig, personnel and vehicle movements and disease status in neighbouring zones or countries, can also assist in targeting surveillance in order to increase efficiency and enhance the likelihood of early detection.

The labour-intensive nature of clinical, pathological, and virological investigations, along with the smaller 'window of opportunity' inherent in virus, rather than antibody detection, has, in the past, resulted in greater emphasis being placed on mass serological screening as the best method for

surveillance. However, surveillance based on clinical and pathological inspection and virological testing should not be underrated. If targeted at high risk groups in particular, it provides an opportunity for early detection that can considerably reduce the subsequent spread of disease. Herds predominated by adult animals, such as nucleus herds and artificial insemination studs, are particularly useful groups to monitor, since infection by low virulence viruses in such groups may be clinically inapparent, yet the degree of spread may be high.

Clinical and virological monitoring may also provide a high level of confidence of rapid detection of disease if a sufficiently large number of clinically susceptible animals is examined. In particular, molecular detection methods are increasingly able to offer the possibility of such large-scale screening for the presence of virus, at reasonable cost.

Wild pigs and, in particular, those with a wholly free-living existence, rarely present the opportunity for clinical observation, but should form part of any surveillance scheme and should ideally be monitored for virus as well as antibody.

Vaccine design and diagnostic methodologies, and in particular, methods of virus detection, are increasingly reliant on up-to-date knowledge of the molecular, antigenic and other biological characteristics of viruses currently circulating and causing disease. Furthermore, epidemiological understanding of the pathways of spread of CSFV can be greatly enhanced by molecular analyses of viruses in endemic areas and those involved in outbreaks in disease free areas. It is therefore essential that CSFV isolates are sent regularly to the regional OIE Reference Laboratory for genetic and antigenic characterisation.

2) Serological surveillance

Serological surveillance aims at the detection of antibodies against CSFV. Positive CSFV antibody test results can have five possible causes:

a) natural infection with CSFV;

b) legal or illegal vaccination against CSF;

c) maternal antibodies derived from an immune sow (maternal antibodies) are usually found only up to 4.5 months of age but in some individuals, maternal antibodies can be detected for considerably longer periods;

d) cross reactions with other pestiviruses;

e) non-specific reactors.

The infection of pigs with other pestiviruses may complicate a surveillance strategy based on serology. Antibodies to bovine viral diarrhoea virus (BVDV) and Border disease virus (BDV) can give positive results in serological tests for CSF, due to common antigens. Such samples will require differential tests to confirm their identity. Although persistently infected immunotolerant pigs are themselves seronegative, they continuously shed virus, so the prevalence of antibodies at the herd level will be high. Chronically infected pigs may have undetectable or fluctuating antibody levels.

It may be possible to use sera collected for other survey purposes for CSF surveillance. However, the principles of survey design described in this Appendix and the requirement for statistical validity should not be compromised.

The discovery of clustering of seropositive reactions should be foreseen. It may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or the presence of infection by field strains or other pestiviruses. Because clustering may signal field strain infection, the investigation of all instances must be incorporated in the survey

design. Clustering of positive animals is always epidemiologically significant and therefore should be investigated.

In countries or zones that are moving towards freedom, serosurveillance can provide valuable information on the disease status and efficacy of any control programme. Targeted serosurveillance of young stock will indicate whether newly circulating virus is present, although the presence of maternal antibody will also need to be considered. If conventional attenuated vaccine is currently being used or has been used in the recent past, serology aimed at detecting the presence of field virus will likewise need to be targeted at unvaccinated animals and after the disappearance of maternal antibody. General usage in such situations may also be used, to assess levels of vaccine coverage.

Vaccines also exist which, when used in conjunction with dedicated serological tests, may allow discrimination between vaccinal antibody and that induced by field infection. Such tools, described in the *Terrestrial Manual*, will need to be fully validated. They do not confer the same degree of protection as that provided by conventional vaccines, particularly with respect to preventing transplacental infections. Furthermore, serosurveillance using such differentiation requires cautious interpretation on a herd basis.

The results of random or targeted serological surveys are important in providing reliable evidence that no CSFV infection is present in a country or zone. It is therefore essential that the survey be thoroughly documented.

Article X.X.X.4.

Country or zone free of CSF in domestic and wild pigs

1) Historically free status

The free status should be reviewed whenever evidence emerges to indicate that changes which may alter the underlying assumption of continuing historical freedom, has occurred. Such changes include but are not limited to:

a) an emergence, or an increase in the prevalence of CSF in countries or zones from which live pigs or products are imported;

b) an increase in the volume of imports or a change in their country or zone of origin;

c) an increase in the prevalence of CSF in the domestic or wild pigs of adjacent countries or zones;

d) an increased entry from, or exposure to, wild pig populations of adjacent countries or zones.

2) Free status as a result of an eradication programme

In addition to the general conditions described in Chapter 2.6.7., a Member Country seeking recognition of CSF freedom for the country or a zone, whether or not vaccination had been practised, should provide evidence for the existence of an effective surveillance programme. The strategy and design of the surveillance programme will depend on the prevailing epidemiological circumstances and will be planned and implemented according to general conditions and methods in this Appendix, to demonstrate the absence of CSFV infection, in domestic and wild pig populations. This requires the support of a national or other laboratory able to undertake identification of CSFV infection through virus detection and serological tests described in the *Terrestrial Manual*.

Article X.X.X.5.

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

1) In addition to the general conditions described in Chapter 2.6.7., a Member Country seeking recognition of CSF freedom for the country or a zone, whether or not vaccination had been practised, should provide evidence for the existence of an effective surveillance programme. The strategy and design of the surveillance programme will depend on the prevailing epidemiological circumstances and will be planned and implemented according to general conditions and methods in this Appendix, to demonstrate the absence of CSFV infection, in domestic and wild pig populations. This requires the support of a national or other laboratory able to undertake identification of CSFV infection through virus detection and serological tests described in the *Terrestrial Manual*.

2) The objective of surveillance in this instance is to demonstrate that the two subpopulations are effectively separated by measures that ensure the biosecurity of domestic pigs. To this end, a biosecurity programme which includes but is not limited to the following provisions should be implemented:

   a) a programme for the management of CSF in wild pigs;

   b) delineation of CSF wild pig control areas around every CSF case reported in wild pigs;

   c) assessment of the presence and mitigative role of natural boundaries;

   d) documentation of the ecology of the wild pig population;

   e) proper containment of domestic pigs;

   f) control of movement of *vehicles* with cleaning and *disinfection* as appropriate;

   g) control of personnel entering into the *establishments* and awareness of risk of fomite spread;

   h) prohibition of introduction to the *establishments* of hunted animals and products;

   i) registry of animal movements into and out of *establishments*;

   j) information and training programmes for farmers, hunters, processors, veterinarians, etc.

3) The biosecurity programme implemented would also require internal and external monitoring by the *Veterinary Authorities*. These elements should include but are not limited to:

   a) periodic clinical and serological monitoring of herds in the country or zone, and adjacent wild pig populations following these guidelines;

   b) herd registration;

   c) official accreditation of biosecurity programme;

   d) periodic monitoring and review.

4) Monitoring the CSF status of wild populations will be of value in assessing the degree of risk they pose to the CSF free domestic population. The design of a monitoring system for wild pigs is dependent on several factors such as the organization of the *Veterinary Services* and resources available. The occurrence of CSF in wild pigs may vary considerably among countries. Surveillance design should be scientifically based and the Member Country must justify its choice of design prevalence and level of confidence based on Appendix 3.8.1.

5) The geographic distribution and approximate size of wild pig populations need to be assessed as a prerequisite for designing a monitoring system. Sources of information may include wildlife conservation organizations, hunter associations and other available sources. The objective of a surveillance programme when the disease is already known to exist should be to determine the geographic distribution and the extent of the infection.

Article X.X.X.6.

Recovery of free status

1) Countries or zones re-seeking freedom from CSF following an outbreak

In addition to the general conditions described in Chapter 2.6.7. of the *Terrestrial Code*, a country re-seeking country or zone freedom from CSF should show evidence of an active surveillance programme for CSF as well as absence of CSFV infection.

Populations under this surveillance programme should include, but not be limited to:

a) *establishments* in the area of the *outbreak*;

b) *establishments* epidemiologically linked to the *outbreak*;

c) animals used to re-populate affected *establishments* and any *establishments* where contiguous culling is carried out;

d) wild pig populations in the area of the *outbreak*.

In all circumstances, a Member Country re-seeking country or zone freedom from CSF with vaccination or without vaccination should report the results of an active and passive surveillance programme in which the pig population undergoes regular clinical, pathological, virological, and/or serological examination, planned and implemented according to general conditions and methods in these guidelines. The surveillance should be based on a statistically representative sample of the populations at risk.

2) Country or zone free of CSF in wild pigs

While the same principles apply, surveillance in wild pigs presents challenges beyond those encountered in domestic populations in each of the following areas:

a) determination of the distribution, size and movement patterns associated with the wild pig population;

b) assessment of the possible presence of CSF within the population;

c) determination of the practicability of establishing zones.

The design of a monitoring system for wild pigs is dependent on several factors such as the organization of the *Veterinary Services* and resources available. The geographic distribution and approximate size of wild pig populations need to be assessed as a prerequisite for designing a monitoring system. Sources of information may include wildlife conservation organisations, hunter associations and other available sources. The objective of a surveillance programme is to determine the geographic distribution and estimation of target population.

Estimates of wild pig population can be made using advanced methods (radio tracking, linear transect method, capture/recapture) or traditional methods based on the number of animals that can be hunted to allow for natural restocking (hunting bags).

For implementation of the monitoring programme, it will be necessary to define the limits of the territory over which wild pigs range in order to delineate the epidemiological units within the monitoring programme. It is often difficult to define epidemiological units for wild animals. The most practical approach is based on natural and artificial barriers.

The monitoring programme should also include animals found dead, road kills, animals showing abnormal behaviour or exhibiting gross lesions during dressing.

There may be situations where a more targeted surveillance programme can provide additional assurance. The criteria to define high risk areas for targeted surveillance can be:

– areas with past history of CSF;

– sub-regions with high wild pig density;
– border regions with CSF affected countries or zones;
– areas of contact between sub-populations;
– picnic and camping areas;
– around farms with free-ranging pigs;
– special risk areas determined by local *Veterinary Authorities*.
– garbage dumps.

Appendix XVI

CHAPTER 2.7.12.

~~HIGHLY PATHOGENIC~~ AVIAN INFLUENZA

Community position:
The Community. can support the amendments proposed below but would like the points noted taken on board. However the Community believes that the application of compartmentalisation is extremely important and that a certain geographical disease freedom must be taken into account..

~~Article 2.7.12.1.~~

~~For the purposes of the *Terrestrial Code*, the *incubation period* for highly pathogenic avian influenza (HPAI) shall be 21 days.~~

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

~~Article 2.7.12.2.~~

~~**HPAI free country**~~

~~A country may be considered free from HPAI when it has been shown that HPAI has not been present for at least the past 3 years.~~

~~This period shall be 6 months after the slaughter of the last affected animal for countries in which a *stamping-out policy* is practised with or without vaccination against HPAI.~~

~~Article 2.7.12.3.~~

~~**HPAI infected zone**~~

~~A zone shall be considered as infected with HPAI until:~~

~~1) at least 21 days have elapsed after the confirmation of the last *case* and the completion of a *stamping-out policy* and *disinfection* procedures, or~~

~~2) 6 months have elapsed after the clinical recovery or death of the last affected animal if a *stamping-out policy* was not practised.~~

~~Article 2.7.12.4.~~

~~*Veterinary Administrations* of *importing countries* should require similar arrangements to those provided in Chapter 2.7.13. (Newcastle disease) of the *Terrestrial Code* for the following *commodities*:~~

~~1) domestic and wild birds;~~

~~2) *day-old birds*;~~

~~3) *hatching eggs*;~~

~~4) semen of domestic and wild birds;~~

~~5) *fresh meat* of domestic and wild birds;~~

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

~~7) *pathological material* and biological products (from birds) which have not been processed to ensure the destruction of the HPAI virus.~~

Article 2.7.12.5.
~~(under study)~~

1) For the purposes of the *Terrestrial Code*, ~~notifiable~~ avian influenza in its notifiable form (NAI) is defined as an infection of poultry caused by any influenza A virus of the H5 or H7 subtypes or by any AI virus with an intravenous pathogenicity index (IVPI) greater than 1.2 (or as an alternative at least 75% mortality) as described below. NAI viruses can be divided into highly pathogenic notifiable avian influenza (HPNAI) and low pathogenicity notifiable avian influenza (LPNAI):

   a) HPNAI viruses have an IVPI in 6-week-old chickens greater than 1.2 or, as an alternative, cause at least 75% mortality in 4-to 8-week-old chickens infected intravenously. H5 and H7 viruses which do not have an IVPI of greater than 1.2 or cause less than 75% mortality in an intravenous lethality test should be sequenced to determine whether multiple basic amino acids are present at the cleavage site of the haemagglutinin molecule (HA0); if the amino acid motif is similar to that observed for other HPNAI isolates, the isolate being tested should be considered as HPNAI.

   b) LPNAI are all influenza A viruses of H5 and H7 subtype that are not HPNAI viruses.

2) Poultry is defined as 'all birds reared or kept in captivity for the production of meat or eggs for consumption, for the production of other commercial products, for restocking supplies of game, or for breeding these categories of birds'.

Community position:

The Community would like the OIE to clarify that fighting cocks, and other poultry/ birds used for shows oe exhibitions are included in this definition as their meat may be used for consumption.

3) For the purpose of international *trade*, this chapter deals not only with the occurrence of clinical signs caused by NAI virus, but also with the presence of infection with NAI virus in the absence of clinical signs.

4) The following defines the occurrence of infection with NAI virus:

   a) HPNAI virus has been isolated and identified as such or ~~specific~~ viral RNA specific for HPNAI has been detected in poultry or a product derived from poultry; or

   b) LPNAI virus has been isolated and identified as such or ~~specific~~ viral RNA specific for LPNAI has been detected in poultry or a product derived from poultry; or

   c) antibodies to H5 or H7 subtype of NAI virus that are not a consequence of vaccination~~, nor indicative of a non-specific reaction, have been detected in poultry; in such cases, virus isolation should be attempted to establish whether the serological positivity is due to LPNAI or HPNAI. If appropriate samples are not available or if results are negative, a thorough epidemiological investigation including further sampling and testing should be carried out to identify the type or exclude the presence of NAI infection.~~ have been detected in poultry. In the case of isolated serological positive results, NAI infection may be ruled out on the basis of a thorough

epidemiological investigation that does not demonstrate further evidence of NAI infection.

~~For the purposes of this *Terrestrial Code*, 'NAI free establishment' means an *establishment* in which there has been no clinical sign of NAI for the past 21 days and is not situated within 3 kilometres of any *establishment* infected with HPNAI and within one kilometre of any *establishment* infected with LPNAI.~~

For the purposes of the *Terrestrial Code*, 'NAI free establishment' means an *establishment* in which the poultry have shown no evidence of NAI infection, based on surveillance in accordance with Appendix XXX.

For the purposes of the *Terrestrial Code*, the *incubation period* for NAI shall be 21 days.

Standards for diagnostic tests are, including pathogenicity testing, described in the *Terrestrial Manual*. Any vaccine used should comply with the standards described in the *Terrestrial Manual*.

Article 2.7.12.6.
~~(under study)~~

The NAI status of a country, a *zone* or a *compartment* can be determined on the basis of the following criteria:

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

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

3) appropriate surveillance is in place to demonstrate the presence of infection in the absence of clinical signs in poultry, and the risk posed by birds other than poultry; this may be achieved through an NAI surveillance programme in accordance with Appendix XXX ~~this Chapter and Chapter 1.3.6~~.

Article 2.7.12.7.
~~(under study)~~

NAI free country, zone or compartment

A country, *zone* or *compartment* may be considered free from NAI when it has been shown that neither HPNAI nor LPNAI infection has been present in the country, *zone* or *compartment* for the past 12 months, based on surveillance in accordance with Appendix XXX. The surveillance may need to be adapted to parts of the country or existing *zones* or c*ompartments* depending on historical or geographical factors, industry structure, population data, or proximity to recent *outbreaks*.

If infection has occurred in a previously free country, *zone* or *compartment*, free status can be regained:

1) In the case of HPNAI infections, 3 months after a *stamping out policy* (including *disinfection* of all affected *establishments*) is applied, providing that surveillance in accordance with Appendix XXX has been carried out during that three-month period.

2) In the case of LPNAI infections, poultry may be kept for slaughter for human consumption subject to specified conditions or a *stamping out policy* applied; in either case, 3 months after the *disinfection* of all affected *establishments*, providing that surveillance in accordance with Appendix XXX has been carried out during that three-month period.

~~A country or *zone/compartment* may be considered free from NAI when it has been shown that NAI infection has not been present for the past 12 months. If infected poultries are slaughtered, this period~~

~~shall be 3 months after the slaughter of the last infected poultry and *disinfection* of all affected *establishments*.~~

~~The NAI status should be determined by an ongoing surveillance and monitoring programme (carried out in conformity with the provisions of Chapter 1.3.6.) based on virus isolation, virus detection or serology. The programme may need to be adapted to target parts of the country or *zone/compartment* at a higher risk due to historical or geographical factors, population data, or proximity to recent *outbreaks*.~~

~~Freedom of infection in a country or zone can be demonstrated with random and/or targeted serological surveillance at a minimum interval of 6 months designed to provide at least a 95% level of confidence of detecting a prevalence of NAI infected enterprises of 1%. Freedom of infection in a *compartment* can be demonstrated with an ongoing surveillance programme designed to provide at least a 95% level of confidence of detecting a prevalence of NAI infection of 10%. Each *establishment* should be sampled to provide a 95% level of confidence of detecting a prevalence of NAI of 25%. For commercial ducks the surveillance programme should be based on virus isolation or detection in the absence of validated serological methods.~~

~~In the case of a country or *zone* in which vaccination is being conducted, the ongoing surveillance and monitoring programme (carried out in conformity with the provisions of Chapter 1.3.6.) based on virus isolation, virus detection or serology should be carried out on all vaccinated flocks at a minimum interval of 6 months. In each vaccinated flock, the number of birds to be tested should provide at least a 95% level of confidence of detecting a prevalence of NAI infection of 25%. In the case of a *compartment* in which vaccination is being conducted, the ongoing surveillance and monitoring programme (carried out in conformity with the provisions of Chapter 1.3.6.) based on virus isolation, virus detection or serology should be carried out to provide at least a 95% level of confidence of detecting a prevalence of NAI infection of 10%. If a serological test is used, it should be able to distinguish vaccinated birds from infected birds. Additional security should be provided by the use of identifiable sentinel birds which can be clinically inspected or tested to help identify field infections in vaccinated flocks.~~

Article 2.7.12.7.bis

HPNAI free country, zone or compartment

A country, *zone* or *compartment* may be considered free from HPNAI when it has been shown that HPNAI infection has not been present in the country, *zone* or *compartment* for the past 12 months, although its LPNAI status may be unknown, when, based on surveillance in accordance with Appendix XXX, it does not meet the criteria for freedom from NAI but any NAI virus detected has not been identified as HPNAI virus. The surveillance may need to be adapted to parts of the country or *zones/compartments* depending on historical or geographical factors, industry structure, population data, or proximity to recent *outbreaks*.

