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Acting Deputy Director General

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**Object: Report of the September 2007 Meeting of the Terrestrial Animal Health Standard Commission – Comments of the European Community**

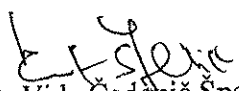
Dear Bernard,

Please find attached as an annex to this letter the Community comments on the report of the meeting of Code Commission last September 2007.

We wish to express our admiration in front of the tremendous work of the TAHSC and the OIE in general in its task for better harmonised and useful standards and guidelines.

As usual the comments are inserted in boxes directly in the drafts, and propose deletions, addenda and/or alternative wording, with justification. In case these would not be agreed by the Code Commission at its next meeting in March 2008, it would be useful that we receive justified answers too, so that a real discussion takes place and the drafts can move on more easily.

We thank you for the continued excellent collaboration and trust you will find our comments constructive and useful.

  
Dr Vida Čadonič Špelič  
CVO Slovenia

  
Paola Testori Coggi  
Deputy Director General

Enclosures: 1

Cc: All CVOs Member States, Croatia, Iceland, Norway, Turkey and Switzerland

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## ANNEX



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

Original: English  
September 2007

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

Paris, 17-28 September 2007

The OIE Terrestrial Animal Health Standards Commission (the Code Commission) met at the OIE Headquarters in Paris on 17 - 28 September 2007.

The members of the Code Commission are listed in [Annex I](#) and the agenda adopted is in [Annex II](#).

The Code Commission reviewed the agenda papers, addressing comments that Members had submitted by 15 August and amending texts in the OIE *Terrestrial Animal Health Code* (the *Code*) where appropriate. The amendments are shown in the usual manner by double underline and ~~strikeout~~ and may be found in the Annexes to the report.

In Annexes IV and XVII (General obligations and classical swine fever), amendments made at this meeting (September 2007) are shown with a coloured background to distinguish them from those made prior to the 75<sup>th</sup> General Session.

Members should note that, unless stated otherwise, texts submitted for comment may be proposed for adoption at the 76th General Session. Depending on the comments received on each text, the Code Commission will identify, in the report of its March 2008 meeting, the texts proposed for adoption in May 2008.

The Code Commission strongly encourages Members to participate in the development of the OIE's international standards by submitting comments on this report. It would be very helpful if comments were submitted as specific proposed text changes, supported by a scientific rationale. Members **should not use the automatic 'track-change' function** provided by word processing software as such changes are lost in the process of collating Members' submissions into the Code Commission's working documents.

Comments on this report must reach OIE Headquarters by **8 February 2008** to be considered at the March 2008 meeting of the Code Commission. Comments should be sent to the International Trade Department at: [trade.dept@oie.int](mailto:trade.dept@oie.int).

Dr Thiermann welcomed members of the Code Commission to OIE Headquarters on behalf of Dr Vallat, Director General, who was unable to join the meeting due to mission travel. He stated that Dr Vallat would meet with the Code Commission on his return. Dr Thiermann commented that the Code Commission had a heavy workload for this meeting and thanked members for taking the responsibility to lead the discussion on particular agenda items. He advised members that joint meetings would be held with the Scientific Commission for Animal Diseases (the Scientific Commission) and with the Biological Standards Commission.

The Code Commission acknowledges comments submitted by Australia, Canada, Chinese Taipei, the European Union (EU), Japan, New Zealand, South Africa, Switzerland and the United States of America (USA).