If infection has occurred in a previously free country, *zone* or *compartment*, free status can be regained 3 months after a *stamping out policy* (including *disinfection* of all affected *establishments*) is applied, providing that surveillance in accordance with Appendix XXX has been carried out during that 3-month period.

Article 2.7.12.8.
~~(under study)~~

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

for live poultry (other than day-old poultry)

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

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

2) were kept in an NAI free country, *zone* or *compartment* since they were hatched or for the past 21 days;

2)bis the required surveillance has been carried out on the *establishment* within the past 21 days.

~~3) either have not been vaccinated against NAI, or have been vaccinated and the date of vaccination and the details of the vaccine are stated.~~

Information concerning the vaccination status of the poultry (including the dates of vaccination and the vaccine used) should be included in the veterinary certificate.

Article 2.7.12.9.
~~(under study)~~

Regardless of the NAI status of the country, *zone* or *compartment* of origin, *Veterinary Administrations* should require:

for live birds other than poultry

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

1) showed no clinical sign of infection with a virus which would be considered NAI in poultry on the day of shipment;

2) were kept in isolation approved by the *Veterinary Services* since they were hatched or for the 21 days prior to shipment and showed no clinical sign of infection with a virus which would be considered NAI in poultry during the isolation period;

3) were subjected to a diagnostic test 7 to 14 days prior to shipment to demonstrate freedom from infection with a virus which would be considered NAI in poultry; and

4) are transported in new containers.

Article 2.7.12.10.
~~(under study)~~

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

for day-old live poultry

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

1) were kept in an NAI free country, *zone* or *compartment* since they were hatched;

2) were derived from parent flocks which had been kept in an NAI free country, *zone* or *compartment* for 21 days prior to and at the time of the collection of the eggs;

~~3) and/or the parent flock had/had not been vaccinated and, if vaccinated, the date of vaccination and the details of the vaccine are stated.~~

Information concerning the vaccination status of the poultry and the parent flocks (including the dates of vaccination and the vaccine used) should be included in the veterinary certificate.

Article 2.7.12.10.bis

When importing from an HPNAI free country, *zone* or *compartment*, *Veterinary Administrations* should

require:

for day-old live poultry

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

1) were kept in an HPNAI free country, *zone* or *compartment* since they were hatched;

2) were derived from parent flocks which had been kept in an NAI free establishment for 21 days prior to and at the time of the collection of the eggs;

3) are transported in new containers.

Information concerning the vaccination status of the poultry and the parent flocks (including the dates of vaccination and the vaccine used) should be included in the veterinary certificate.

Article 2.7.12.11.
~~(under study)~~

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

for *hatching eggs*

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

1) came from an NAI free country, *zone* or *compartment*;

2) were derived from parent flocks which had been kept in an NAI free country, *zone* or *compartment* for 21 days prior to and at the time of the collection of the eggs.

~~3) were derived from parent flocks which had not been vaccinated against NAI, or which had been vaccinated against NAI and the date of vaccination and the details of the vaccine are stated.~~

Information concerning the vaccination status of the parent flocks (including the dates of vaccination and the vaccine used) should be included in the veterinary certificate.

Article 2.7.12.11.bis

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

for *hatching eggs*

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

1) came from an HPNAI free country, *zone* or *compartment*;

2) were derived from parent flocks which had been kept in an NAI free establishment for 21 days prior to and at the time of the collection of the eggs;

3) are transported in new packing material.

Information concerning the vaccination status of the parent flocks (including the dates of vaccination and the vaccine used) should be included in the veterinary certificate.

Article 2.7.12.12.
~~(under study)~~

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

for eggs for human consumption

the presentation of an *international veterinary certificate* attesting that the eggs come from an NAI free country, *zone* or *compartment*.

Article 2.7.12.13.
~~(under study)~~

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

for eggs for human consumption

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

1) come from a country, *zone* or *compartment* free from HPNAI infection; and

2) come from *establishments* in which there has been no evidence of NAI in the past 21 days;

3) are transported in new ~~disposable~~ packing material.

~~Article 2.7.12.14.~~
~~(under study)~~

~~When importing from a country or *zone/compartment* not known to be free from HPNAI, *Veterinary Administrations* should require:~~

~~for eggs for consumption~~

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

~~1) which have been kept in an NAI free *establishment*;~~

~~2) which have been tested serologically or by virus detection to give a 95% probability of detecting a 5% prevalence of NAI infection, every 21 days, with negative results.~~

Article 2.7.12.15.
~~(under study)~~

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

for egg products

the presentation of an *international veterinary certificate* attesting that the egg products come from, and were processed in, an NAI free country, *zone* or *compartment*.

~~Article 2.7.12.16.~~
~~(under study)~~

~~When importing from a country or *zone/compartment* free from HPNAI infection, *Veterinary*~~

~~*Administrations* should require:~~

~~for egg products~~

~~the presentation of an *international veterinary certificate* attesting that the egg products come from, and were processed in a country or *zone/compartment* free from HPNAI infection.~~

Article 2.7.12.17.
~~(under study)~~

Regardless of the NAI status of the country, *zone* or *compartment* of origin ~~When importing from a country, *zone* or *compartment* not known to be free from HPNAI~~, *Veterinary Administrations* should require:

for egg products

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

1) are derived from eggs ~~for consumption~~ which meet the requirements of Articles 2.7.12.11, 2.7.12.11.bis, 2.7.12.12., or 2.7.12.13. ~~or 2.7.12.14.~~; or

2) were processed to ensure the destruction of NAI virus (under study), and the necessary precautions were taken after processing to avoid contact of the commodity with any source of NAI virus.

Article 2.7.12.18.
~~(under study)~~

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

for poultry semen

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

1) showed no clinical sign of NAI on the day of semen collection;

2) were kept in an NAI free country, *zone* or *compartment* for the 21 days prior to and at the time of semen collection.

Article 2.7.12.18.bis

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

for poultry semen

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

1) came from an HPNAI free country, *zone* or *compartment*;

2) were kept in an NAI free *establishment* for 21 days prior to and at the time of semen collection.

Information concerning the vaccination status of the donor flocks (including the dates of vaccination and the vaccine used) should be included in the veterinary certificate.

Article 2.7.12.19.

~~(under study)~~

Regardless of the NAI status of the country, *zone* or *compartment* of origin, *Veterinary Administrations* should require:

for semen of birds other than poultry

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

1) were kept in isolation approved by the *Veterinary Services* for the 21 days prior to semen collection;

2) showed no clinical sign of infection with a virus which would be considered NAI in poultry during the isolation period;

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

Article 2.7.12.20.
~~(under study)~~

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

for *fresh meat* ~~and *meat products*~~ of poultry~~, and poultry viscera~~

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

1) which have been kept in an NAI free country, *zone* or *compartment* since they were hatched or for the past 21 days;

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

Article 2.7.12.21.
~~(under study)~~

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

for *fresh meat* ~~and *meat products*~~ of poultry ~~(other than turkey)~~

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

1) which have been kept in an *establishment* since they were hatched or for the past 21 days and in which there has been no ~~clinical sign~~ evidence of NAI in the past 21 days; and

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

~~Article 2.7.12.22.~~
~~(under study)~~

~~When importing from a country or *zone/compartment* not known to be free from HPNAI, *Veterinary Administrations* should require:~~

~~for *fresh meat* and *meat products* of poultry and poultry viscera (other than turkey)~~

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

~~1) which have been kept in a free *establishment*;~~

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

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

~~Article 2.7.12.23.~~
~~(under study)~~

~~When importing from a country or *zone/compartment* not known to be free from NAI, *Veterinary Administrations* should require:~~

~~for *fresh meat* and *viscera* of turkey~~

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

~~1) which have been kept in a free *establishment*;~~

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

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

Article 2.7.12.24.
~~(under study)~~

Regardless of the NAI status of the ~~When importing from a~~ country, *zone* or *compartment* of origin ~~not known to be free from NAI~~, *Veterinary Administrations* should require:

for *meat products* ~~and processed viscera~~ of poultry

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

1) the *commodity* is derived from *fresh meat* ~~and/or *meat products* and/or viscera~~ which meet the requirements of Articles 2.7.12.20. or 2.7.12.21. ~~or 2.7.12.22.~~; or

2) the *commodity* has been processed to ensure the destruction of NAI virus;

3) the necessary precautions were taken ~~after processing~~ to avoid contact of the *commodity* with any source of NAI virus.

Article 2.7.12.25.
~~(under study)~~

Regardless of the NAI status of the ~~When importing from an NAI free~~ country, *zone* or *compartment* of origin, *Veterinary Administrations* should require:

for products of poultry origin intended for use in animal feeding, or for agricultural or industrial use

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

1) these *commodities* come from birds which have been kept in an NAI free country, *zone* or *compartment* since they were hatched or for the past 21 days; or

2) these *commodities* have been processed to ensure the destruction of NAI virus;

3) the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

~~Article 2.7.12.26.~~
~~(under study)~~

~~When importing from a country or *zone/compartment* not considered free from NAI, *Veterinary Administrations* should require:~~

~~for meal containing meat and/or feathers and/or bones (from poultry)~~

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

~~1) the commodity has been processed to ensure the destruction of the NAI virus;~~

~~2) the necessary precautions were taken after processing to avoid contact of the *commodity* with any source of NAI virus.~~

Article 2.7.12.27.
~~(under study)~~

Regardless of the NAI status of the ~~When importing from an NAI free~~ country, *zone* or *compartment* of origin, *Veterinary Administrations* should require:

for feathers and down (from poultry)

~~the presentation of an *international veterinary certificate* attesting that the entire consignment of feathers or down comes from birds which have been kept in an NAI free country or *zone/compartment* since they were hatched or for the past 21 days.~~

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

1) these *commodities* come from birds which have been kept in an NAI free country, *zone* or *compartment* since they were hatched or for the past 21 days; or

2) these *commodities* have been processed to ensure the destruction of NAI virus;

3) the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

~~Article 2.7.12.28.~~
~~(under study)~~

~~When importing from a country or *zone/compartment* not known to be free from NAI, *Veterinary Administrations* should require:~~

~~for feathers and down (from poultry)~~

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

~~1) the *commodity* has been processed to ensure the destruction of the NAI virus;~~

~~2) the necessary precautions were taken after processing to avoid contact of the *commodity* with any source of NAI virus.~~

Article 2.7.12.29.
~~(under study)~~

Regardless of the NAI status of the country, *zone* or *compartment*, *Veterinary Administrations* should require for the importation of:

meat or other products from birds other than poultry

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

1) the *commodity* has been processed to ensure the destruction of NAI virus;

2) the necessary precautions were taken after processing to avoid contact of the *commodity* with any source of NAI virus.

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

~~—~~ text deleted

Appendix XVII

APPENDIX 3.X.X.

GUIDELINES FOR THE SURVEILLANCE OF AVIAN INFLUENZA

Community position:
The Community. can support this draft but would ask the OIE to continue to develop the draft further with experts including examples of surveillance designs.

Article 3.X.X.1.

Introduction

This Appendix defines the principles and provides a guide for the surveillance of notifiable avian influenza (NAI) in accordance with Appendix 3.8.1., applicable to countries seeking recognition for a declared NAI status, with or without the use of vaccination. This may be for the entire country, *zone* or *compartment*. Guidance for countries seeking free status following an *outbreak* and for the maintenance of NAI status are provided. This Appendix complements Chapter 2.7.12.

The presence of NAI in wild birds creates a particular problem. In essence, no country can declare itself free from avian influenza (AI) in wild birds. However, the definition of NAI in Chapter 2.7.12. refers to the infection in poultry only and this Appendix was developed under this definition.

The impact and epidemiology of NAI differ widely in different regions of the world and therefore it is impossible to provide specific guidelines for all situations. It is axiomatic that the surveillance strategies employed for demonstrating freedom from NAI at an acceptable level of confidence will need to be adapted to the local situation. Variables such as the frequency of contacts of poultry with wild birds, different biosecurity levels and production systems and the commingling of different susceptible species including domestic waterfowl require specific surveillance strategies to address each specific situation. It is incumbent upon the country to provide scientific data that explains the epidemiology of NAI in the region concerned and also demonstrates how all the risk factors are managed. There is therefore considerable latitude available to Member Countries to provide a well-reasoned argument to prove that absence of NAI virus (NAIV) infection is assured at an acceptable level of confidence.

Surveillance for NAI should be in the form of a continuing programme designed to establish that the country, *zone* or *compartment*, for which application is made, is free from NAIV infection.

Article 3.X.X.2.

General conditions and methods

1) A surveillance system in accordance with Appendix 3.8.1. should be under the responsibility of the *Veterinary Administration*. In particular:

   a) a formal and ongoing system for detecting and investigating *outbreaks of disease* should be in place;

   b) a procedure should be in place for the rapid collection and transport of samples from suspect cases of NAI to a laboratory for NAI diagnosis as described in the *Terrestrial Manual*;

c) a system for recording, managing and analysing diagnostic and surveillance data should be in place.

2) The NAI surveillance programme should:

a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers, who have day-to-day contact with poultry, as well as diagnosticians, should report promptly any suspicion of NAI to the *Veterinary Authority*. They should be supported directly or indirectly (e.g. through private veterinarians or *veterinary para-professionals*) by government information programmes and the *Veterinary Administration*. All suspected cases of NAI should be investigated immediately. Where suspicion cannot be resolved by epidemiological and clinical investigation, as is frequently the case with LPNAI virus infections, samples should be taken and submitted to an *approved laboratory*. This requires that sampling kits and other equipment are available for those responsible for surveillance. Personnel responsible for surveillance should be able to call for assistance from a team with expertise in NAI diagnosis and control. In cases where potential public health implications are suspected, notification to the appropriate public health authorities is essential;

b) implement, when relevant, regular and frequent clinical inspection, serological and virological testing of high-risk groups of animals, such as those adjacent to an NAI infected country, *zone* or *compartment*, places where birds and poultry of different origins are mixed, such as live bird markets, poultry in close proximity to waterfowl or other sources of NAIV.

An effective surveillance system will periodically identify suspicious cases that require follow up and investigation to confirm or exclude that the cause of the condition is NAIV. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from NAIV infection should, in consequence, provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of laboratory testing and the control measures to which the animals concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

Article 3.X.X.3.

Surveillance strategies

The target population for surveillance aimed at identification of *disease* and *infection* should cover all the susceptible poultry species within the country, *zone* or *compartment*. Active and passive surveillance for NAI should be ongoing. The frequency of active surveillance should be at least every 6 months. Surveillance should be composed of random and targeted approaches using virological, serological and clinical methods.

The strategy employed may be based on randomised sampling requiring surveillance consistent with demonstrating the absence of NAIV infection at an acceptable level of confidence. The frequency of sampling should be dependent on the epidemiological situation. Random surveillance is conducted using serological tests described in the *Terrestrial Manual*. Positive serological results should be followed up with virological methods.

Targeted surveillance (e.g. based on the increased likelihood of *infection* in particular localities or species) may be an appropriate strategy. Virological and serological methods should be used concurrently to define the NAI status of high risk populations.

A country should justify the surveillance strategy chosen as adequate to detect the presence of NAIV infection in accordance with Appendix 3.8.1. and the prevailing epidemiological situation. It may, for example, be appropriate to target clinical surveillance at particular species likely to exhibit clear clinical signs (e.g. chickens). Similarly, virological and serological testing could be targeted to species that may not show clinical signs (e.g. ducks).

If a Member Country wishes to declare freedom from NAIV infection in a specific *zone* or *compartment*, the design of the survey and the basis for the sampling process would need to be aimed at the population within the *zone* or *compartment*.

For random surveys, the design of the sampling strategy will need to incorporate epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect *infection* if it were to occur at a predetermined minimum rate. The sample size and expected disease prevalence determine the level of confidence in the results of the survey. The applicant country must justify the choice of design prevalence and confidence level based on the objectives of surveillance and the epidemiological situation, in accordance with Appendix 3.8.1. Selection of the design prevalence in particular clearly needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the survey approach selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the vaccination/infection history and the different species in the target population.

Irrespective of the testing system employed, surveillance system design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether they are indicative of infection or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as flocks which may be epidemiologically linked to it.

The principles involved in surveillance for *disease/infection* are technically well defined. The design of surveillance programmes to prove the absence of NAIV infection/circulation needs to be carefully followed to avoid producing results that are either insufficiently reliable to be accepted by the OIE or international trading partners, or excessively costly and logistically complicated. The design of any surveillance programme, therefore, requires inputs from professionals competent and experienced in this field.

1) Clinical surveillance

Clinical surveillance aims at the detection of clinical signs of NAI at the flock level. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, surveillance based on clinical inspection should not be underrated. Monitoring of production parameters, such as increased mortality, reduced feed and water consumption, presence of clinical signs of a respiratory disease or a drop in egg production, is important for the early detection of NAIV infection. In some cases, the only indication of LPNAIV infection may be a drop in feed consumption or egg production.

Clinical surveillance and laboratory testing should always be applied in series to clarify the status of NAI suspects detected by either of these complementary diagnostic approaches. Laboratory testing may confirm clinical suspicion, while clinical surveillance may contribute to confirmation of positive serology. Any sampling unit within which suspicious animals are detected should be classified as infected until evidence to the contrary is produced.

Identification of suspect flocks is vital to the identification of sources of NAIV and to enable the molecular, antigenic and other biological characteristics of the virus to be determined. It is essential that NAIV isolates are sent regularly to the regional Reference Laboratory for genetic and antigenic characterization.

2) Virological surveillance

Virological surveillance using tests described in the *Terrestrial Manual* should be conducted:

a) to monitor at risk populations;

b) to confirm clinically suspect cases;

c) to follow up positive serological results;

d) to test 'normal' daily mortality, to ensure early detection of infection in the face of vaccination or in *establishments* epidemiologically linked to an *outbreak*.

3) Serological surveillance

Serological surveillance aims at the detection of antibodies against NAIV. Positive NAIV antibody test results can have four possible causes:

a) natural infection with NAIV;

b) vaccination against NAI;

c) maternal antibodies derived from a vaccinated or infected parent flock are usually found in the yolk and can persist in progeny for up to 4 weeks;

d) positive results due to the lack of specificity of the test.

It may be possible to use serum collected for other survey purposes for NAI surveillance. However, the principles of survey design described in these guidelines and the requirement for a statistically valid survey for the presence of NAIV should not be compromised.

The discovery of clusters of seropositive flocks may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or infection. As clustering may signal infection, the investigation of all instances must be incorporated in the survey design. Clustering of positive flocks is always epidemiologically significant and therefore should be investigated.

If vaccination cannot be excluded as the cause of positive serological reactions, diagnostic methods to differentiate antibodies due to infection or vaccination should be employed.

The results of random or targeted serological surveys are important in providing reliable evidence that no NAIV infection is present in a country, *zone* or *compartment*. It is therefore essential that the survey be thoroughly documented.

3) Virological and serological surveillance in vaccinated populations

The surveillance strategy is dependent on the type of vaccine used. The protection against AI is haemagglutinin subtype specific. Therefore, two broad vaccination strategies exist: 1) inactivated whole AI viruses, and 2) haemagglutinin expression-based vaccines.

In the case of vaccinated populations, the surveillance strategy should be based on virological and/or serological methods and clinical surveillance. It may be appropriate to use sentinel birds for this purpose. These birds should be unvaccinated, AI virus antibody free birds and clearly and permanently identified. The interpretation of serological results in the presence of vaccination is described in 3.X.X.6.

Article 3.X.X.4.

Documentation of NAI or HPNAI free status

1) Countries declaring freedom from NAI or HPNAI for the country, zone or compartment

In addition to the general conditions described in Chapter 2.7.12. of the *Terrestrial Code*, a Member Country declaring freedom from NAI for the entire country, or a *zone* or a *compartment* should provide evidence for the existence of an effective surveillance programme. The strategy and design of the surveillance programme will depend on the prevailing epidemiological circumstances and should be planned and implemented according to general conditions and methods described in this Appendix, to demonstrate absence of NAIV infection, during the preceding 12 months in susceptible poultry populations (vaccinated and non-vaccinated). This requires the support of a laboratory able to undertake identification of NAIV infection through virus detection and antibody tests described in the *Terrestrial Manual*. This surveillance may be targeted to poultry population at specific risks linked to the types of production, possible direct or indirect contact with wild birds, multi-age flocks, local trade patterns including live bird markets, use of possibly contaminated surface water, and the presence of more than one species on the holding and poor biosecurity measures in place.

2) Additional requirements for countries, zones or compartments that practise vaccination

Vaccination to prevent the transmission of HPNAI virus may be part of a disease control programme. The level of flock immunity required to prevent transmission will depend on the flock size, composition (e.g. species) and density of the susceptible poultry population. It is therefore impossible to be prescriptive. The vaccine must also comply with the provisions stipulated for NAI vaccines in the *Terrestrial Manual*. Based on the epidemiology of NAI in the country, *zone* or *compartment*, it may be that a decision is reached to vaccinate only certain species or other poultry subpopulations.

In all vaccinated flocks there is a need to perform virological and serological tests to ensure the absence of virus circulation. The use of sentinel poultry may provide further confidence of the absence of virus circulation. The tests have to be repeated at least every 6 months or at shorter intervals according to the risk in the country, *zone* or *compartment*.

Evidence to show the effectiveness of the vaccination programme should also be provided.

Article 3.X.X.5.

Countries, zones or compartments re-declaring freedom from NAI or HPNAI following an outbreak

In addition to the general conditions described in Chapter 2.7.12., a country re-declaring for country, *zone* or *compartment* freedom from NAI or HPNAI virus infection should show evidence of an active surveillance programme depending on the epidemiological circumstances of the *outbreak* to demonstrate the absence of the *infection*. This will require surveillance incorporating virus detection and antibody tests described in the *Terrestrial Manual*.

A Member Country declaring freedom of country, *zone* or *compartment* after an *outbreak* of NAI or HPNAI (with or without vaccination) should report the results of an active surveillance programme in which the NAI or HPNAI susceptible poultry population undergoes regular clinical examination and active surveillance planned and implemented according to the general conditions and methods described in these guidelines. The surveillance should at least give the confidence that can be given by a randomized representative sample of the populations at risk.

Article 3.X.X.6.

NAI free establishments within HPNAI free compartments

The declaration of NAI free *establishments* requires the demonstration of absence of NAIV infection. Birds in these *establishments* should be randomly tested using virus detection or isolation tests, and serological methods, following the general conditions of these guidelines. The frequency of testing should be based on the risk of infection and at a maximum interval of 21 days.

Article 3.X.X.7.

The use and interpretation of serological and virus detection tests

Poultry infected with NAI virus produce antibodies to haemagglutinin (HA), neuraminidase (NA), nonstructural proteins (NSPs), nucleoprotein/matrix (NP/M) and the polymerase complex proteins. Detection of antibodies against the polymerase complex proteins will not be covered in this Appendix. Tests for NP/M antibodies include direct and blocking ELISA, and agar gel immunodiffusion (AGID) tests. Tests for antibodies against NA include the neuraminidase inhibition (NI), indirect fluorescent antibody and direct ELISA tests. For the HA, antibodies are detected in haemagglutination inhibition (HI) and neutralization (SN) tests. The HI test is reliable in avian species but not in mammals. The SN test can be used to detect subtype specific antibodies to the haemagglutinin and is the preferred test for mammals and some avian species. The AGID test is reliable for detection of NP/M antibodies in chickens and turkeys, but not in other avian species. As an alternative, blocking ELISA tests have been developed to detect NP/M antibodies in all avian species.

The HI and NI tests can be used to subtype AI viruses into 15 haemagglutinin and 9 neuraminidase subtypes. Such information is helpful for epidemiological investigations and in categorization of AI viruses.

Poultry can be vaccinated with a variety of AI vaccines including inactivated whole AI virus vaccines, and haemagglutinin expression-based vaccines. Antibodies to the haemagglutinin confer subtype specific protection. Various strategies can be used to differentiate vaccinated from infected birds including serosurveillance in unvaccinated sentinel birds or specific serological tests in the vaccinated birds.

AI virus infection of unvaccinated birds including sentinels is detected by antibodies to the NP/M, subtype specific HA or NA proteins, or NSP. In poultry vaccinated with haemagglutinin expression-based vaccines, antibodies are detected to the specific HA, but not any of the other AI viral proteins. Infection is evident by antibodies to the NP/M or NSP, or the specific NA protein of the field virus. Poultry vaccinated with inactivated whole AI vaccines may develop low titres of antibodies to NSP, but the titre in infected birds will be markedly higher. Alternatively, usage of a vaccine strain with a different NA subtype than the field virus can allow differentiation of vaccinated from infected birds (DIVA) by detection of subtype specific NA antibodies of the field virus. Vaccines used should comply with the standards of the *Terrestrial Manual.*

All flocks with seropositive results should be investigated. Epidemiological and supplementary laboratory investigation results should document the status of NAI infection/circulation for each positive flock.

A confirmatory test should have a higher specificity than the screening test and sensitivity at least equivalent than that of the screening test.

Information should be provided on the performance characteristics and validation of tests used.

1) The follow up procedure in case of positive test results if vaccination is used

In case of vaccinated populations, one has to exclude the likelihood that positive test results are indicative of virus circulation. To this end the following procedure should be followed in the investigation of positive serological test results derived from surveillance conducted on NAI-vaccinated poultry. The investigation should examine all evidence that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were not due to virus circulation. All the epidemiological information should be substantiated and the results should be collated in the final report.

Knowledge of the type of vaccine used is crucial in developing a serological based strategy to differentiate infected from vaccinated animals.

a) Inactivated whole AI virus vaccines can use either homologous or heterologous neuraminidase subtypes between the vaccine and field strains. If poultry in the population have antibodies to NP/M and were vaccinated with inactivated whole AI virus vaccine, the following strategies should be applied:

   i) sentinel birds should remain NP/M antibody negative. If positive for NP/M antibodies, indicating AI virus infection, specific HI tests should be performed to identify H5 or H7 AI virus infection;

   ii) if vaccinated with inactivated whole AI virus vaccine containing homologous NA to field virus, the presence of antibodies to NSP could be indicative of infection. Sampling should be initiated to exclude the presence of NAIV by either virus isolation or detection of virus specific genomic material or proteins;

   iii) if vaccinated with inactivated whole AI virus vaccine containing heterologous NA to field virus, presence of antibodies to the field virus NA or NSP would be indicative of infection. Sampling should be initiated to exclude the presence of NAIV by either virus isolation or detection of virus specific genomic material or proteins.

b) Hemagglutinin expression-based vaccines contain the HA protein or gene homologous to the HA of the field virus. Sentinel birds as described above can be used to detect AI infection. In vaccinated or sentinel birds, the presence of antibodies against NP/M, NSP or field virus NA is indicative of infection. Sampling should be initiated to exclude the presence of NAIV by either virus isolation or detection of virus specific genomic material or proteins.

2) The follow up procedure in case of positive test results indicative of infection for determination of infection due to HPNAI or LPNAI virus

The detection of antibodies indicative of a NAI virus infection as indicated in point a)i) above will result in the initiation of epidemiological and virological investigations to determine if the infections are due to HPNAI or LPNAI viruses.

Virological testing should be initiated in all antibody-positive and at risk populations. The samples should be evaluated for the presence of AI virus, by virus isolation and identification, and/or detection of influenza A specific proteins or nucleic acids (Figure 2). Virus isolation is the gold standard for detecting infection by AI virus and the method is described in the *Terrestrial Manual*. All AI virus isolates should be tested to determine HA and NA subtypes, and *in vivo* tested in chickens and/or sequencing of HA proteolytic cleavage site of H5 and H7 subtypes for determination of classification as HPNAI, LPNAI or LPAI (not notifiable) viruses. As an alternative, nucleic acid detection tests have been developed and validated; these tests have the sensitivity of virus isolation, but with the advantage of providing results within a few hours. Samples with detection of H5 and H7 HA subtypes by nucleic acid detection methods should either be submitted for virus isolation, identification, and *in vivo* testing in chickens, or sequencing of nucleic acids for determination of proteolytic cleavage site as HPNAI or LPNAI viruses. The antigen detection systems, because of low sensitivity, are best suited for screening clinical field cases for infection by Type A influenza virus looking for NP/M proteins. NP/M positive samples should be submitted for virus isolation, identification and pathogenicity determination.

Laboratory results should be examined in the context of the epidemiological situation. Corollary information needed to complement the serological survey and assess the possibility of viral circulation includes but is not limited to:

a) characterization of the existing production systems;

b) results of clinical surveillance of the suspects and their cohorts;

c) quantification of vaccinations performed on the affected sites;

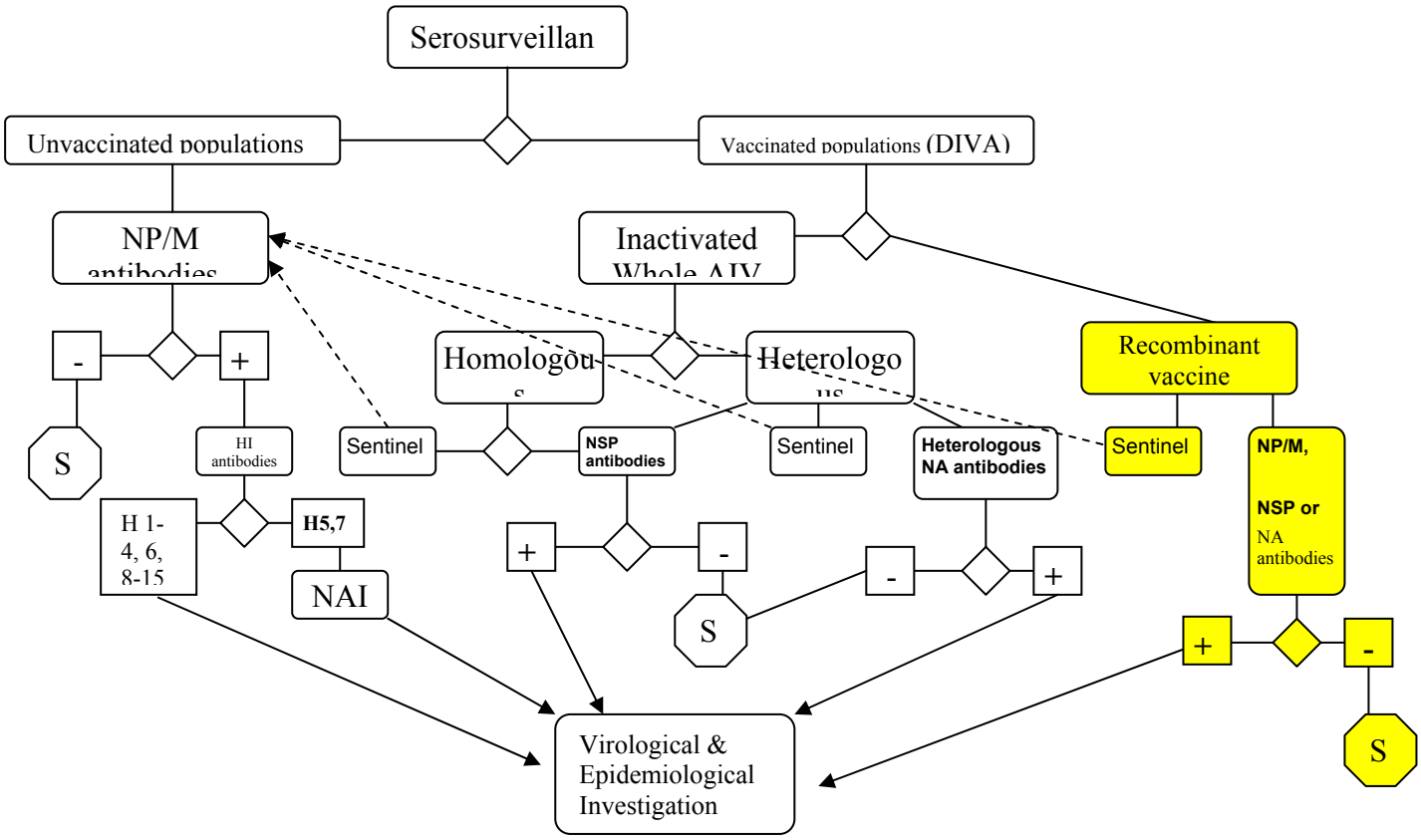
d) sanitary protocol and history of the affected establishments;

e) control of animal identification and movements;

f) other parameters of regional significance in historic NAIV transmission.

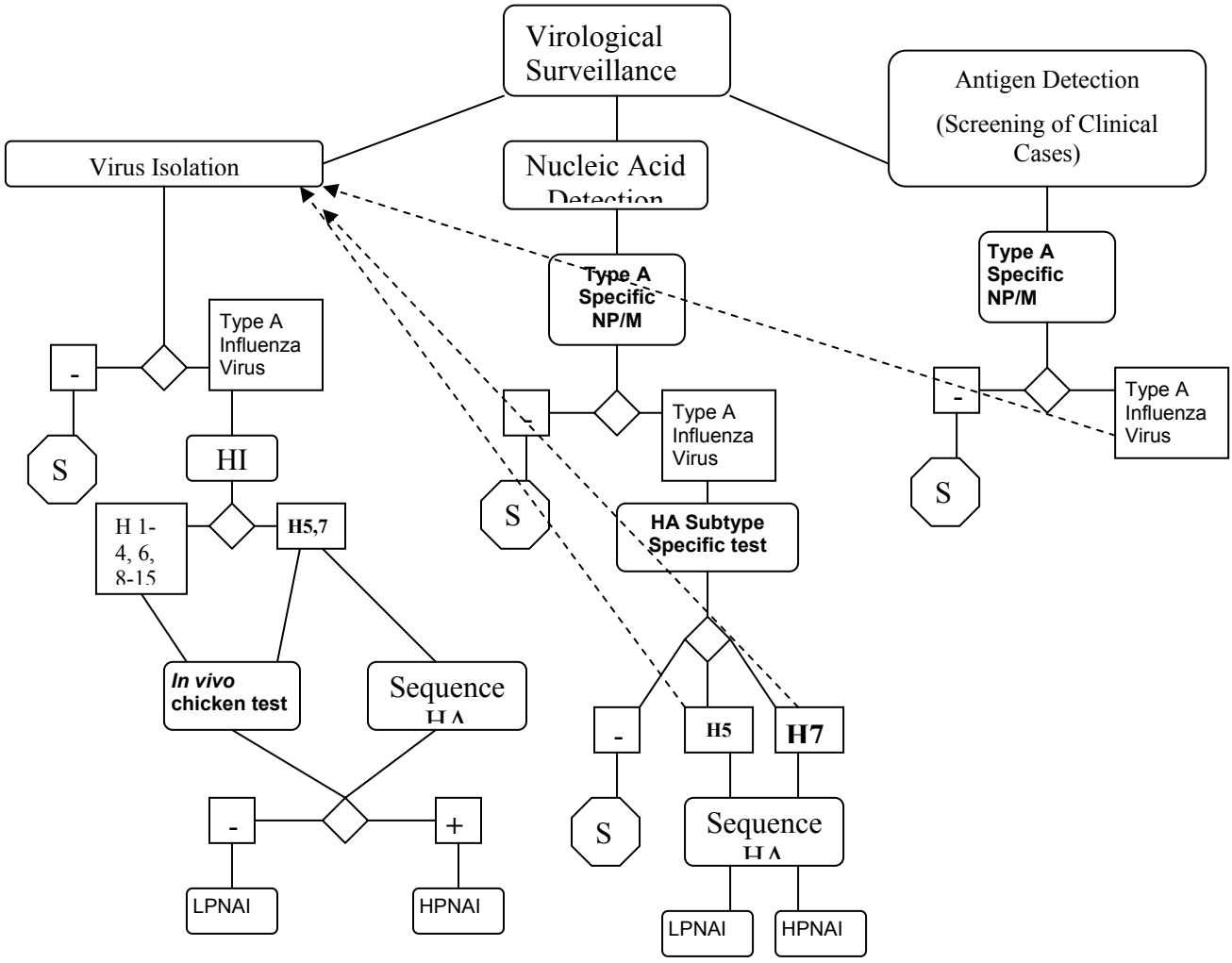
The entire investigative process should be documented as standard operating procedure within the epidemiological surveillance programme.

Figure 1 - ***Schematic representation of laboratory tests for determining evidence of NAI infection through or following serological surveys***



Appendix XVII (contd)

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



The above diagram indicates the tests which are recommended for use in the investigation of poultry flocks.

Key:

AGID	Agar gel immunodiffusion
DIVA	Differentiating infected from vaccinated animals
ELISA	Enzyme-linked immunosorbant assay
HA	Haemagglutinin
HI	Haemagglutination inhibition
NA	Neuraminidase
NI	Neuraminidase inhibition
NP/M	Nucleoprotein and matrix protein
NSP	Nonstructural protein
SN	Serum neutralization
S	No evidence of NAIV

Appendix XVIII

APPENDIX 3.3.5.

CATEGORISATION OF DISEASES AND PATHOGENIC AGENTS BY THE INTERNATIONAL EMBRYO TRANSFER SOCIETY

Community position:

The Community. can support the amendments proposed below but would like the points noted taken on board. However the Community wishes to caution about non-peer reviewed findings and emphasises the risks of manipulating FMD infected animals, irrespective of the status of the embryo. It is furthermore important to differentiate between in-vivo derived and in-vitro produced embryos.