#### **Community comments:**

**The Community thanks and congratulates the OIE and especially the TAHSC for the tremendous work achieved. It reiterates its will to continue participating in this work as much as possible.**

**Community general comments are included in Part C of this report and specific comments in each Annex.**

**The first general comment would be that the answers given by the OIE to the Community's last comments lack some precision and argumentation. The Community tries as much as possible to give rationale to its comments, and if these comments are not taken on board, then it should also be better justified by arguments directly contradicting the rationale or strong enough not to retain them. It should not be felt that some changes of the Code are not motivated by a wish of actual improvement and based upon solid and practical argumentation.**

**Another general comment concerns the deletion of the word "approved" before "laboratory" (see below paragraph B.1.j): even if the definition of *laboratory* implies official approval, it should be clearly brought to the attention of the Members who read the chapters; thus it seems much preferable to retain the former wording of "approved laboratory".**

**Finally, it appears that the translation of the drafts in some places differs too much from the English version; this should be addressed after the next TAHSC meeting.**

### **A. MEETING WITH THE DIRECTOR GENERAL**

Dr Vallat joined the Code Commission for a discussion on strategic issues. He advised the Code Commission on important developments in Africa, particularly the view of some African Members that the OIE is not addressing the need for 'commodity-based standards'. Dr Vallat instructed the Code Commission to ensure that *Code* provisions relevant to trade in commodities be made more visible, perhaps by working with an expert to develop guidelines on using the current *Code* to support trade on a commodity basis. Clearly the OIE must take into account the disease status of a country. However, if procedures or treatments can be used to manage risk, the *Code* currently supports export according to appropriate treatments.

On classical swine fever (CSF), Dr Vallat noted that the OIE supports the use of the DIVA principle (differentiating infected and vaccinated animals) but, for the moment, the OIE cannot recommend the use of commercially available marker vaccines in domestic pigs in all situations. The Biological Standards Commission will address this question. The OIE does, however, recommend and support the use of oral vaccines in wild pigs and this approach should be strengthened and be accompanied by systematic surveillance of wildlife for CSF infection based on the standards of the OIE. Dr Vallat noted that a new *Code* chapter on this topic is needed soon. The Director General noted that according to the current *Code*, the OIE could not treat CSF in the same way as it treats avian influenza and that the CSF situation in wild pigs should be taken into account in determining the CSF status of a country/zone. In regard to vector borne diseases, Dr Vallat mentioned the worrying situation with bluetongue in Europe and advised his view that vaccination will certainly be needed to prevent disruption of live animal trade. Used correctly, vaccines can help provide conditions for safe trade. Therefore, it would be appropriate that the OIE update its recommendations on the topic of bluetongue vaccines.

On rinderpest, the Director General noted Dr Thiermann's advice that further work is to be done in formatting the chapter and appendix but that no significant change to the text adopted in May was proposed.

On animal welfare, Dr Vallat reminded the Code Commission of the need to take account of the constraints of developing countries when producing *Code* texts. The OIE should take a practical rather than a philosophical approach and aim to develop standards that can be applied by all OIE Members.

Dr Vallat noted that the Code Commission endorsed the revised OIE PVS Tool. He also commented that the concept of 'community animal health worker' is very important in Africa and other regions. The OIE will develop some guidance on this topic, which will be addressed by the *ad hoc* Group on Evaluation of Veterinary Services.

## **B. JOINT MEETINGS OF COMMISSIONS**

### **1. Meeting of the Code Commission and the Scientific Commission**

#### **a) Definitions of surveillance, monitoring and infection (Chapter 1.1.1.)**

The Commissions discussed the difficulties in reaching universal consensus and agreed to use relevant dictionary definitions of these terms, without variation.

A new definition was agreed for *infection*: 'the entry and development or multiplication of an infectious agent in the body of man or animals' (from *A Dictionary of Epidemiology* 4<sup>th</sup> Ed. 2001 Edited by John M. Last. Oxford University Press).

#### **b) Requirement for a buffer zone (Chapter 2.2.10.)**

The Code Commission discussed the Scientific Commission's recommendation that it should not be obligatory to require a buffer zone or physical/geographical barrier in Articles 2.2.10.3., 2.2.10.4. and 2.2.10.5. The two Commissions could not reach a consensus and the Code Commission decided not to make these amendments, but welcomes comments from Members on this proposal.