Article 3.3.5.1.

In 20042~~002~~, the Research Subcommittee of the International Embryo Transfer Society (IETS) Health and Safety Advisory Committee again reviewed available research and field information on infectious diseases which have been studied regarding the risk of their transmission via *in vivo* derived embryos. As a result of this review, the IETS has categorised the following diseases and pathogenic agents into four categories. Please note that this categorisation applies only to *in vivo* derived embryos.

The following methodology is used by the Research Subcommittee to categorise infectious diseases with regard to the risk of their transmission:

1) Research procedures used to handle and process the embryos will comply with criteria that have been set out by A. Bielanksi and W.C.D. Hare in Appendix A of the IETS Manual*.

2) The data used by the Sub-committee to categorise or re-categorise diseases will have been published in peer-reviewed articles in reputable scientific journals. This is to ensure that scientific procedures and results, as well as the interpretation of results, have undergone another level of review.

3) Decisions regarding disease categorisation are based on a consensus judgement which is taken annually by the Sub-committee. The names of members of the Sub-committee who are present when the decisions are made are recorded, as are the names of any others whose opinions were solicited in the decision making process.

4) Questions considered in the decision-making process include the following:

   a) What is the nature of the disease? For example, is the causal agent a uterine pathogen? Does it occur in blood? Does it persist in blood? Do asymptomatic shedders occur? What is the minimum infective dose?

   b) Has the causal agent been found in the ovarian/oviductal/uterine (OOU) environment?

   c) Is the causal agent's presence in the OOU environment incidental or is it a consequence of the pathogenesis of the disease?

d) Is the causal agent's presence in the OOU environment consistent with obtaining viable embryos?

e) Has the causal agent been found in flushing fluids?

f) Has the causal agent been found to penetrate or cross the intact zona pellucida (ZP)?

g) Has the causal agent been found to adhere to the ZP?

h) Is the causal agent removed by washing the embryo?

i) Will special treatments (e.g. with trypsin) remove or inactivate the causal agent?

j) How many embryos have been transferred with or without disease transmission?

k) What is the accumulated evidence for non-transmission of the disease by embryo transfer?

l) What evidence is there that the disease* could be transmitted by embryo transfer?

m) Have negative (or positive) results been duplicated by the same or different investigators?

n) Has evidence been accumulated for different animal species as well as for a range of different types and strains of the causal agent?

Article 3.3.5.2.

Category 1

Category 1 diseases or pathogenic agents are those for which sufficient evidence has accrued to show that the risk of transmission is negligible provided that the embryos are properly handled between collection and transfer according to the IETS Manual*.

The following diseases or pathogenic agents are in category 1:

– Bluetongue (cattle)
– Bovine spongiform encephalopathy (cattle)
– *Brucella abortus* (cattle)
– Enzootic bovine leukosis
– Foot and mouth disease (cattle)
– Infectious bovine rhinotracheitis: trypsin treatment required
– Aujeszky's disease (pseudorabies) (swine): trypsin treatment required.

Article 3.3.5.3.

Category 2

Category 2 diseases are those for which substantial evidence has accrued to show that the risk of transmission is negligible provided that the embryos are properly handled between collection and transfer according to the IETS Manual*, but for which additional transfers are required to verify existing data.

The following diseases are in category 2:

– Bluetongue (sheep)
– Classical swine fever (hog cholera)
– Scrapie (sheep).

Article 3.3.5.4.

Category 3

Category 3 diseases or pathogenic agents are those for which preliminary evidence indicates that the risk of transmission is negligible provided that the embryos are properly handled between collection and transfer according to the IETS Manual* , but for which additional *in vitro* and *in vivo* experimental data are required to substantiate the preliminary findings.

The following diseases or pathogenic agents are in category 3:

– Bovine immunodeficiency virus
– Bovine spongiform encephalopathy (goats)
– Bovine viral diarrhea virus (cattle)
– *Campylobacter fetus* (sheep)
– Caprine arthritis/encephalitis
– Foot and mouth disease (swine, sheep, and goats)
– *Haemophilus somnus (*cattle)
– *Mycobacterium paratuberculosis* (cattle)
– *Neospora caninum* (cattle)
– Ovine pulmonary adenomatosis
– Porcine reproductive and respiratory disease syndrome (PRRS)
– Rinderpest (cattle)
– Swine vesicular disease.

Article 3.3.5.5.

Category 4

Category 4 diseases or pathogenic agents are those ~~on which preliminary work has been conducted or is in progress~~ for which studies have been done, or are in progress, that indicate:

a) that no conclusions are yet possible with regard to the level of transmission risk, or

b) the risk of transmission via embryo transfer might not be negligible even if the embryos are properly handled according to the IETS Manual***** between collection and transfer.

The following diseases or pathogenic agents are in category 4:

– African swine fever
– Akabane (cattle)
– Bovine anaplasmosis
– Bluetongue (goats)
– Border disease (sheep)
– Bovine herpesvirus-4
– Ovine epididymitis (B*rucella ovis*)
– *Chlamydia psittaci* (cattle, sheep)
– Enterovirus (cattle, swine)
– *Escherichia coli* O9:K99 (cattle)
– *Leptospira borgpetersenii* serovar *hardjobovis* (cattle)
– *Leptospira* sp. (swine)
– Maedi-visna (sheep)
– *Mycobacterium bovis* (cattle)
– ~~*Mycobacterium paratuberculosis* (cattle)~~
– *Mycoplasma* spp. (swine)
– Parainfluenza-3 virus (cattle)
– Parvovirus (swine)
– Scrapie (goats)
– *Trichomonas foetus* (cattle)

– Porcine circovirus (type 2) (pigs)
– *Ureaplasma/Mycoplasma* spp. (cattle, goats)
– Vesicular stomatitis (cattle, swine).

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

— text deleted

* Manual of the International Embryo Transfer Society (1998).

Appendix XIX

APPENDIX 3.2.1.

BOVINE AND SMALL RUMINANT SEMEN

Community position:

The Community can support this proposal but would like the OIE to take on board the points mentioned below.

Article 3.2.1.1.

General considerations

The purposes of official sanitary control of semen production are to:

1) maintain the health of animals on an *artificial insemination centre* at a level which permits the international distribution of semen with a negligible risk of infecting other animals or humans with pathogens transmissible by semen;

2) ensure that semen is hygienically collected, processed and stored.

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

Article 3.2.1.2.

Conditions applicable to artificial insemination centres

1) The *artificial insemination centre* is comprised of:

   a) animal accommodation areas (including one isolation facility for sick animals) and a semen collection room, these two premises hereon designated as semen collection facilities; accommodation areas should be species specific where relevant;

   b) a semen laboratory and semen storage areas;

   c) administration offices.

   A *quarantine station* may also be attached to the centre, provided that it is on a different location from that of those two first parts.

2) The centre should be officially approved by the *Veterinary Administration.*

3) The centre should be under the supervision and control of the *Veterinary Authority* which will be responsible for regular audits, at an interval of no more than 6 months, of protocols, procedures and prescribed records on the health and welfare of the animals in the centre and on the hygienic production, storage and dispatch of semen.

4) The centre should be under the direct supervision and control of a veterinarian designated by the *artificial insemination centre* and accredited by the *Veterinary Administration* for relevant official tasks.

Article 3.2.1.3.

Conditions applicable to semen collection facilities

1) The semen collection facilities should include separate and distinct areas for accommodating resident animals, for semen collection, for feed storage, for manure storage, and for the isolation of suspect animals.

Community position:
The Community feels that the word "suspect animal" is not clear enough and proposes the following "of animals suspected of being diseased".

2) Only animals associated with semen production should be permitted to enter the semen collection facilities. Other species of animals may be resident at the centre, if necessary for the movement or handling of the donors and teasers or for security, but contact with the donors and teasers should be minimised. All animals resident at the semen collection facilities must meet the minimum health requirements for donors.

3) The donors and teasers should be adequately isolated to prevent the transmission of diseases from farm livestock and other animals. Measures should be in place to prevent the entry of wild animals.

4) Personnel at the centre should be technically competent and observe high standards of personal hygiene to preclude the introduction of pathogenic organisms. Special protective clothing and footwear for use only at the semen collection facilities should be provided and worn at all times inside.

5) Visitors to the semen collection facilities should be kept to a minimum and visits should be subject to formal authorisation and control. Equipment for use with the livestock should be dedicated to the semen collection facilities or disinfected prior to entry. All equipment and tools brought on to the premises must be examined and treated if necessary to ensure that they cannot introduce disease.

6) *Vehicles* used for transport of animals to and from the semen collection facilities should not be allowed to enter the facilities.

7) The semen collection area should be cleaned daily after collection. The animals' accommodation and semen collection areas should be cleaned and disinfected at least once a year.

8) Fodder introduction and manure removal should be done in a manner which poses no significant animal health risk.

Article 3.2.1.4.

Conditions applicable to semen laboratories

1) The semen laboratory should be physically separated from the semen collection facilities, and include separate areas for artificial vagina cleaning and preparation, semen evaluation and processing, semen pre-storage and storage. Entry to the laboratory should be prohibited to unauthorised personnel.

2) The laboratory personnel should be technically competent and observe high standards of personal hygiene to preclude the introduction of pathogenic organisms during semen evaluation, processing and storage.

3) Visitors to the laboratory should be kept to a minimum and visits should be subject to formal authorisation and control.

Community position:
The Community proposes that the above is strengthened to read "Visitors to the laboratory should be kept to a minimum and visits should be subject to formal authorisation and control **with the provision of normal biosecurity procedures including separate protective clothing .**

4) The laboratory should be constructed with materials that permit effective cleaning and *disinfection*.

5) The laboratory should be regularly cleaned. Work surfaces for semen evaluation and processing should be cleaned and disinfected at the end of each workday.

6) The laboratory should be treated against rodents and insects on a regular basis as needed to control these pests.

7) The storage rooms and individual semen containers should be easy to clean and disinfect.

8) Only semen collected from donors having a health status equivalent to or better than the donors at the semen collection facilities should be processed in the laboratory.

Community position:
The Community believes that provided there is separate handing and an appropriate cleaning and disinfection then semen of a lesser status could be handled.

Article 3.2.1.5.

Conditions applicable to testing of bulls and teaser animals

Bulls and teaser animals can enter an *artificial insemination centre* only if they fulfil the requirements laid down by the *Veterinary Administration*.

1) Pre-quarantine

The animals should comply with the following requirements prior to entry into isolation at the *quarantine station*.

a) Bovine brucellosis

The animals should comply with point 3 or 4 of Article 2.3.1.5. of the *Terrestrial Code*.

b) Bovine tuberculosis

The animals should comply with point 3 or 4 of Article 2.3.3.4. of the *Terrestrial Code*.

c) Bovine viral diarrhoea-mucosal disease (BVD-MD)

The animals should be subjected to the following tests:

i) a virus isolation test or a test for virus antigen, with negative results;

ii) a serological test to determine the serological status of every animal.

d) Infectious bovine rhinotracheitis-infectious pustular vulvovaginitis (IBR/IPV)

If the *artificial insemination centre* is to be considered as IBR/IPV free, the animals should either:

i) come from an IBR/IPV free herd as defined in Article 2.3.5.3.; or

ii) be subjected, with negative results, to a serological test for IBR/IPV on a blood sample.

e) Bluetongue

The animals should comply with Article 2.2.13.6., 2.2.13.7. or 2.2.13.8., depending on the bluetongue status of the country of origin of the animals.

2) Testing in the quarantine station prior to entering the semen collection facilities

Prior to entering the semen collection facilities of the *artificial insemination centre*, bulls and teaser animals should be kept in a *quarantine station* for at least 28 days. The animals should be subjected to diagnostic tests as described below a minimum of 21 days after entering the *quarantine station*, except for *Campylobacter fetus* and *Trichomonas foetus*, for which testing may commence after 7 days in quarantine. All the results should be negative except in the case of BVD-MD antibody serological testing (see point 2b)i) below).

Community position
It should be specified above that it concerns *Campylobacter fetus subsp. venerealis*.

a) Bovine brucellosis

The animals should be subjected to a serological test with negative results.

b) BVD-MD

i) All animals should be tested for viraemia as described in point 1c) above.

Only when all the animals in quarantine test negative for viraemia may the animals enter the semen collection facilities upon completion of the 28-day quarantine period.

ii) After 21 days in quarantine, all animals should be subjected to a serological test to determine the presence or absence of BVD-MD antibodies.

Community position:
In i and ii) the text as regards the testing requirements for BVD is not clear enough. It would be better to copy the text under 1ci and 1cii.

It is not clear whether PCR-testing is an accepted method.

iii) Only if no sero-conversion occurs in the animals which tested seronegative before entry into the *quarantine station*, may any animal (seronegative or seropositive) be allowed entry into the semen collection facilities.

iv) If sero-conversion occurs, all the animals that remain seronegative should be kept in quarantine over a prolonged time until there is no more seroconversion in the group for a period of 3 weeks. Serologically positive animals may be allowed entry into the semen collection facilities.

c) Campylobacter *fetus* subsp. *venerealis*

i) Animals less than 6 months old or kept since that age only in a single sex group prior to quarantine should be tested once on a preputial specimen, with a negative result.

ii) Animals aged 6 months or older that could have had contact with females prior to quarantine should be tested three times at weekly intervals on a preputial specimen, with a negative result in each case.

d) *Trichomonas foetus*

i) Animals less than 6 months old or kept since that age only in a single sex group prior to quarantine, should be tested once on a preputial specimen, with a negative result.

ii) Animals aged 6 months or older that could have had contact with females prior to quarantine should be tested three times at weekly intervals on a preputial specimen, with a negative result in each case.

e) IBR/IPV

If the *artificial insemination centre* is to be considered as IBR/IPV free, the animals should be subjected, with negative results, to a diagnostic test for IBR/IPV on a blood sample. If any animal tests positive, the animal should be removed immediately from the *quarantine station* and the other animals of the same group should remain in quarantine and be retested, with negative results, not less than 21 days after removal of the positive animal.

f) Bluetongue

The animals should comply with Article 2.2.13.9., 2.2.13.10. or 2.2.13.11., depending on the bluetongue status of the country of origin of the animals.

3) Testing for BVD-MD prior to the initial dispatch of semen from each serologically positive bull

Prior to the initial dispatch of semen from BVD-MD serologically positive bulls, a semen sample from each animal should be subjected to a virus isolation or virus antigen ELISA test for BVD-MD. In the event of a positive result, the bull should be removed from the centre and all of its semen destroyed.

4) Testing of frozen semen for IBR/IPV in artificial insemination centres not considered as IBR/IPV free

Each aliquot of frozen semen should be tested as per Article 2.3.5.7.

5) Testing programme for bulls and teasers resident in the semen collection facilities

All bulls and teasers resident in the semen collection facilities should be tested at least annually for the following diseases, with negative results, where the country of origin is not free:

a) Bovine brucellosis

b) Bovine tuberculosis

c) BVD-MD

Animals negative to previous serological tests should be retested to confirm absence of antibodies.

Should an animal become serologically positive, every ejaculate of that animal collected since the last negative test should be either discarded or tested for virus with negative results.

d) Campylobacter *fetus* subsp. *Venerealis*

i) A preputial specimen should be cultured.

ii) Only bulls on semen production or having contact with bulls on semen production need to be tested. Bulls returning to collection after a lay off of more than 6 months should be tested not more than 30 days prior to resuming production.

e) Bluetongue

The animals should comply with the provisions referred to in Article 2.2.13.9., 2.2.13.10. or 2.2.13.11., depending on the bluetongue status of the country of origin of the animals.

f) *Trichomonas foetus*

i) A preputial specimen should be cultured.

ii) Only bulls on semen production or having contact with bulls on semen production need to be tested. Bulls returning to collection after a lay off of more than 6 months should be tested not more than 30 days prior to resuming production.

g) IBR/IPV

If the *artificial insemination centre* is to be considered as IBR/IPV free, the animals should comply with the provisions in point 2)c) of Article 2.3.5.3.

Community position:
Should an animal become serological positive, all former sero-negative animals in the herd/centre shall be retested. This applies to all diseases and circumstances.

Article 3.2.1.5.bis

Conditions applicable to testing of rams/bucks and teaser animals

Rams/bucks and teaser animals can enter an *artificial insemination centre* only if they fulfil the requirements laid down by the *Veterinary Administration*.

1) Pre-quarantine

The animals should comply with the following requirements prior to entry into isolation at the *quarantine station*.

a) Caprine and ovine brucellosis

The animals should comply with Article 2.4.2.6.

b) Ovine epididymitis

The animals should comply with Article 2.4.1.3.

c) Contagious agalactia

The animals should comply with points 1 and 2 of Article 2.4.3.1.

d) Peste des petits ruminants

The animals should comply with points 1, 2, 4 and 5 of Article 2.4.9.7.

e) Contagious caprine pleuropneumonia

The animals should comply with Article 2.4.6.5. or Article 2.4.6.7., depending on the CCPP status of the country of origin of the animals.

f) Caseous lymphadenitis

The animal should be free from clinical signs for the past 12 months.

g) Paratuberculosis

The animals should be free from clinical signs for the past 2 years.

h) Scrapie

If the animals do not originate from a scrapie free country or *zone* as defined in Article 2.4.8.3., the animals should comply with points 1 and 2 of Article 2.4.8.8.

i) Maedi-visna

The animals should comply with Article 2.4.5.2.

j) Caprine arthritis/encephalitis

The animals should comply with Article 2.4.4.2.

k) Bluetongue

The animals should comply with Article 2.2.13.6., 2.2.13.7. or 2.2.13.8., depending on the bluetongue status of the country of origin of the animals.

l) Tuberculosis

In the case of goats, the animals should be subject to a single or comparative tuberculin test, with negative results.

m) Border disease

The animals should be subject to a viral agent isolation test with negative results.

2) Testing in the quarantine station prior to entering the semen collection facilities

Prior to entering the semen collection facilities of the *artificial insemination centre*, rams/bucks and teasers should be kept in a *quarantine station* for at least 28 days. The animals should be subjected to diagnostic tests as described below a minimum of 21 days after entering the *quarantine station*, with negative results:

a) Caprine and ovine brucellosis

The animals should be subject to testing as described in point 1 b) or c) of Article 2.4.2.8.

b) Ovine epididymitis

The animals and semen should be subject to testing as described in points 1 d) and 2 of Article 2.4.1.4.

c) Maedi-visna or CAE

The animals should be subjected to a serological test.

d) Bluetongue

The animals should comply with the provisions referred to in Article 2.2.13.9., 2.2.13.10. or 2.2.13.11., depending on the bluetongue status of the country of origin of the animals.

3) Testing programme for rams/bucks and teasers resident in the semen collection facilities

All rams/bucks and teasers resident in the semen collection facilities should be tested at least annually for the following diseases, with negative results, where the country of origin is not free:

a) caprine and ovine brucellosis;

b) ovine epididymitis;

c) Maedi-visna or CAE;

d) tuberculosis (for goats only);

e) bluetongue.