#### **c) Containment zone (Chapter 2.2.10.)**

The Commissions jointly examined Members' comments and agreed to modify existing text in Chapter 2.2.10. as follows:

- An effective containment strategy (not necessarily stamping out) is required.
- The primary outbreak and the likely source of the outbreak should be identified.
- The period to establish a *containment zone* should read 'no new cases...within a minimum of two incubation periods...?'

The modified text on containment zone from Chapter 2.2.10. was taken into account in drafting a generic text on containment zone and incorporated into Chapter 1.3.5.

The amended text may be found at Annex VII.

#### **d) Compartmentalisation for vector borne diseases**

The Commissions discussed the potential application of the concept of compartmentalisation for vector borne diseases. While the two Commissions did not reach consensus on whether compartmentalisation could be systematically applied to these diseases, it was agreed to add the term '*establishment*' in Article 3.8.10.3., to be congruent with the definition of compartmentalisation in the *Code*.

**e) Classical swine fever (Chapter 2.6.7.)**

The Commissions discussed the rationale for the *Code*'s treatment of classical swine fever (CSF) infection in wildlife, noting that findings of FMD in wildlife affect the FMD status of the country whereas findings of avian influenza (AI) in wild birds do not affect the AI status of the country. It was agreed that the key factor to consider is whether CSF is endemic in the wild pigs or occurring sporadically (e.g. incursions from a neighbouring country). On the basis of discussion between the Director General and the Code Commission, it was decided that findings of CSF infection in wild pigs would continue to be taken into account in determining the status of the country or zone.

**f) Checklist on the application of compartmentalisation**

It was agreed that no further work need be done on the Checklist on the application of compartmentalisation for AI/ND for the time being.

**g) BSE chapters and appendices (Chapter 2.3.13. and Appendices 3.8.4. and 3.8.5.)**

It was agreed that an *ad hoc* Group on BSE would be convened to review *Code* texts on BSE (Chapter 2.3.13., Appendix 3.8.4. and Appendix 3.8.5.) and the BSE country status questionnaire to ensure congruency. In the course of this work, the *ad hoc* Group would be asked to review Members' comments on Appendix 3.8.5. The Commissions agreed that once guidelines and questionnaires for categorisation of countries had been revised, they should be adopted and published in the *Code*.

**h) Commodity-based measures in the Code**

On trade in livestock commodities, the Commissions agreed that an expert group should be convened to develop, if possible, an appropriate 'systems approach' to make more visible and to give more details on safe commodities, starting with deboned, matured and pH tested beef.

**i) Equine influenza (Chapter 2.5.5.)**

Article 2.5.5.3. (surveillance for equine influenza) was discussed in light of a Member's comment. The requirement for surveillance was considered to be too prescriptive and the text was modified accordingly.

**j) Approved laboratory**

The Scientific Commission requested to use "*laboratory which is approved*" instead of "*approved laboratory*". As the definition of "*laboratory*" in the *Code* includes the requirement for approval by the Veterinary Authority, the Code Commission decided to delete the word "*approved*" before "*laboratory*" throughout the *Code*.

**k) Administrative procedure for reconfirmation of disease status of countries / zones**

In keeping with the Resolution adopted at the 75<sup>th</sup> General Session, the Scientific Commission asked the Code Commission to add requirements for annual reconfirmation of country and zone disease status as currently required for FMD. The Code Commission made the appropriate changes.

The amended text may be found at Annexes VII, VIII, IX and XII.

**2. Meeting of the Code Commission and the Biological Standards Commission**

**a) Rabies (Chapter 2.2.5.)**

The Commissions discussed the question of whether findings of bat lyssavirus infection should affect the rabies free status of a country, noting the advice of the Scientific Commission that European and Australian bat lyssaviruses should be treated equally. The Commissions agreed that it is important to encourage reporting of lyssaviruses in bats to get a better understanding of how the virus behaves in

wildlife and to protect human health. The *Code* should encourage reporting and at the same time discourage unnecessary impediments to international trade. In the short term, the Commissions agreed that the *Code* should be amended to the effect that findings of Australian bat lyssaviruses do not affect a country's rabies free status.

The Commissions noted the policy of the World Health Organization (WHO) that a rabies free country is one that has not reported lyssavirus infection in man or any animal species, including bats, at any time during the previous two years and agreed that the OIE should review the treatment of lyssaviruses in the *Code* in view of the increasing importance of these emerging viruses.

**b) Paratuberculosis (Chapter 2.2.6.)**

On paratuberculosis, the Commissions agreed that the Biological Standards Commission would track developments in diagnostic testing. Once effective diagnostic methods are available, the OIE should develop a chapter on paratuberculosis.

**c) Bovine tuberculosis (Chapter 2.3.3.)**

On bovine tuberculosis, the Biological Standards Commission undertook to examine alternatives to tuberculin testing and draft appropriate text for inclusion in the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (the *Manual*).

**d) Classical swine fever (Chapter 2.6.7.)**

On classical swine fever, Dr Edwards advised that the current marker vaccines have shortcomings and it is not yet appropriate to include them in Chapter 2.1.13. of the *Manual*. However, the Biological Standards Commission will keep this matter under review.

**e) Equine rhinopneumonitis (Chapter 2.5.7.)**

On equine rhinopneumonitis, the Commissions discussed the proposal of a Member to clarify that 'clinical signs of equine herpesvirus type 1 (EHV1) infection' refers to the abortigenic or paralytic forms of infection. The Commissions agreed that EHV1 is virtually ubiquitous and that the *Code* should not impose unnecessary measures on trade. Clinical signs of EHV1 and EHV4 infection can be indistinguishable. A wide variety of clinical signs may be found in EHV1 infection. Therefore, it was agreed to retain the title of the chapter as Equine rhinopneumonitis.

**f) Porcine reproductive and respiratory syndrome**

The Commissions discussed the priority to develop a text on porcine reproductive and respiratory syndrome (PRRS) in the chapter, given the serious impact of the disease recently in Asia. PRRS is listed by the OIE and the *Manual* contains guidance on the disease. Dr Thiermann undertook to raise this with the Director General of the OIE.

**g) Equine encephalosis**

On equine encephalosis, the Biological Standards Commission advised that this orbivirus infection, which is among the differential diagnoses for African horse sickness, appears to be an emerging disease in Africa. Dr Edwards indicated that the Biological Standards Commission would be examining it further. Dr Thiermann clarified that the Code Commission does not intend to work on this disease at this time.

**h) West Nile fever**

The Commissions discussed the West Nile fever test requirements. At this time, validated tests are only available for horses and no test has yet been validated for poultry. As ducks and geese pose a risk of transmitting West Nile virus (WNV), the Commissions agreed that the testing requirement should

apply to these poultry. The Biological Standards Commission considered that the PCR based test, validated for horses, is likely to be applicable to ducks and geese and they are studying this matter.

The changes to the *Code* chapter are reflected in Annex XX.

**i) Evaluation of veterinary services**

The Commissions discussed the revised OIE PVS Tool with particular reference to the new section dealing with the quality of diagnostic laboratories. Dr Edwards expressed some concern that a complete review of diagnostic laboratories may be beyond the scope of a PVS evaluation. The Biological Standards Commission has developed a detailed quality standard for laboratories, including competence in quality assurance systems.

While it is clear that the PVS evaluation does not have the goal of assessing laboratories against the OIE laboratories quality standard, the Biological Standards Commission felt that some expertise on laboratory operation and management should be included in the *ad hoc* Group on Evaluation of Veterinary Services and that the proposed criteria should be reviewed.

**j) Reformatting of the *Code* and the *Manual***

The Commissions discussed the proposal to move pertinent sections between the *Code* and the *Manual*. The Commissions agreed in principle to the proposal and asked the responsible departments of the OIE to advise on how best to manage this.