Article 3.2.1.6.

General considerations for hygienic collection and handling of semen

Observation of the recommendations described in the Articles below will very significantly reduce the likelihood of the semen being contaminated with common bacteria which are potentially pathogenic.

Article 3.2.1.7.

Conditions applicable to the management of bulls, rams and bucks

The objective is to keep the animals in a satisfactory state of cleanliness, particularly of the lower thorax and abdomen.

1) Whether on pasture or housed, the animal should be kept under hygienic conditions. If housed, the litter must be kept clean and renewed as often as necessary.

2) The coat of the animal should be kept clean.

3) For bulls, the length of the tuft of hairs at the preputial orifice, which is invariably soiled, should be cut to about 2 cm. The hair should not be removed altogether, because of its protective role. If cut too short, irritation of the preputial mucosa may result because these hairs aid the drainage of urine.

4) The animal should be brushed regularly, and where necessary on the day before semen collection, paying special attention to the underside of the abdomen.

5) In the event of obvious soiling, there should be careful cleaning, with soap or a detergent, of the preputial orifice and the adjoining areas, followed by thorough rinsing and drying.

6) When the animal is brought into the collection area, the technician must make sure that it is clean, and that it is not carrying any excessive litter or particles of feed on its body or its hooves, for such materials are always heavily contaminated.

Measures similar to the above should be adapted to rams and bucks.

Article 3.2.1.8.

Conditions applicable to the collection of semen

1) The floor of the mounting area should be easy to clean and to disinfect. A dusty floor should be avoided.

2) The hindquarters of the teaser, whether a dummy or a live teaser animal, must be kept clean. A dummy must be cleaned completely after each period of collection. A teaser animal must have its hindquarters cleaned carefully before each collecting session. The dummy or hindquarters of the teaser animal should be sanitized after the collection of each ejaculate. Disposable plastic covers may be used.

3) The hand of the person collecting the semen must not come into contact with the bull's penis. Disposable gloves should be worn by the collector and changed for each collection.

4) The artificial vagina must be cleaned completely after each collection. It should be dismantled, its various parts washed, rinsed and dried, and kept protected from dust. The inside of the body of the device and the cone should be disinfected before re-assembly using approved *disinfection* techniques such as those involving the use of 70° ethyl or 98-99° isopropyl alcohol, ethylene oxide or steam. Once re-assembled, it should be kept in a cupboard which is regularly cleaned and disinfected.

5) The lubricant used should be clean. The rod used to spread the lubricant must be clean and should not be exposed to dust between successive collections.

6) The artificial vagina should not be shaken after ejaculation, otherwise lubricant and debris may pass down the cone to join the contents of the collecting tube.

7) When successive ejaculates are being collected, a new artificial vagina should be used for each mounting. The vagina should also be changed when the bull has inserted its penis without ejaculating.

8) The collecting tubes should be sterile, and either disposable or sterilised by autoclaving or heating in an oven at 180°C for at least 30 minutes. They should be kept sealed to prevent exposure to the environment while awaiting use.

9) After semen collection, the tube should be left attached to the cone and within its sleeve until it has been removed from the collection room for transfer to the laboratory.

Article 3.2.1.9.

Conditions applicable to the handling of semen and preparation of semen samples in the laboratory

1) Diluents

   a) All receptacles used should have been sterilised.

   b) Buffer solutions employed in diluents prepared on the premises should be sterilized by filtration (0.22 μm) or by autoclaving (121°C for 30 minutes) or be prepared using sterile water before adding egg yolk (if applicable) or equivalent additive and antibiotics.

   c) If the constituents of a diluent are supplied in commercially available powder form, the water used must have been distilled or demineralised, sterilized (121°C for 30 minutes or equivalent), stored correctly and allowed to cool before use.

   d) When egg yolk is used, it should be separated from eggs using aseptic techniques. Alternatively, commercial egg yolk prepared for human consumption or egg yolk treated by, for example, pasteurisation or irradiation to reduce bacterial contamination, may be used. Other additives must also be sterilized before use.

   e) Diluent should not be stored for more than 72 hours at +5°C before use. A longer storage period is permissible for storage at -20°C. Storage vessels should be stoppered.

   f) A mixture of antibiotics should be included with a bactericidal activity at least equivalent to that of the following mixtures in each ml of frozen semen: either gentamicin (250 μg), tylosin (50 μg), lincomycin-spectinomycin (150/300 μg) or penicillin (500 IU), streptomycin (500 μg), lincomycin-spectinomycin (150/300 μg).

      The names of the antibiotics added and their concentration should be stated in the *international veterinary certificate*.

2) Procedure for dilution and packing

a) The tube containing freshly collected semen should be sealed as soon as it arrives in the laboratory, and kept sealed until processed.

b) After dilution and during refrigeration, the semen should also be kept in a stoppered container.

c) During the course of filling receptacles for dispatch (such as insemination straws), the receptacles and other disposable items should be used immediately after being unpacked. Materials for repeated use should be sterilised with alcohol, ethylene oxide, steam or other approved sterilisation techniques.

d) If sealing powder is used, care should be taken to avoid its being contaminated.

3) Conditions applicable to the storage of semen

Semen for export should be stored separately from other genetic material not meeting these guidelines in fresh liquid nitrogen in sterilised/sanitised flasks before being exported.

Semen straws should be sealed and code marked in line with the international standards of the International Committee for Animal Recording (ICAR)*.

Containers should be sealed with an official numbered seal under the responsibility of the *Veterinary Administration* before export and accompanied by an *international veterinary certificate* listing the contents.

---

* The ICAR international standards on straws are contained in *Recording Guidelines* - Appendices to the international agreement of recording practices. Section 9, Appendix B relating to semen straw identification.

Appendix XX

CHAPTER 2.2.14

RIFT VALLEY FEVER

Community position:

The Community can support this proposal but would like the points noted below taken on board.

Article 2.2.14.1.

For the purposes of the *Terrestrial Code*, the *infective period* for Rift Valley fever (RVF) shall be 30 days.

For the purposes of this Chapter, ruminants include camels.

Community position:

The Community proposes that the word 'camels' replaced by "camelidae".

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

This historic distribution of RVF is the sub-Saharian 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-epidemic periods that may last for several decades in arid areas and, during these 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 epidemics have recently occurred.

Article 2.2.14.2.

RVF infection free country or zone

A country or a zone may be considered free from RVF infection when the disease is notifiable in animals throughout the country and either:

1) the country or zone lies outside the historically infected regions, and not adjacent to historically infections; or

2) a surveillance and monitoring programme as described in Article 2.2.14.1. has demonstrated no evidence of RVF infection in humans, animals or mosquitoes in the country or zone during the past 4 years following a RVF epidemic.

The provisions of the last paragraph of Article .2.14.1. 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 2.2.14.3.

RVF infected country/zone without disease

A RVF disease free country or zone is a country/zone that is not infection free (see Article 2.2.14.2.) but in which disease has not occurred in humans or animals in the past 6 months provided that climatic changes predisposing to *outbreaks* of RVF have not occurred during this time.

Article 2.2.14.4.

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 past 6 months.

Article 2.2.14.5.

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;

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 2.2.14.6.

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

for ruminants

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

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

   b) were protected from mosquito attack at all times when transiting through an infected zone.

Article 2.2.14.7.

When importing from RVF infection 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/free zone since birth or for the last 30 days.

Article 2.2.14.8.

When importing from RVF infected countries/zones without disease, *Veterinary Administrations* should require:

for ruminants

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

1) showed no evidence of RFV 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 the *place of shipment* and at the *place of shipment*;

AND

5) did not transit through an infected zone with disease during transportation of the *place of shipment*.

Article 2.2.14.9.

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 or 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.

Article 2.2.14.10.

When importing from RVF infected countries or zones with disease, *Veterinary Administrations* should require:

for ruminants

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

1) showed no evidence of RVF on the day of shipment;

2) vaccinated against RVF at least 21 days prior to shipment with modified live virus vaccine;

OR

3) 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 mosquito attack between quarantine and the *place of shipment* and at the *place of shipment*.

Article 2.2.14.11.

When importing from RVF infected countries or zones 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.

Article 2.2.14.12.

When importing from RVF infected countries or zones with disease, *Veterinary Administrations* should require:

for *in vivo* derived embryos of ruminants

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

1) showed no evidence of RVF within the period from 28 days prior to 28 days following collection of the embryos;

2) were vaccinated against RVF at least 21 days prior to collection with modified live virus vaccine;

OR

3) were serologically tested on the day of collection and at least 14 days following collection using an ELISA on the samples, and showing no significant rise in titre.

Appendix XXI

APPENDIX 3.9.3.

GUIDELINES FOR THE RESPONSIBLE AND PRUDENT USE OF ANTIMICROBIAL AGENTS IN VETERINARY MEDICINE

Community position:

The Community has already sent in extensive comments on this chapter and is very surprised that none appear to have been taken on board. The Community requests that these and the additional points noted below are taken into account.

Article 3.9.3.1.

Purpose

These guidelines provide guidance for the responsible and prudent use of antimicrobials in veterinary medicine, with the aim of protecting both animal and human health. The competent authorities responsible for the registration and control of all groups involved in the production, distribution and use of veterinary antimicrobials have specific obligations.

Prudent use is principally determined by the outcome of the marketing authorisation procedure and by the implementation of specifications when antimicrobials are administered to animals.

Article 3.9.3.2.

Objectives of prudent use

Prudent use includes a set of practical measures and recommendations intended to prevent and/or reduce the selection of antimicrobial-resistant bacteria in animals to:

1) maintain the efficacy of antimicrobial agents and to ensure the rational use of antimicrobials in animals with the purpose of optimising both their efficacy and safety in animals;

2) comply with the ethical obligation and economic need to keep animals in good health;

3) prevent, or reduce, as far as possible, the transfer of bacteria (with their resistance determinants) within animal populations;

4) maintain the efficacy of antimicrobial agents used in food-producing animals ~~livestock~~;

Community position:

Even non food producing animal like pets or animals kept for other purposes (hobby farmers or rural development purposes, even zoos) should be taken into account for the purposes of this chapter Furthermore it is important to prolong the usefulness of the antimicrobials in veterinary medicine as well. Therefore the Community proposes the following wording: "maintain the efficacy of antimicrobial agents used in both food-producing and pet animals

livestock and prolong the usefulness of the antimicrobials.".

5) prevent or reduce the transfer of resistant bacteria or resistance determinants from animals to humans;

6) maintain the efficacy of antimicrobial agents used in human medicine and prolong the usefulness of the antimicrobials;

7) prevent the contamination of animal-derived food with antimicrobial residues that exceed the established maximum residue limit (MRL);

8) protect consumer health by ensuring the safety of food of animal origin.

Article 3.9.3.3.

Responsibilities of the regulatory authorities

1) Marketing authorisation

The national regulatory authorities are responsible for granting marketing authorisation. This should be done in accordance with the provisions of the *Terrestrial Code*. They have a significant role in specifying the terms of this authorisation and in providing the appropriate information to the veterinarian.

2) Submission of data for the granting of the marketing authorisation

The pharmaceutical industry has to submit the data requested for the granting of the marketing authorisation. The marketing authorisation is granted only if the criteria of safety, quality and efficacy are met. An assessment of the potential risks and benefits to both ~~the~~ animals and humans ~~the consumer~~ resulting from the use of antimicrobial agents in food-producing animals should ~~must~~ be carried out. The evaluation should focus on each individual antimicrobial product and the findings not be generalised to the class of antimicrobials to which the particular active principle belongs. ~~If dose ranges or different durations of treatment are suggested~~, Guidance on usage should be provided for all dose ranges or different durations of treatment that are proposed.

Community position:

The use of antimicrobial agents in pet animals should be included in the assessment of the potential risks and benefits. The Community proposes the following wording to replace the sentence above: "An assessment of the potential risks and benefits to both the animals and humans the consumer resulting from the use of antimicrobial agents in both food-producing and pet animals should must be carried out."

3) Market approval

Regulatory authorities should attempt to expedite the market approval process of a new antimicrobial in order to address a specific need for the treatment of disease.

4) Registration procedures

Countries lacking the necessary resources to implement an efficient registration procedure for veterinary medicinal products (VMPs), and whose supply principally depends on imports from foreign countries, should ~~must~~ undertake the following measures:

a) check the efficacy of administrative controls on the import of these VMPs;

b) check the validity of the registration procedures of the exporting and manufacturing country as appropriate;

c) develop the necessary technical co-operation with experienced authorities to check the quality of imported VMPs as well as the validity of the recommended conditions of use.

Regulatory authorities of importing countries should request the pharmaceutical industry to provide quality certificates prepared by the competent authority of the exporting and manufacturing country as appropriate. All countries should make every effort to actively combat the manufacture, advertisement, trade, distribution and use of unlicensed and counterfeit bulk active pharmaceutical ingredients and products.

5) Quality control of antimicrobial agents

Quality controls should be performed:

a) in compliance with the provisions of good manufacturing practices;

b) to ensure that analysis specifications of antimicrobial agents used as active ingredients comply with the provisions of approved monographs;

c) to ensure that the quality and concentration (stability) of antimicrobial agents in the marketed dosage form(s) are maintained until the expiry date, established under the recommended storage conditions;

d) to ensure the stability of antimicrobials when mixed with feed or drinking water;

e) to ensure that all antimicrobials are manufactured to the appropriate quality and purity in order to guarantee their safety and efficacy.

6) Assessment ~~Control~~ of therapeutic efficacy

a) Preclinical trials

i) Preclinical trials should:

– establish the range of activity of antimicrobial agents on both pathogens and non-pathogens (commensals);

– assess the ability of the antimicrobial agent to select for resistance ~~resistant bacteria~~ *in vitro* and *in vivo,* taking into consideration pre-existing resistant strains;

– establish an appropriate dosage regimen necessary to ensure the therapeutic efficacy of the antimicrobial agent and limit the selection of antimicrobial resistance ~~resistant bacteria~~. (Pharmacokinetic pharmacodynamic data and models can assist in this appraisal.)

ii) The activity of antimicrobial agents towards the targeted micro-organism ~~bacteria~~ should be established by pharmacodynamics. The following criteria should be taken into account:

– mode and spectrum of activity ~~action~~;

– minimum inhibitory and bactericidal concentrations;

– time- or concentration-dependent activity or co-dependency;

– activity at the site of infection.

iii) The dosage regimens allowing maintenance of effective antimicrobial levels should be established by pharmacokinetics. The following criteria should be taken into account:

– bio-availability according to the route of administration;

– concentration of the antimicrobial at the site of infection and its distribution in the treated animal;

– metabolism that may lead to the inactivation of antimicrobials;

– excretion routes;

– use of combinations of antimicrobial agents should be scientifically supported ~~justified~~.

b) Clinical trials

Clinical trials should be performed to confirm the validity of the claimed therapeutic indications and dosage regimens established during the preclinical phase. The following criteria should be taken into account:

i) diversity of the clinical cases encountered when performing multi-centre trials;

ii) compliance of protocols with good clinical practice, such as Veterinary International Cooperation on Harmonisation (VICH) guidelines;

iii) eligibility of studied clinical cases, based on appropriate criteria of clinical and bacteriological diagnoses;

iv) parameters for qualitatively and quantitatively assessing the efficacy of the treatment.

7) Assessment of the potential of antimicrobials to select for resistance ~~resistant bacteria~~

Other studies may be requested in support of the assessment of the potential of antimicrobials to select for resistance ~~resistant bacteria~~. ~~The interpretation of their results should be undertaken with great caution~~. The party applying for market authorisation should, where possible, supply data derived in target animal species under the intended conditions of use.

For this the following may be considered ~~Considerations may include~~:

a) the concentration of active compound in the gut of the animal (where the majority of potential food-borne pathogens reside) at the defined dosage level;

b) the route and level of human exposure to food-borne or other resistant organisms ~~bacteria~~;

c) the degree of cross-resistance within the class of antimicrobials and between classes of antimicrobials;

d) the pre-existing level of resistance in the pathogens of human health concern (baseline determination) in both animals and humans.

~~Other studies may be requested in support of the assessment of the potential of antimicrobials to select for resistant bacteria. The interpretation of their results should be undertaken with great caution.~~

8) Establishment of acceptable daily intake, maximum residue level and withdrawal periods for antimicrobial compounds

a) When setting the acceptable daily intake (ADI) and MRL for an antimicrobial substance, the safety evaluation should also include the potential biological effects on the intestinal flora of

humans.

b) The establishment of an ADI for each antimicrobial agent, and an MRL for each animal-derived food, should be undertaken.

c) For each VMP containing antimicrobial agents, withdrawal periods should be established in order to produce food in compliance with the MRL, taking into account:

i) the MRL established for the antimicrobial agent under consideration;

ii) the composition of the product and the pharmaceutical form;

iii) the target animal species;

iv) the dosage regimen and the duration of treatment;

v) the route of administration.

d) The applicant should provide methods for regulatory testing of residues in food.

9) Protection of the environment

An assessment of the impact of the proposed antimicrobial use on the environment should be conducted. Efforts should be made to ensure that the environmental impact of antimicrobial use ~~contamination with antimicrobials~~ is restricted to a minimum.

10) Establishment of a summary of product characteristics for each veterinary antimicrobial ~~medicinal~~ product (VAP)

The summary of product characteristics contains the information necessary for the appropriate use of VAPs ~~VMPs~~ and constitutes the official reference for their labelling and package insert. This summary should ~~always~~ contain the following items:

a) active ingredient and class,

b) pharmacological properties

c) any potential adverse effects,

d) target animal species,

e) therapeutic indications,

f) target micro-organisms ~~bacteria~~,

g) dosage and administration route,

h) withdrawal periods,

i) incompatibilities,

j) shelf-life ~~expiry date~~,

k) operator safety,

l) particular precautions before use,

m) particular precautions for the proper disposal of un-used or expired products,

n) information on conditions of use relevant to the potential for selection of resistance.

~~Antimicrobials that are considered to be important in treating critical diseases in humans should only be used in animals when alternatives are either unavailable or inappropriate.~~

~~Consideration should be given to providing such guidance by means of the product label and data sheet.~~

~~The oral route should be used with caution.~~

11) Post-marketing antimicrobial surveillance

The information collected through existing pharmacovigilance programmes, including lack of efficacy, should form part of the comprehensive strategy to minimise antimicrobial resistance. In addition to this the following should be considered:

a) General epidemiological surveillance

The surveillance of animal bacteria resistant to antimicrobial agents is essential. The relevant authorities should implement a programme according to the *Terrestrial Code*.

Community position:

The term "animal bacteria" should be defined: Does it mean animal pathogens, indicator bacteria, zoonotic bacterial or all of them?

b) Specific surveillance

Specific surveillance to assess the impact of the use of a specific antimicrobial may be implemented after the granting of the marketing authorisation The surveillance programme should evaluate not only resistance development in target animal pathogens, but also in food-borne pathogens and/or commensals. Such surveillance will also contribute to general epidemiological surveillance of antimicrobial resistance.