## C. EXAMINATION OF MEMBERS' COMMENTS AND WORK OF RELEVANT EXPERT GROUPS

### 1. General definitions

**Community comments:**

**The Community can only support the draft changes if its comments are taken into account.**

**The Community would point out that the OIE should try to avoid inconsistencies when the general definitions are changed with regard to the definitions in specific chapters. The Community does not believe that just copy and pasting from an epidemiology book achieves clear and correct definitions as far as the *Code* and its use are concerned.**

The Code Commission examined comments from New Zealand, South Africa, the Scientific Commission, the *ad hoc* Group on Epidemiology and an expert.

- a) **General definitions (Chapter 1.1.1.)**
- b) **Status report on incorporation of new definitions (Veterinary Authority, etc.)**
- c) **New definition proposed by the Permanent Animal Welfare Working Group (PAWWG)**

Submissions were received on the definition 'Slaughterhouse/Abattoir, Collecting centre, Flock, Herd, Infection, Laying birds, Monitoring, Notifiable disease, Notification, Clustering, Official veterinary control, Quarantine station, Risk, Risk assessment, Sanitary measure, Surveillance and Veterinary Services'.

The Code Commission considered that definitions should be harmonized with those in the *Aquatic Code* and Codex wherever possible. It accepted recommendations on amending and deleting certain definitions and on including some new definitions and made appropriate modifications.

The Code Commission agreed with the PAWWG that there is a need to develop a definition for 'animal welfare' in the *Code* and supported the definition proposed by the PAWWG. The proposed definition is consistent with the general principles for animal welfare contained in the *Code* (including, for example, the 'five freedoms') and also consistent with the approach taken in the *Code* to date, whereby the texts focus on outcomes rather than the design of systems. It also addresses the

concept whereby animal welfare can be 'good' or 'bad'. The Code Commission considered that this definition would be appropriate for inclusion in the *Code* and amended Article 1.1.1.1. accordingly.

The revised chapter, which is presented at [Annex III](#), is provided to Members for comment.

## 2. Model certificates

The Code Commission considered comments from Australia, the EU, Japan, New Zealand, Switzerland and an expert.

### a) General obligations (Chapter 1.2.1.)

The Code Commission noted that several Members commented positively on the recommendations of the *ad hoc* Group on Model Veterinary Certificates. However, at least one Member indicated that the proposed requirements are excessive in some respects. The Code Commission recommended that the *ad hoc* Group continue working on this topic and prepare a revised text, taking into account Members' comments, for the Code Commission to review at its spring meeting.

The Code Commission examined Members' comments on the text of the chapter and introduced appropriate changes.

#### Community comments:

**The Community can support the draft changes, but asks the TAHSC to take into account a few specific comments in Annex IV.**

### b) Notes for guidance on veterinary certificates for international trade in live animals, hatching eggs and products of animal origin (Appendix X.X.X.)

The Code Commission recommended that the *ad hoc* Group continue working on this topic and prepare a revised text, taking into account Members' comments, for the Code Commission to review at its spring meeting.

#### Community comments:

**The Community wishes to continue and help in this matter, as the model certificates seem now to be nearly ready for an adoption in May 2008.**

### c) Other horizontal chapters

An expert provided advice on the harmonisation of several horizontal *Code* chapters with those in the *Aquatic Animal Health Code* (see discussion under the agenda item on dividing the *Code* into two volumes).

#### Community comments:

**The Community can support the draft changes, but asks the TAHSC to take into account a few specific comments in Annex IV.**

The revised chapters, which are presented at [Annex IV](#), are provided to Members for comment.

## 3. Evaluation of Veterinary Services

### a) Chapter 1.3.3. and Chapter 1.3.4.

### b) Report of the *ad hoc* Group on the Evaluation of Veterinary Services

### c) OIE Tool for the Evaluation of Performance of Veterinary Services (OIE PVS Tool)

The Code Commission noted the report of the *ad hoc* Group on Evaluation of Veterinary Services ([Annex XXIX](#)) and concurred with the Group's recommendations, including on modification of the



content and name ('OIE Tool for the Evaluation of Performance of Veterinary Services', OIE PVS Tool). The Code Commission noted that the revised PVS Tool would be further discussed at a Seminar for PVS assessors that will take place in Lyon on 20-22 November 2007.