Community position:

The term "zoonotic bacteria" is more suitable in this context that the term "food borne pathogens". The resistance development of indicator bacteria is to be evaluated as well. The word 'or' should be deleted.

Ex-ante specific evaluation of the impact of a specific antimicrobial before the granting of the marketing authorization is also desirable to allow an assessment of the impact on resistance before and after its introduction.

12) Supply and administration ~~Distribution~~ of the antimicrobial agents used in veterinary medicine

The relevant authorities should ensure that all the antimicrobial agents used in animals are:

a) prescribed by a veterinarian or other ~~suitably trained and~~ *authorised* person;

~~b) delivered by an authorised animal health professional~~;

b) supplied only through licensed/authorised distribution systems;

c) administered to animals by a veterinarian or under the supervision of a veterinarian or by other authorised persons;

d) the relevant authorities should develop effective procedures for the safe collection and

destruction of unused or expired VAPs.

13) Control of advertising

All advertising of antimicrobials should be controlled by a code of advertising standards, and the relevant authorities must ensure that the advertising of antimicrobial products:

a) complies with the marketing authorisation granted, in particular regarding the content of the summary of product characteristics;

b) is restricted to authorised professionals, according to national legislation in each country.

14) Training of antibiotic users

The training of users of antimicrobials ~~antibiotic users~~ should involve all the relevant organisations, such as regulatory authorities, pharmaceutical industry, veterinary schools, research institutes, veterinary professional organisations and other approved users such as food-animal owners. This training should focus on:

a) information on disease prevention and management strategies;

b) the ability of antimicrobials to select for resistance in food-producing animals;

Community position:

The training of the users should include both the owners of food producing animals and other animals. To point b should be added pet animals since the use of antimicrobials do select resistant bacteria in pet animals as well.

c) the need to observe responsible use recommendations for the use of antimicrobial agents in animal husbandry in agreement with the provisions of the marketing authorisations.

15) Research

The relevant authorities should encourage public- and industry-funded research.

Article 3.9.3.4.

Responsibilities of the veterinary pharmaceutical industry

1) Marketing authorisation of VAPs ~~VMPs~~

The veterinary pharmaceutical industry has responsibilities to:

a) supply all the information requested by the national regulatory authorities;

b) guarantee the quality of this information in compliance with the provisions of good manufacturing, laboratory and clinical practices;

c) implement a pharmacovigilance programme and on request, specific surveillance for bacterial susceptibility and resistance.

2) Marketing and export of VAPs ~~VMPs~~

For the marketing and export of VAPs ~~VMPs~~:

a) only licensed and officially approved VAPs ~~VMPs~~ should be sold and supplied, and then only through licensed/authorised distribution systems;

b) the pharmaceutical industry should provide quality certificates prepared by the Competent Authority of the exporting and/or manufacturing countries to the importing country ~~only VMPs that have been authorised in the (exporting) country in which the product(s) is approved for sale or the quality of which is certified by a regulatory authority should be exported~~;

c) the national regulatory authority should be provided with the information necessary to evaluate the amount of antimicrobial agents marketed.

3) Advertising

The veterinary pharmaceutical industry should:

a) disseminate information in compliance with the provisions of the granted authorisation;

b) ensure that the advertising of antimicrobials directly to the food animal ~~livestock~~ producer is discouraged.

Community position:
The Community proposes the following wording for point b: "The advertising of antimicrobials should be limited only to authorised professionals", as stated in point 13b (regulatory authorities).
[In addition non food producing animal like pets or animals kept for other purposes (hobby farmers or rural development purposes, even zoos) should be taken into account for this purpose.]

4) Training

The veterinary pharmaceutical industry should participate in training programmes as defined in point 14 of Article 3.9.3.3.

5) Research

The veterinary pharmaceutical industry should contribute to research as defined in point 15 of Article 3.9.3.3.

Article 3.9.3.5.

Responsibilities of wholesale and retail distributors ~~pharmacists~~

1) Retailers distributing VAPs ~~Pharmacists~~ should only do so on the prescription of a veterinarian or other suitably trained person authorised in accordance with national legislation and all products should be appropriately labelled ~~distribute veterinary antimicrobials on prescription. All products should be appropriately labelled (see point 5 of Article 3.9.3.6.)~~.

2) The guidelines on the responsible use of antimicrobials should be reinforced by retail distributors ~~pharmacists~~ who should keep detailed records of:

a) date of supply,

b) name of prescriber,

c) name of user,

d) name of product,

e) batch number,

f) quantity supplied.

3) Distributors ~~Pharmacists~~ should also be involved in training programmes on the responsible use of antimicrobials, as defined in point 14 of Article 3.9.3.3.

Community position:
Wholesale and retail distributors should supply all the information requested by the national regulatory authorities as well as the veterinary pharmaceutical industry.

Article 3.9.3.6.

Responsibilities of veterinarians

The ~~prime~~ concern of the veterinarian is to promote public health and animal health and welfare. The veterinarian's responsibilities include preventing, identifying and treating animal diseases. The promotion of sound animal husbandry methods, hygiene procedures and vaccination strategies (good farming practice) can help ~~encourage good farming practice in order~~ to minimise the need for antimicrobial use in food-producing animals ~~livestock~~.

Community position:

A sentence " The veterinarian should not use unnecessarily antimicrobials to food-producing or pet animals" should be added, since veterinarians do also treat pet animals with antimicrobials.

Veterinarians should only prescribe antimicrobials for animals under their care.

1) Use of antimicrobial agents

The responsibilities of veterinarians ~~in this area~~ are to carry out a proper clinical examination of the animal(s) and then:

a) only prescribe antimicrobials when necessary;

b) make an appropriate choice of the antimicrobial based on experience of the efficacy of treatment.

Community position:

Experience is not the best criteria to choose appropriate antimicrobials. The choice should be made after considering the resistance situation, the properties of the antimicrobial and the indication for the use of that certain antimicrobial.

~~On certain occasions, a group of animals that may have been exposed to pathogenic bacteria may need to be treated without recourse to an accurate diagnosis and antimicrobial susceptibility testing to prevent the development of clinical disease and for reasons of animal welfare.~~

2) Choosing an antimicrobial agent

a) The expected efficacy of the treatment is based on:

i) the clinical experience of the veterinarian;

ii) the activity towards the pathogens ~~pathogenic bacteria~~ involved;

iii) the appropriate route of administration;

iv) known pharmacokinetics/tissue distribution to ensure that the selected therapeutic agent is active at the site of infection;

v) the epidemiological history of the rearing unit, particularly in relation to the antimicrobial resistance profiles of the pathogens ~~pathogenic bacteria~~ involved.

Should a first-line antibiotic treatment fail or should the disease recur, a second line treatment should ideally be based on the results of diagnostic tests.

To minimise the likelihood of antimicrobial resistance developing, it is recommended that antimicrobials be targeted to pathogens ~~bacteria~~ likely to be the cause of infection.

On certain occasions, a group of animals that may have been exposed to pathogens may need to be treated without recourse to an accurate diagnosis and antimicrobial susceptibility testing to prevent the development of clinical disease and for reasons of animal welfare.

b) Use of combinations of antimicrobial agents should be scientifically supported. Combinations of antimicrobials may be ~~are~~ used for their synergistic effect to increase therapeutic efficacy or to broaden the spectrum of activity. ~~Furthermore, the use of combinations of antimicrobials can be protective against the selection of resistance in cases in which bacteria exhibit a high mutation rate against a given antimicrobial.~~

~~Some combinations of antimicrobials may, in certain cases, lead to an increase in the selection of resistance.~~

3) Appropriate use of the antimicrobial agent chosen

A prescription for antimicrobial agents should ~~must~~ indicate precisely the treatment regime, the dose, the treatment ~~dosage~~ intervals, the duration of the treatment, the withdrawal period and the amount of drug to be delivered, depending on the dosage and the number of animals to be treated.

The off-label use of a veterinary antimicrobial drug may be permitted in appropriate circumstances and should be in agreement with the national legislation in force including the withdrawal periods to be used. It is the veterinarian's responsibility to define the conditions of responsible use in such a case including the therapeutic regimen, the route of administration, and the duration of the treatment. ~~As far as 'Off-label use' (extra-label use) of veterinary medicinal products is concerned, although all medicinal products should be prescribed and used in accordance with the specifications of the marketing authorisation, the prescriber should have the discretion to adapt these in exceptional circumstances~~.

4) Recording

Records on veterinary antimicrobial drugs should be kept in conformity with national legislation. Information records should include the following ~~All available information should be consolidated into one form or database. This information should~~:

a) ~~allow monitoring of the~~ quantities of medication used;

b) ~~contain~~ a list of all medicines supplied to each food-producing animal ~~livestock~~ holding;

Community position:
The veterinarian should keep record on all the antimicrobials used or supplied. This includes the pet animals as well.

c) ~~contain~~ a list of medicine withdrawal periods ~~and a system for allowing information to be updated;~~

Community position:
The information records should contain the withdrawal periods only when appropriate.

d) ~~contain~~ a record of antimicrobial susceptibilities;

e) ~~provide~~ comments concerning the response of animals to medication;

f) ~~allow~~ the investigation of adverse reactions to antimicrobial treatment, including lack of response due to antimicrobial resistance. Suspected adverse reactions should be reported to the appropriate regulatory authorities.

Veterinarians should also periodically review farm records on the use of VAPs to ensure compliance with their directions and use these records to evaluate the efficacy of treatment regimens.

5) Labelling

All medicines supplied by a veterinarian should be ~~adequately~~ labelled according to national legislation ~~with the following minimum information:~~

~~a) the name of the owner/keeper or person who has control of the animal(s);~~

~~b) the address of the premises where the animal(s) is kept;~~

~~c) the name and address of the prescribing veterinarian;~~

~~d) identification of the animal or group of animals to which the antimicrobial agent was administered;~~

~~e) the date of supply;~~

~~f) the indication 'For animal treatment only';~~

~~g) the warning 'Keep out of the reach of children';~~

~~h) the relevant withdrawal period, even if this is nil.~~

~~The label should not obscure the expiry date of the preparation, batch number or other important information supplied by the manufacturer~~.

6) Training

Veterinary professional organisations should participate in the training programmes as defined in point 14 of Article 3.9.3.3. It is recommended that veterinary professional organisations develop for their members species-specific clinical practice guidelines on the responsible use of VAPs.

Article 3.9.3.7.

Responsibilities of food-animal ~~livestock~~ producers

1) Food-animal ~~Livestock~~ producers with the assistance of a veterinarian, ~~where possible,~~ are responsible for ~~preventing outbreaks of disease and~~ implementing health and welfare programmes on their farms (good farming practice) in order to promote animal health.

2) Food-animal ~~Livestock~~ producers should ~~have to~~:

a) draw up a health plan with the attending veterinarian ~~in charge~~ that outlines preventative measures (feedlot health plans, mastitis control plans, endo- and ectoparasite control ~~worming~~ and vaccination programmes, etc.);

b) use antimicrobial agents only on prescription, and according to the provisions of the prescription;

c) use antimicrobial agents in the species, for the uses and at the dosages ~~doses~~ on the approved/registered labels and in accordance with product label instructions or the advice of a veterinarian familiar with the animals and the production site;

d) isolate sick animals, when appropriate, to avoid the transfer of pathogens ~~resistant bacteria~~. Dispose of dead or dying animals promptly under conditions approved by the relevant authorities;

e) comply with the storage conditions of antimicrobials in the rearing unit, according to the provisions of the leaflet and package insert;

f) address hygienic conditions regarding contacts between people (veterinarians, breeders, owners, children) and the animals treated;

g) comply with the recommended withdrawal periods to ensure that residue levels in animal-derived food do not present a risk for the consumer;

h) dispose of surplus antimicrobials under safe conditions for the environment; ~~partially used~~ medicines should only be used within the expiry date, for the condition for which they were prescribed and, if possible, in consultation with the prescribing veterinarian;

i) maintain all the laboratory records of bacteriological and susceptibility tests; these data should be made available to the veterinarian responsible for treating the animals;

j) keep adequate records of all medicines used, including the following:

   i) name of the product/active substance and batch number,

   ii) name of prescriber and/or the supplier,

   iii) date of administration,

   iv) identification of the animal or group of animals to which the antimicrobial agent was administered,

   v) ~~diagnosis/~~clinical conditions treated,

   vi) dosage ~~quantity of the antimicrobial agent~~ administered,

   vii) withdrawal periods,

   viii) result of laboratory tests,

   ix) effectiveness of therapy;

k) inform the responsible veterinarian of recurrent disease problems.

- - - - - - - - - - - - - -

— text deleted

Appendix XXI (contd)

APPENDIX 3.9.4.

RISK ~~ANALYSIS~~ ASSESSMENT FOR ANTIMICROBIAL RESISTANCE ARISING FROM THE USE OF ANTIMICROBIALS IN ANIMALS

Community position:
The Community has already sent in extensive comments on this chapter and is very surprised that none appear to have been taken on board. The Community requests that these and the additional points noted below are taken into account.

Article 3.9.4.1.

Guidelines for analysing the risks to animal and public health from antimicrobial resistant bacteria of animal origin

1) Introduction

The use of antimicrobials for therapy, prophylaxis and growth promotion in animals can reduce their efficacy in animal and human medicine, through the development of antimicrobial resistant strains of pathogenic bacteria. This risk may be represented by the loss of therapeutic efficacy of one or several antimicrobial drugs and includes the emergence of multi-resistant bacteria.

2) Objective

The principal aim of risk analysis for antimicrobial resistance in bacteria from animals is to provide Member Countries with a transparent, objective and scientifically defensible method of assessing and managing the human and animal health risks associated with the development of resistance arising from the use of antimicrobials in animals.

3) The risk analysis process

The principles of risk analysis are described in Section 1.3. of the *Terrestrial Code*.

A qualitative risk assessment should always be undertaken. Its outcome will determine whether progression to a quantitative risk assessment is feasible and/or necessary.

4) Hazard identification

For the purposes of this Appendix, the hazard is the resistance determinant that emerges as a result of the use of a specific antimicrobial in animals. This definition reflects the development of resistance in a species of pathogenic bacteria, as well as the development of a resistance determinant that may be passed from one species of bacteria to another. The conditions under which the hazard might produce adverse consequences include any ~~feasible~~ scenarios through which humans or animals could become exposed to a pathogen which contains that resistance determinant, fall ill and then be treated with an antimicrobial that is no longer effective because of the resistance.

5) Risk assessment

The assessment of the risk to human and animal health from antimicrobial-resistant bacteria resulting from the use of antimicrobials in animals should examine:

a) the likelihood of emergence of resistant bacteria arising from the use of antimicrobial(s), or more particularly, production of the resistant determinants if transmission is possible between bacteria;

b) consideration of all pathways and their importance, by which humans could be exposed to these resistant bacteria or resistance determinants, together with the possible ~~dose of bacteria in the~~ degree of exposure;

c) the consequences of exposure and the estimated probability of its occurrence.

Article 3.9.4.2.

Analysis of risks to human health

1) Definition of the risk

The infection of humans with bacteria that have acquired resistance to a specific antimicrobial used in animals, and resulting in the loss of benefit of antimicrobial therapy used to manage the human infection.

Community position:
The risk should be defined as: "The infection of humans with bacteria that have acquired in animal populations resistance to a specific antimicrobial used in animals, and resulting in the loss of benefit of antimicrobial therapy used to manage the human infection.

The fact to assess is if the bacteria that have developed resistance have been selected by its pass through animal populations due to the use of certain antimicrobials.

2) Hazard identification

- Bacteria that have acquired resistance, (including multiple resistance) arising from the use of an antimicrobial(s) in animals.

- Bacteria having obtained a resistance determinant(s) from other bacteria which have acquired resistance arising from the use of an antimicrobial(s) in animals.

The identification of the hazard must include consideration of the class or subclass of the antimicrobial(s). This definition should be read in conjunction with point 4) of Article 3.9.4.1.

3) Release assessment

A release assessment describes the biological pathways necessary for the use of a specific antimicrobial in animals to lead to the release of resistant bacteria or resistance determinants into a particular environment, and estimating either qualitatively or quantitatively the probability of that complete process occurring. The release assessment describes the probability of the release of each of the potential hazards under each specified set of conditions with respect to amounts and timing, and how these might change as a result of various actions, events or measures.

The following factors should be considered in the release assessment:

- species of animal treated with the antimicrobial(s) in question

- number of animals treated, geographical distribution of those animals

- amounts used and duration of treatment

- variation in methods and routes of administration of the antimicrobial(s)
- the pharmacodynamics/pharmacokinetics of the antimicrobial(s)
- bacteria developing resistance as a result of the antimicrobial(s) use
- mechanism of direct or indirect transfer of resistance
- cross-resistance and/or co-resistance with other antimicrobials
- surveillance of animals, ~~animal~~ products of animal origin and animal waste products for the existence of resistant bacteria.

4) Exposure assessment

An exposure assessment describes the biological pathways necessary for exposure of humans to the resistant bacteria or resistance determinants released from a given antimicrobial use in animals, and estimating the probability of the exposures occurring. The probability of exposure to the identified hazards is estimated for specified exposure conditions with respect to amounts, timing, frequency, duration of exposure, routes of exposure and the number, species and other characteristics of the human populations exposed.

The following factors should be considered in the exposure assessment:

- human demographics and food consumption patterns, including traditions and cultural practices
- prevalence of resistant bacteria in food
- ~~animal environment contaminated~~ environmental contamination with resistant bacteria
- prevalence of animal feed contaminated with resistant bacteria
- cycling of resistant bacteria between humans, animals and the environment
- steps of microbial decontamination of food
- microbial load in contaminated food at the point of consumption
- survival capacity and redistribution of resistant bacteria during the food production process (including slaughtering, processing, storage, transportation and retailing)
- disposal practices for waste products and the opportunity for human exposure to resistant bacteria or resistance determinants in those waste products
- point of consumption of food (professional catering, home cooking)
- variation in consumption and food-handling methods of exposed populations and subgroups of the population
- capacity of resistant bacteria to become established in ~~human intestinal flora~~ humans
- human-to-human transmission of the bacteria under consideration
- capacity of resistant bacteria to transfer resistance to human commensal bacteria and zoonotic agents
- amount and type of antimicrobials used in response to human illness
- dose, route of administration (oral, parenteral) and duration of human treatment
- pharmacokinetics (metabolism, bioavailability, access to intestinal flora).

5) Consequence assessment

A consequence assessment describes the relationship between specified exposures to resistant bacteria or resistance determinants and the consequences of those exposures. A causal process must exist by which exposures produce adverse health or environmental consequences, which may in turn lead to socio-economic consequences. The consequence assessment describes the potential consequences of a given exposure and estimates the probability of them occurring.