**Community comments:**

**The Community wishes to continue and help in this matter.**

A Member sought clarification on the status of the OIE PVS Tool under the SPS Agreement. The Code Commission advised that Chapters 1.3.3. and 1.3.4. are international standards and the OIE PVS Tool is a practical guide on applying these standards.

#### 4. Zoning and compartmentalisation

The Code Commission reviewed comments from the EU, Japan and the *ad hoc* Group on Epidemiology.

**Community comments:**

**The Community can support the draft changes, but asks the TAHSC to take into account a few specific comments in Annex V.**

**The Community will soon send to the OIE the outcome of its work on the compartmentalisation concept and its practical implementation for trade.**

- a) Chapter 1.3.5.
- b) General guidelines on the application of compartmentalisation (Appendix X.X.X.)
- c) Checklist on the practical application of compartmentalisation for avian influenza and Newcastle disease
- d) Use of the compartmentalisation concept for vector borne diseases

The Code Commission examined Members' comments on Chapter 1.3.5. (Zoning and compartmentalisation), the General guidelines on the application of compartmentalisation (Appendix X.X.X.) and the comments of the *ad hoc* Group on Epidemiology on the Checklist on the practical application of compartmentalisation for avian influenza and Newcastle disease (the Checklist).

The Code Commission reviewed the text in Chapter 2.2.10. on a containment zone for FMD and included similar text, modified to be generally applicable, in Chapter 1.3.5. The containment zone is considered to be a particular example of zoning. While its establishment depends upon similar general considerations, some specific provisions apply to the establishment of a containment zone. At this stage, the containment zone has been discussed in the context of FMD and Members' comments address the containment zone for this disease. The Code Commission is of the opinion that a containment zone could be applied to other diseases in the Code and therefore added a generic reference in Chapter 1.3.5.

The Code Commission and the Scientific Commission did not support the proposal of the *ad hoc* Group on Epidemiology to review the Checklist at its next meeting. The Code Commission agreed that a review could be done at some time in the future but felt that it would be more useful to wait for countries to gain some practical experience in applying compartmentalisation for avian diseases then use this experience in reviewing the document.

The revised chapters and appendices, which are presented at Annex V, are provided to Members for comment.

#### 5. Rabies (Chapter 2.2.5.) (also see meeting with Biological Standards Commission)

**Community comments:**

**The Community can support the draft changes, but asks the TAHSC to take into account a specific comment in Annex VI.**

The Code Commission discussed Members' comments with regard to the status of a free country where bat lyssavirus infection is reported. In the short term, the Code Commission decided to amend the *Code* to the effect that the presence of Australian bat lyssaviruses does not affect rabies free status (same as for European bat lyssaviruses).

The revised chapter, which is presented at [Annex VI](#), is provided to Members for comment.

## 6. Foot and mouth disease

The Code Commission reviewed comments from Australia, the EU, Japan, South Africa and the *ad hoc* Group on Epidemiology.

### a) Chapter 2.2.10.

**Community comments:**

**The Community can only approve the proposed changes, if its comments are taken on board.**

The Code Commission reviewed Members' comments and the advice of the *ad hoc* Group on Epidemiology on Chapter 2.2.10. The Code Commission accepted several recommendations of this Group as it agreed with the rationale proposed.

In the case of containment zone (Article 2.2.10.7.), the Code Commission agreed with the Scientific Commission that 'two incubation periods' is the minimum required period to demonstrate the effective establishment of a containment zone.

The Code Commission did not accept a Member's recommendation to address 'associated risk' as it considered that these concepts were already covered by the epidemiological investigation to be carried out by the Veterinary Authority in seeking to establish the containment zone. In regard to the proposal to establish a buffer zone around the containment zone, the Code Commission considered that the general provisions for zoning already address this point.

The Code Commission did not accept the recommendation of the *ad hoc* Group on Epidemiology to add 'single case or clustering of cases' because it considered that this was too narrow in comparison with the previously adopted text.