The following factors should be considered in the consequence assessment:

- dose–response relationships
- variation in disease susceptibility of exposed populations or subgroups of those populations
- variation and frequency of human health effects resulting from loss of efficacy of antimicrobials
- changes in human medicinal practices resulting from reduced confidence in antimicrobials
- changes in food consumption patterns due to loss of confidence in the safety of food products and any associated secondary risks
- associated costs
- interference with ~~a classical~~ first line/choice antimicrobial therapy in humans
- perceived future usefulness of the antimicrobial (time reference)
- prevalence of resistance in human bacterial pathogens under consideration.

6) Risk estimation

A risk estimation integrates the results from the release assessment, exposure assessment and consequence assessment to produce overall estimates of risks associated with the hazards. Thus, risk estimation takes into account the whole of the risk pathway from hazard identification to the unwanted consequences.

The following factors should be considered in the risk estimation:

- number of people falling ill and the proportion of that number affected with resistant strains of bacteria
- increased severity or duration of infectious disease
- number of person/days of illness per year
- deaths (total per year; probability per year or lifetime for a random member of the population or a member of a specific more exposed sub-population)
- importance of the pathology caused by the target bacteria
- absence of alternate antimicrobial therapy
- incidence of resistance observed in humans
- ~~some arbitrary scale of~~ consequences to allow weighted summation of different risk impacts (e.g. illness and hospitalisation).

7) Risk management options and risk communication

Risk management options and risk communication have to be continuously monitored and reviewed in order to ensure that the objectives are being achieved.

Article 3.9.4.3.

Analysis of risks to animal health

1) Definition of the risk

The infection of animals with bacteria that have acquired resistance from the use of a specific antimicrobial(s) in animals, and resulting in the loss of benefit of antimicrobial therapy used to manage the animal infection.

2) Hazard identification

- Bacteria that have acquired resistance, (including multiple resistance) arising from the use of an antimicrobial(s) in animals.
- Bacteria having obtained a resistance determinant(s) from ~~another~~ other bacteria which have acquired resistance arising from the use of an antimicrobial(s) in animals.

The identification of the hazard must include considerations of the class or subclass of the antimicrobial(s). This definition should be read in conjunction with point 4) of Article 3.9.4.1.

3) Release assessment

The following factors should be considered in the release assessment:

- animal species treated
- number of animals treated, sex, age and their geographical distribution
- amounts used and duration of treatment
- variation in methods and routes of administration of the antimicrobial(s)
- the pharmacodynamics/ pharmacokinetics of the antimicrobial(s)
- site and type of infection
- development of resistant bacteria
- mechanisms and pathways of resistance transfer
- cross-resistance and/or co-resistance
- surveillance of animals, ~~animal~~ products of animal origin and animal waste products for the existence of resistant bacteria.

4) Exposure assessment

The following factors should be considered in the exposure assessment:

- prevalence and trends of resistant bacteria in clinically ill and clinically unaffected animals
- prevalence of resistant bacteria in feed /the animal environment
- animal-to-animal transmission of the resistant bacteria
- number/percentage of animals treated
- dissemination of resistant bacteria from animals (animal husbandry methods, movement of animals)

- quantity of antimicrobial(s) used in animals
- treatment regimens (dose, route of administration, duration)
- survival capacity of resistant bacteria
- exposure of wild life to resistant bacteria
- disposal practices for waste products and the opportunity for animal exposure to resistant bacteria or resistance determinants in those products
- capacity of resistant bacteria to become established in animal intestinal flora
- exposure to resistance determinants from other sources
- dose, route of administration and duration of treatment
- pharmacokinetics (metabolism, bioavailability, access to intestinal flora)
- cycling of resistant bacteria between humans, animals and the environment.

5) Consequence assessment

The following factors should be considered in the consequence assessment:

- dose–response relationships
- variation in disease susceptibility of exposed populations and subgroups of ~~the~~ those populations
- variation and frequency of animal health effects resulting from loss of efficacy of antimicrobials
- changes in ~~veterinary medicine~~ practices resulting from reduced confidence in antimicrobials
- associated cost
- perceived future usefulness of the drug (time reference).

6) Risk estimation

The following factors should be considered in the risk estimation:

- number of therapeutic failures due to resistant bacteria
- animal welfare
- economic cost
- deaths (total per year; probability per year or lifetime for a random member of the population or a member of a specific more exposed sub-population)
- incidence of resistance observed in animals.

7) Risk management options and risk communication

Risk management options and risk communication have to be continuously monitored and reviewed in order to ensure that the objectives are being achieved.

The relevant recommendations (Articles 1.3.2.7., 1.3.2.5. and 1.3.2.6.) in the *Terrestrial Code* apply.

A range of risk management options is available to minimize the emergence and spread of antimicrobial resistance and these include both regulatory and non-regulatory risk management options, such as the development of codes of practice concerning the use of antimicrobials in animal husbandry. Risk management decisions need to consider fully the implications of these different options for human health and animal health and welfare and also take into account economic considerations and any associated environmental issues. Effective control of certain bacterial diseases of animals will have the dual benefit of reducing the risks linked to antimicrobial resistance, in cases where the bacterial disease under consideration has also developed antimicrobial resistance. Appropriate communication with all stakeholders is essential throughout the risk assessment process.

- - - - - - - - - - - - - -

— text deleted

Appendix XXV

Organisation Mondiale de la Santé Animale
World Organisation for Animal Health
Organización Mundial de Sanidad Animal

Original: English
November 2004

REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON AVIAN INFLUENZA

Padova (Italy), 8-10 November 2004

The OIE *ad hoc* Group on Avian Influenza met at the Istituto Zooprofilattico Sperimentale delle Venezie Laboratorio Virologia in Padova (Italy) from 8 to 10 November 2004.

The members of the OIE *ad hoc* Group and other participants are listed in Appendix I. The Agenda adopted is given in Appendix II.

On behalf of Dr B. Vallat, Director General of the OIE, Dr D. Wilson, Head of the International Trade Department, welcomed the experts and thanked them for their willingness to continue their work on revising the chapter of the OIE *Terrestrial Animal Health Code* (hereafter referred to as the "*Terrestrial Code*") on avian influenza (AI). He noted the following priorities for the work of the *ad hoc* Group: a definition of AI which took into account the associated notification obligations, compartmentalisation as a practical concept, vaccination, and measures for commodities commonly traded (addressing the different risks presented by low pathogenic AI [LPAI] and highly pathogenic AI [HPAI]). Dr A. Thiermann, President of the OIE Terrestrial Animal Health Standards Commission, provided a summary of discussions on AI since the previous meeting of the *ad hoc* Group. The OIE International Committee had adopted the new text proposed by the OIE Terrestrial Animal Health Standards Commission (hereafter referred to as the "Code Commission") 'under study' and this provided Delegates with an opportunity to study the articles in advance of their implementation.

The *ad hoc* Group stressed the need for the concepts of zoning and compartmentalisation to be better implemented by Member Countries as a way of minimising unjustified trade restrictions on countries reporting LPAI and of permitting commercial companies to move material safely. Effective compartmentalisation requires strong collaboration between the private and public sectors, with the biosecurity measures being developed by the former and auditing being carried out by the relevant competent authority. Accurate and timely disease reporting is an essential component of the process in order to gain and maintain credibility. The *ad hoc* Group agreed that a geographic factor may need to be included in the descriptions of some compartments to address the epidemiology of AI applicable in particular situations. The *ad hoc* Group strongly encouraged Member Countries to establish compartments and zones compatible with their particular situations, prior to the occurrence of outbreaks.

Update on Avian Influenza virus

Several review articles are referred to in (Appendix III), one discussing the present international situation regarding AI, a second the inactivation of the virus in various commercial egg products, and the third the distribution of virus in avian tissues. These are attached as pdf files.

Dr D. Swayne reported on some research which showed that AI viruses were inactivated during the normal commercial pasteurisation processes except the process carried out to produce powdered egg white (unless the egg raw materials had been pasteurised in its liquid form). There is ongoing research on the inactivation of the AI viruses in meat; data generated from current experimental work may allow extrapolation into the heat inactivation of the AI viruses in meat, however it is clear that several factors contribute to variation including virus titre and the species infected.

The presence or otherwise of LPAI viruses in meat is unresolved. Some research to date had shown that specific LPAI viruses were not present in chicken meat and bone, and viraemia was not a feature of the infection; however, virus had been found in the respiratory and intestinal tracts which indicated that carcass contamination with LPAI viruses was possible during the acute phase of the disease but was highly unlikely 21 days after the onset of clinical signs. This is supported by the fact that there is no record of LPAI viruses being transmitted via meat. There are some indications which suggest that LPAI viruses may be found in the meat of certain species in the acute phase of the disease and ongoing research will clarify some of these issues. In contrast, HPAI viruses did cause viraemia and could be found in meat, bones, blood and the interior of eggs in moderate to high levels, and hence HPAI infected poultry should not be used as a source of human food.

The *ad hoc* Group agreed that the behaviour of LPAI viruses is different in turkeys and ostriches in that these birds may show clinical signs, with virus being found in some organs. Definitive data had not been developed for turkey meat.

The *ad hoc* Group agreed that vaccination within a compartment was useful to reduce the level of virus in flocks during eradication campaigns but that it should be used only as a temporary measure as the virus could become endemic. As a result, vaccinated flocks needed to be under constant surveillance. Immunisation was shown to be able to prevent viraemia and the infection of meat and internal organs with HPAI viruses; however, immunisation will reduce but may not eliminate virus shedding from the respiratory and intestinal tracts.

While HPAI viruses are not generally pathogenic in adult ducks (although the 2002 Hong Kong strain has been reported to cause high rates of mortality), the virus could be found in meat. The *ad hoc* Group noted reports of mortalities in tigers and crows.

The *ad hoc* Group discussed the issues regarding AI in wild birds. In Asia, their contribution was difficult to assess although traditionally, HPAI has not been found in wild birds. Surveillance in wild birds adds knowledge of the ecology of AI viruses. There appears to be no predictive value in a positive finding in wild birds for AI infection in poultry. Isolation of AI viruses from wild birds alone should not compromise the status of a country or zone. Dr M.L. Perdue indicated that a World Health Organization research priority was to identify the influenza gene pool existing in animal reservoirs to better target surveillance towards the linkage between domestic animals and wild birds.

Review of the Highly Pathogenic Avian Influenza chapter in the 2004 *Terrestrial Code*

The *ad hoc* Group revised the proposals made at its November 2003 meeting, taking into account the latest information on the disease, the discussion at the OIE 72nd General Session, the risks presented by avian commodities usually traded and the comments received from Member Countries since December 2003. The revised proposals are at Appendix IV.

The proposal from South Africa that pigeons be included in the definition of 'poultry' was not adopted, as while pigeons could act as mechanical carriers, they are rarely infected themselves.

To address the New Zealand comment regarding the presence of NAI viruses in non-poultry species, the *ad hoc* Group redrafted the relevant articles.

The paragraphs on surveillance were deleted from the chapter as this issue will be addressed in an appendix on surveillance for NAI being developed by a separate *ad hoc* Group reporting to the Scientific Commission for Animal Diseases.

The incubation period of 21 days takes into account the maximum period for a flock of 14 days usually cited in the literature.

The *ad hoc* Group considered that the risk of virus transmission was highest for live birds and that surveillance to substantiate the safe export of live poultry from NAI free countries or zones/compartments should take into account the need to minimise the interval between testing and export of the live birds; routine surveillance would be sufficient for trade in product due to the inherently lower risks. Article 2.7.12.8 was modified accordingly.

Due to the systemic spread of HPNAI viruses, the likelihood of virus being present in product was considered to be higher than for LPNAI viruses. For hatching eggs, surface contamination was an issue for LPNAI virus but account needed to be taken of the presence of HPNAI within the egg.

For Article 2.7.12.13, the *ad hoc* Group agreed that surface decontamination was required to reduce virus levels on the surface of eggs; in this regard, LPNAI virus was more stable in faecal material than HPNAI virus.

Article 2.7.12.14 and Article 2.7.12.22 were deleted to address the public health risks associated with consumers being exposed to live virus from zones/compartments not free from HPNAI and the likelihood of diversion of material into pig or bird feed.

In Article 2.7.12.21, the exceptional requirements for turkey meat were removed.

.../Appendices

Appendix XXV (contd)

Appendix I

MEETING OF THE OIE *AD HOC* GROUP ON AVIAN INFLUENZA

Padova (Italy), 8-10 November 2004

List of Participants

AD HOC GROUP MEMBERS

Dr Dennis Alexander
VLA Weybridge
New Haw
Addlestone
Surrey KT15 3NB
UNITED KINGDOM
Tel: 44 1932 35 74 66
Fax: 44 1932 35 72 39
Email:
d.j.alexander@vla.defra.gsi.gov.uk

Dr Ilaria Capua
Istituto Zooprofilattico Sperimentale delle Venezie
Laboratorio Virologia
Via Romea 14/A
35020 Legnaro
Padova
ITALY
Tel: 39 49 808 43 69
Fax: 39 49 808 43 60
Email: icapua@izsvenezie.it

Dr David Swayne
Southeast Poultry Research Laboratory
USDA-ARS
934 College Station Road
Athens, GA 30605
UNITED STATES OF AMERICA
Tel: 1 706 546 3433
Fax: 1 706 546 3161
Email: dswayne@seprl.usda.gov

Dr Wolf-Arno Valder
National Expert
Directorate General for Health and Consumer Protection
Directorate E, Unit 2
European Commission
Rue Froissart 101/ 3-72
Brussels
BELGIUM
Tel: 32 2 29 58916
E-mail:
wolf-arno.valder@cec.eu.int

Dr Hernan Rojas
Director, Departmento de Protección Pecuaria
Servicio Agricola y Ganadero
Ministerio de Agricultura
Avenida Bulnes 140, 7 piso
Casilla 4088
Santiago
CHILE
Tel: 56-2-3451400
Fax:56-2-3451403
Email: hernan.rojas@sag.gob.c

Dr Maria Pittman
European Food Safety Authority
Assistant-Coordinator for the Panel on animal health and welfare
Rue Geneve 10-3/18
B-1040 Brussels
BELGIUM
Tel: 322 3372 446
Email: maria.pittman@efsa.eu.int

Dr Michael L. Perdue
Animal Influenza Liaison
Global Influenza Program, WHO
Geneva,
SWITZERLAND
41-22-791-3004
Email: perduem@who.int

OTHER PARTICIPANT

Dr Alex Thiermann
(President of the OIE Terrestrial Animal Health Standards Commission)
US Mission to the Organization for Economic Co-operation and Development
19, rue Franqueville
75016 Paris
FRANCE
Tel: 33 1 44 15 18 69
Fax: 33 1 42 67 09 87
E-mail: a.thiermann@oie.int

OIE CENTRAL BUREAU

Dr David Wilson
Head
International Trade Department
Tel.: 33 1 44 15 18 88
Fax: 33 1 42 67 09 87
E-mail: d.wilson@oie.int

Dr Tomoko Ishibashi
Chargée de mission
International Trade Department
Tel.: 33 1 44 15 18.88
Fax: 33 1 42 67 09 87
E-mail: t.ishibashi@oie.int

MEETING OF THE OIE *AD HOC* GROUP ON AVIAN INFLUENZA

Padova (Italy), 8-10 November 2004

Agenda

1. Introduction
2. Update on scientific and epidemiological information on avian influenza
3. Update on discussions at OIE General Session and other OIE fora
4. Review of the *Terrestrial Code* chapter
5. Other issues
6. Future work programme

Appendix III

RELEVANT ARTICLES

- Avian influenza: recent developments
  Ilaria Capua and Dennis J. Alexander
  Avian Pathology (August 2004) 33(4), 393-404

- Heat inactivation of avian influenza and Newcastle disease viruses in egg products
  David E. Swayne and Joan R. Beck
  Avian Pathology (October 2004) 33(5), 512-518

- Experimental Study to Determine if Low Pathogenicity and High Pathogenicity Avian Influenza Viruses Can Be Present in Chicken Breast and Thigh Meat following Intranasal Virus Inoculation,
  Swayne, D.E. and J.R. Beck. (2005)
  Avian Diseases 49(1): in press.

Appendix XXV (contd)

Appendix IV

CHAPTER 2.7.12.

HIGHLY PATHOGENIC AVIAN INFLUENZA

~~Article 2.7.12.1.~~

~~For the purposes of the *Terrestrial Code*, the *incubation period* for highly pathogenic avian influenza (HPAI) shall be 21 days.~~

~~Standards for diagnostic tests are described in the *Terrestrial Manual.*~~

~~Article 2.7.12.2.~~

~~**HPAI free country**~~

~~A country may be considered free from HPAI when it has been shown that HPAI has not been present for at least the past 3 years.~~

~~This period shall be 6 months after the slaughter of the last affected animal for countries in which a *stamping-out policy* is practised with or without vaccination against HPAI.~~

~~Article 2.7.12.3.~~

~~**HPAI infected zone**~~

~~A zone shall be considered as infected with HPAI until:~~

~~1)~~ ~~at least 21 days have elapsed after the confirmation of the last *case* and the completion of a *stamping-out policy* and *disinfection* procedures, or~~

~~2)~~ ~~6 months have elapsed after the clinical recovery or death of the last affected animal if a *stamping-out policy* was not practised.~~

~~Article 2.7.12.4.~~

~~*Veterinary Administrations* of *importing countries* should require similar arrangements to those provided in Chapter 2.7.13. (Newcastle disease) of the *Terrestrial Code* for the following *commodities*:~~

~~1)~~ ~~domestic and wild birds;~~

~~2)~~ ~~*day-old birds*;~~

~~3)~~ ~~*hatching eggs*;~~

~~4)~~ ~~semen of domestic and wild birds;~~

~~5)~~ ~~*fresh meat* of domestic and wild birds;~~

~~6)~~ ~~*products of animal origin* (from birds) *intended for use in animal feeding* or *for agricultural or industrial use*;~~

~~7) *pathological material* and biological products (from birds) which have not been processed to ensure the destruction of the HPAI virus.~~

Article 2.7.12.5.
~~(under study)~~

1. For the purposes of this *Terrestrial Code*, notifiable avian influenza (NAI) is defined as an infection of poultry caused by any influenza A virus of the H5 or H7 subtypes or by any AI virus with an intravenous pathogenicity index (IVPI) greater than 1.2 (or as an alternative at least 75% mortality) as described below. NAI viruses can be divided into highly pathogenic notifiable avian influenza (HPNAI) and low pathogenicity notifiable avian influenza (LPNAI):

   a) HPNAI viruses have an IVPI in 6-week-old chickens greater than 1.2 or, as an alternative, cause at least 75% mortality in 4-to 8-week-old chickens infected intravenously. H5 and H7 viruses which do not have an IVPI of greater than 1.2 or cause less than 75% mortality in an intravenous lethality test should be sequenced to determine whether multiple basic amino acids are present at the cleavage site of the haemagglutinin molecule (HA0); if the amino acid motif is similar to that observed for other HPNAI isolates, the isolate being tested should be considered as HPNAI.

   b) LPNAI are all influenza A viruses of H5 and H7 subtype that are not HPNAI viruses.

2. Poultry is defined as 'all birds reared or kept in captivity for the production of meat or eggs for consumption, for the production of other commercial products, for restocking supplies of game, or for breeding these categories of birds'.

3. For the purpose of international *trade*, this chapter deals not only with the occurrence of clinical signs caused by an NAI virus, but also with the presence of infection with an NAI virus in the absence of clinical signs.

4. The following defines the occurrence of infection with an NAI virus:

   a) HPNAI virus has been isolated and identified as such or ~~specific~~ viral RNA specific for HPNAI has been detected in poultry or a product derived from poultry, or

   b) LPNAI virus has been isolated and identified as such or ~~specific~~ viral RNA specific for LPNAI has been detected in poultry or a product derived from poultry, or

   c) antibodies to H5 or H7 subtype of NAI virus that are not a consequence of vaccination~~, nor indicative of a non-specific reaction, have been detected in poultry; in such cases, virus isolation should be attempted to establish whether the serological positivity is due to LPNAI or HPNAI. If appropriate samples are not available or if results are negative, a thorough epidemiological investigation including further sampling and testing should be carried out to identify the type or exclude the presence of NAI infection.~~ have been detected in poultry. In the case of isolated serological positive results, NAI infection may be ruled out on the basis of a thorough epidemiological investigation that does not indicate further evidence of NAI infection.

For the purposes of this *Terrestrial Code*, 'NAI-free establishment' means an *establishment* in which the birds on the *establishment* have shown ~~there has been no clinical sign~~ no evidence of NAI infection ~~for the past 21 days~~ based on surveillance in accordance with Appendix XXX, and the *establishment* is situated within a country, *zone/compartment* free from HPNAI, but not ~~situated~~ within 3 kilometres of any *establishment* infected with HPNAI or ~~and~~ within one kilometre of any

establishment infected with LPNAI within the past 21 days.

For the purposes of this *Terrestrial Code*, the *incubation period* for NAI shall be 21 days.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Any vaccine used should comply with the standards described in the *Terrestrial Manual*.

Article 2.7.12.6.
~~(under study)~~

The NAI status of a country or a *zone/compartment* can be determined on the basis of the following criteria:

1) the outcome of a risk assessment identifying all potential factors for NAI occurrence and their historic perspective;

2) NAI is notifiable in the whole country, an on-going NAI awareness programme is in place, and all notified suspect occurrences of NAI are subjected to field and, where applicable, laboratory investigations;

3) appropriate surveillance is in place to demonstrate the presence of infection in the absence of clinical signs in poultry, and the risk posed by birds other than poultry; this may be achieved through an NAI surveillance programme in accordance with Appendix XXX ~~this Chapter and Chapter 1.3.6~~.

Article 2.7.12.7.
~~(under study)~~

NAI free country or zone/compartment

A country or *zone/compartment* may be considered free from NAI when it has been shown that NAI infection has not been present in the country or *zone/compartment* for the past 12 months based on surveillance in accordance with Appendix XXX. The surveillance may need to be adapted to parts of the country or existing *zones/compartments* depending on historical or geographical factors, industry structure, population data, or proximity to recent *outbreaks*.

If infected poultry are slaughtered or a *stamping out policy* is carried out, this period shall be 3 months after ~~the slaughter of the last infected poultry and~~ *disinfection* of all affected *establishments*, providing that surveillance in accordance with Appendix XXX has been carried out during that 3-month period. In the case of HPNAI infections, a *stamping out policy* should be applied; in LPNAI infections, poultry may be slaughtered for human consumption subject to specified conditions.

~~The NAI status should be determined by an ongoing surveillance and monitoring programme (carried out in conformity with the provisions of Chapter 1.3.6.) based on virus isolation, virus detection or serology. The programme may need to be adapted to target parts of the country or *zone/compartment* at a higher risk due to historical or geographical factors, population data, or proximity to recent *outbreaks*.~~

~~Freedom of infection in a country or zone can be demonstrated with random and/or targeted serological surveillance at a minimum interval of 6 months designed to provide at least a 95% level of confidence of detecting a prevalence of NAI infected enterprises of 1%. Freedom of infection in a *compartment* can be demonstrated with an ongoing surveillance programme designed to provide at least a 95% level of confidence of detecting a prevalence of NAI infection of 10%. Each *establishment* should be sampled to provide a 95% level of confidence of detecting a~~

~~prevalence of NAI of 25%. For commercial ducks the surveillance programme should be based on virus isolation or detection in the absence of validated serological methods.~~

~~In the case of a country or *zone* in which vaccination is being conducted, the ongoing surveillance and monitoring programme (carried out in conformity with the provisions of Chapter 1.3.6.) based on virus isolation, virus detection or serology should be carried out on all vaccinated flocks at a minimum interval of 6 months. In each vaccinated flock, the number of birds to be tested should provide at least a 95% level of confidence of detecting a prevalence of NAI infection of 25%. In the case of a *compartment* in which vaccination is being conducted, the ongoing surveillance and monitoring programme (carried out in conformity with the provisions of Chapter 1.3.6.) based on virus isolation, virus detection or serology should be carried out to provide at least a 95% level of confidence of detecting a prevalence of NAI infection of 10%. If a serological test is used, it should be able to distinguish vaccinated birds from infected birds. Additional security should be provided by the use of identifiable sentinel birds which can be clinically inspected or tested to help identify field infections in vaccinated flocks.~~

Article 2.7.12.7.bis

HPNAI free country or zone/compartment

A country or *zone/compartment* may be considered free from HPNAI when, based on surveillance in accordance with Appendix XXX, it does not meet the criteria for freedom from NAI and, based on subsequent surveillance in accordance with Appendix XXX, no NAI virus detected has been identified as HPNAI virus. The surveillance may need to be adapted to parts of the country or existing *zones/compartments* depending on historical or geographical factors, industry structure, population data, or proximity to recent *outbreaks*.

If infected poultry are slaughtered or a *stamping out policy* is carried out, this period shall be 3 months after *disinfection* of all affected *establishments*, providing that surveillance in accordance with Appendix XXX has been carried out during that 3-month period. In the case of HPNAI infections, a *stamping out policy* should be applied.

Article 2.7.12.8.
~~(under study)~~

When importing from an NAI free country or *zone/compartment*, *Veterinary Administrations* should require:

for live poultry (other than day-old poultry)

the presentation of an *international veterinary certificate* attesting that:

1) the poultry showed no clinical sign of NAI on the day of shipment;

2) the poultry were kept in an NAI free country or *zone/compartment* since they were hatched or for the past 21 days;

2bis the required surveillance has been carried out on the *establishment* within the past 21 days;

3) the poultry either have not been vaccinated against NAI, or have been vaccinated and the date of vaccination and the details of the vaccine are stated.

Article 2.7.12.9.
~~(under study)~~

Regardless of the NAI status of the country or *zone/compartment* of origin, *Veterinary Administrations* should require:

for live birds other than poultry

the presentation of an *international veterinary certificate* attesting that the birds:

1) showed no clinical sign of infection with a virus which would be considered NAI in poultry on the day of shipment;

2) were kept in isolation approved by the *Veterinary Services* since they were hatched or for the 21 days prior to shipment and showed no clinical sign of infection with a virus which would be considered NAI in poultry during the isolation period;

3) were subjected to a diagnostic test 7 to 14 days prior to shipment to demonstrate freedom from infection with a virus which would be considered NAI in poultry.

Article 2.7.12.10.
~~(under study)~~

When importing from an NAI free country or *zone/compartment*, *Veterinary Administrations* should require:

for day-old live poultry

the presentation of an *international veterinary certificate* attesting that:

1) the poultry were kept in an NAI free country or *zone/compartment* since they were hatched;
2) the poultry were derived from parent flocks which had been kept in an NAI free country or *zone/compartment* for 21 days prior to and at the time of the collection of the eggs;
3) and/or the parent flock had/had not been vaccinated and, if vaccinated, the date of vaccination and the details of the vaccine are stated.

Article 2.7.12.10.bis

When importing from an HPNAI free country or *zone/compartment*, *Veterinary Administrations* should require:

for day-old live poultry

the presentation of an *international veterinary certificate* attesting that:

1) the poultry were kept in an HPNAI free country or *zone/compartment* since they were hatched;
2) the poultry were derived from parent flocks which had been kept in an NAI free *establishment* for 21 days prior to and at the time of the collection of the eggs;
3) and/or the parent flock had/had not been vaccinated and, if vaccinated, the date of vaccination and the details of the vaccine are stated.

Article 2.7.12.11.
~~(under study)~~

When importing from an NAI free country or *zone/compartment*, *Veterinary Administrations* should require:

for *hatching eggs*

the presentation of an *international veterinary certificate* attesting that the eggs:

1) came from an NAI free country or *zone/compartment*;

2) were derived from parent flocks which had been kept in an NAI free country or *zone/compartment* for 21 days prior to and at the time of the collection of the eggs;

3) were derived from parent flocks which had not been vaccinated against NAI, or which had been vaccinated against NAI and the date of vaccination and the details of the vaccine are stated.

Article 2.7.12.11.bis

When importing from a HPNAI free country or *zone/compartment*, *Veterinary Administrations* should require:

for *hatching eggs*

the presentation of an *international veterinary certificate* attesting that the eggs:

1) came from an HPNAI free country or *zone/compartment*;

2) were derived from parent flocks which had been kept in an NAI free *establishment* for 21 days prior to and at the time of the collection of the eggs;

3) were derived from parent flocks which had not been vaccinated against NAI, or which had been vaccinated against NAI and the date of vaccination and the details of the vaccine are stated.

Article 2.7.12.12.
~~(under study)~~

When importing from an NAI free country or *zone/compartment*, *Veterinary Administrations* should require:

for eggs for consumption

the presentation of an *international veterinary certificate* attesting that the eggs come from an NAI free country or *zone/compartment*.

Article 2.7.12.13.
~~(under study)~~

When importing from a HPNAI free country or *zone/compartment*, *Veterinary Administrations* should require:

for eggs for consumption

the presentation of an *international veterinary certificate* attesting that the eggs:

1) come from a country or *zone/compartment* free from HPNAI infection;

2) come from an NAI free *establishment*; or

3) have had their surfaces decontaminated, and are transported in new disposable packing material.

~~Article 2.7.12.14.~~
~~(under study)~~

~~When importing from a country or *zone/compartment* not known to be free from HPNAI, *Veterinary Administrations* should require:~~

~~for eggs for consumption~~

~~the presentation of an *international veterinary certificate* attesting that the entire consignment of eggs comes from birds:~~

~~1) which have been kept in an NAI free *establishment*;~~

~~2) which have been tested serologically or by virus detection to give a 95% probability of detecting a 5% prevalence of NAI infection, every 21 days, with negative results.~~

Article 2.7.12.15.
~~(under study)~~

When importing from an NAI free country or *zone/compartment*, *Veterinary Administrations* should require:

for egg products

the presentation of an *international veterinary certificate* attesting that the egg products come from, and were processed in, an NAI free country or *zone/compartment*.

~~Article 2.7.12.16.~~
~~(under study)~~

~~When importing from a country or *zone/compartment* free from HPNAI infection, *Veterinary Administrations* should require:~~

~~for egg products~~

~~the presentation of an *international veterinary certificate* attesting that the egg products come from, and were processed in a country or *zone/compartment* free from HPNAI infection.~~

Article 2.7.12.17.
~~(under study)~~

When importing from a country or *zone/compartment* not known to be free from ~~HP~~NAI, *Veterinary Administrations* should require:

for egg products

the presentation of an *international veterinary certificate* attesting that the egg products:

1) are derived from eggs ~~for consumption~~ which meet the requirements of Articles 2.7.12.11., 2.7.12.11.bis, 2.7.12.12., or 2.7.12.13. ~~or 2.7.12.14.~~; or

2) were processed to ensure the destruction of NAI virus, and the necessary precautions were taken after processing to avoid contact of the *commodity* with any source of an NAI virus.

Article 2.7.12.18.
~~(under study)~~

When importing from an NAI free country or *zone/compartment*, *Veterinary Administrations* should require:

for poultry semen

the presentation of an *international veterinary certificate* attesting that the donor poultry:

1) showed no clinical sign of NAI on the day of semen collection;

2) were kept in an NAI free country or *zone/compartment* for the 21 days prior to and at the time of semen collection.

Article 2.7.12.18.bis

When importing from a HPNAI free country or *zone/compartment*, *Veterinary Administrations* should require:

for poultry semen

the presentation of an *international veterinary certificate* attesting that the donor poultry:

1) came from an HPNAI free country or *zone/compartment*;

2) were kept in an NAI free *establishment* for 21 days prior to and at the time of semen collection;

3) had not been vaccinated against NAI, or which had been vaccinated against NAI and the date of vaccination and the details of the vaccine are stated.

Article 2.7.12.19.
~~(under study)~~

Regardless of the NAI status of the country or *zone/compartment* of origin, *Veterinary Administrations* should require:

for semen of birds other than poultry

the presentation of an *international veterinary certificate* attesting that the donor birds:

1) were kept in isolation approved by the *Veterinary Services* for the 21 days prior to semen collection;

2) showed no clinical sign of infection with a virus which would be considered NAI in poultry during the isolation period;

3) were tested between 7 and 14 days prior to semen collection and shown to be free of NAI.

Article 2.7.12.20.
~~(under study)~~

When importing from an NAI free country or *zone/compartment*, *Veterinary Administrations* should require:

for *fresh meat* and *meat products* of poultry, and poultry viscera

the presentation of an *international veterinary certificate* attesting that the entire consignment of *fresh meat* comes from birds:

1) which have been kept in an NAI free country or *zone/compartment* since they were hatched or for the past 21 days;

2) which have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for NAI with favourable results.

Article 2.7.12.21.
(under study)

When importing from a HPNAI free country or *zone/compartment*, *Veterinary Administrations* should require:

for *fresh meat* and *meat products* of poultry (other than turkey)

the presentation of an *international veterinary certificate* attesting that the entire consignment of *fresh meat* comes from birds:

1) which were derived from flocks which came from an NAI free *establishment*; or

2) which have been kept in an *establishment* since they were hatched or for the past 21 days and in which there has been no clinical sign evidence of NAI in the past 21 days; and

2)bis were derived from flocks which have been tested for the presence of NAI viruses, using virus detection or isolation tests, with negative results, 7-10 days prior to the slaughter of the birds;

3) which have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for NAI with favourable results.

Article 2.7.12.22.
(under study)

When importing from a country or *zone/compartment* not known to be free from HPNAI, *Veterinary Administrations* should require:

for *fresh meat* and *meat products* of poultry and poultry viscera (other than turkey)

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat or *meat product* comes from birds:

1) which have been kept in a free *establishment*;

2) which have been tested to give a 95% probability of detecting a 5% prevalence of NAI infection not more than 7 days prior to slaughter using virus detection or virus isolation tests, and serological tests, with negative results in all cases;

3) which have been slaughtered in an *approved abattoir* which has not processed poultry infected with NAI since last cleaned and disinfected, and have been subjected to ante-mortem and post-mortem inspections for NAI with favourable results.

Article 2.7.12.23.
(under study)

When importing from a country or *zone/compartment* not known to be free from NAI, *Veterinary Administrations* should require:

~~for *fresh meat* and *viscera* of turkey~~

~~the presentation of an *international veterinary certificate* attesting that the entire consignment of meat comes from birds:~~

~~1) which have been kept in a free *establishment*;~~

~~2) which have been tested to give a 95% probability of detecting a 5% prevalence of NAI infection not more than 7 days prior to slaughter using virus detection or virus isolation tests, and serological tests, with negative results in all cases;~~

~~3) which have been slaughtered in an *approved abattoir* which has not processed poultry infected with NAI since last cleaned and disinfected, and have been subjected to ante mortem and post mortem inspections for NAI with favourable results.~~

Article 2.7.12.24.
~~(under study)~~

Regardless of the NAI status of the ~~When importing from a~~ country or *zone/compartment* of origin ~~not known to be free from NAI~~, *Veterinary Administrations* should require:

for *meat products* ~~and processed viscera~~ of poultry

the presentation of an *international veterinary certificate* attesting that:

1) the *commodity* is derived from *fresh meat* ~~and/or *meat products* and/or viscera~~ which meet the requirements of Articles 2.7.12.20. or 2.7.12.21. ~~or 2.7.12.22.;~~ or

2) the *commodity* has been processed to ensure the destruction of the NAI virus;

3) the necessary precautions were taken ~~after processing~~ to avoid contact of the *commodity* with any source of NAI virus.

Article 2.7.12.25.
~~(under study)~~

Regardless of the NAI status of the ~~When importing from an NAI free~~ country or *zone/compartment* of origin, *Veterinary Administrations* should require:

for products of poultry origin intended for use in animal feeding, or for agricultural or industrial use

the presentation of an *international veterinary certificate* attesting that:

2) these products come from birds which have been kept in an NAI free country or *zone/compartment* since they were hatched or for the past 21 days; or

2) these products have been processed to ensure the destruction of the NAI virus;

3) the necessary precautions were taken to avoid contact of the products with any source of NAI virus.

~~Article 2.7.12.26.~~
~~(under study)~~

~~When importing from a country or *zone/compartment* not considered free from NAI, *Veterinary Administrations* should require:~~

~~for meal containing meat and/or feathers and/or bones (from poultry)~~

~~the presentation of an *international veterinary certificate* attesting that:~~

~~1) the commodity has been processed to ensure the destruction of the NAI virus;~~

~~2) the necessary precautions were taken after processing to avoid contact of the *commodity* with any source of NAI virus.~~

Article 2.7.12.27.
~~(under study)~~

Regardless of the NAI status of the ~~When importing from an NAI free~~ country or *zone/compartment* of origin, *Veterinary Administrations* should require:

for feathers and down (from poultry)

the presentation of an *international veterinary certificate* attesting that:

2) ~~the entire consignment of feathers or down~~ these products come from birds which have been kept in an NAI free country or *zone/compartment* since they were hatched or for the past 21 days; or

2) these products have been processed to ensure the destruction of the NAI virus;

3) the necessary precautions were taken to avoid contact of the products with any source of NAI virus.

~~Article 2.7.12.28.~~
~~(under study)~~

~~When importing from a country or *zone/compartment* not known to be free from NAI, *Veterinary Administrations* should require:~~

~~for feathers and down (from poultry)~~

~~the presentation of an *international veterinary certificate* attesting that:~~

~~1) the *commodity* has been processed to ensure the destruction of the NAI virus;~~

~~2) the necessary precautions were taken after processing to avoid contact of the *commodity* with any source of NAI virus.~~

Article 2.7.12.29.
~~(under study)~~

Regardless of the NAI status of the country or *zone/compartment* of origin, *Veterinary Administrations* should require for the importation of:

meat or other products from birds other than poultry

the presentation of an *international veterinary certificate* attesting that:

1) the *commodity* has been processed to ensure the destruction of the NAI virus;

2) the necessary precautions were taken after processing to avoid contact of the *commodity* with any source of an NAI virus.