The Code Commission accepted a Member's proposal that effective control measures, other than stamping out, could be a basis for the establishment of a containment zone.

In regards to comments regarding a need to demonstrate the effectiveness of vaccination, the Code Commission noted that the definition of vaccination already addresses this point.

In response to requests of some African Members (also see discussion under meeting with the Scientific Commission), the Code Commission decided to continue the work of developing lists of 'safe commodities', as currently found in Article 2.3.13.1. (BSE). As a next step, the Code Commission will ask the Director General to convene an expert group to provide more advice on trade in deboned, matured and pH tested beef, and other commodities, from countries/zones that are not free of FMD and other serious diseases.

### b) Guidelines on surveillance for foot and mouth disease (Appendix 3.8.7)

**Community comments:**

**The Community can approve the proposed changes.**

On surveillance guidelines for FMD, the Code Commission noted but did not accept the recommendation of the *ad hoc* Group on Epidemiology to replace Article 3.8.7.6. (countries or zones applying for freedom from FMD following an outbreak). The Code Commission considers that the existing text is appropriate. It has been developed over a number of years on the basis of considerable Members' comments and there is insufficient rationale to make the proposed text amendment.

**c) Virus inactivation procedures (Appendix 3.6.2)**

**Community comments:**

**The Community can approve the proposed changes.**

On the basis of expert advice, the Code Commission added a new article (3.2.6.8) on casings of small ruminants and pigs. The expert advised that these conditions could be extended to cattle, based on the fact that FMDV tropism is similar in cattle and in small ruminants. Given that the original experiment (see Wijnker *et al.*, [2007] Removal of foot-and-mouth disease virus infectivity in salted natural casings by minor adaptation of standardized industrial procedures. *International Journal of Food Microbiology*, **115**, 214–219) was performed on casings of small ruminants, the Code Commission decided that the application of Article 3.2.6.8. to cattle should be studied further.

The revised chapters and appendices, which are presented at [Annex VII](#), are provided to Members for comment.

**7. Rinderpest**

**a) Chapter 2.2.12.**

**Community comments:**

**The Community cannot approve the proposed changes.**

**b) Guidelines on surveillance for rinderpest (Appendix 3.8.2.)**

**Community comments:**

**The Community can approve the proposed changes.**

The Code Commission noted that the *ad hoc* Group on Epidemiology had reviewed Chapter 2.2.12. and Appendix 3.8.2. and had recommended some amendments to the chapter (to include the concept of zoning and to amend Articles 2.2.12.2. and 2.2.12.3.) and had completely rewritten the surveillance guidelines. The Code Commission examined proposals for amendments to this chapter and guidelines. As these amendments resulted in extensive reformatting of the chapter and guidelines, the Code Commission requested that the Scientific Department highlight the changes by double underline and strikeout for the Code Commission to consider at its March meeting.

The revised chapter and appendix, which are presented at [Annex VIII](#), are provided to Members for comment.

**8. Contagious bovine pleuropneumonia (Chapter 2.3.15. and Appendix 3.8.3.)**

The Code Commission reviewed several recommendations of the *ad hoc* Group on Epidemiology on Chapter 2.3.15. and noted that the Group recommended revision of the related Appendix 3.8.3. The Code Commission noted that the Scientific Commission is continuing to work on these texts.

**Community comments:**

**The Community can only approve the proposed changes in Chapter 2.3.15, if its comments are taken on board. It approves the changes in Appendix 3.8.3.**

The revised chapter and appendix, which are presented at Annex IX, are provided to Members for comment.

#### 9. General guidelines on animal health surveillance (Appendix 3.8.1.)

The Code Commission did not accept a proposal from the *ad hoc* Group on Epidemiology to modify Article 3.8.1.4. on sampling methods, on the basis that it is too prescriptive. The *Code* should retain some flexibility to provide for the different conditions that apply in Members' territories.

#### 10. Bluetongue

The Code Commission considered comments from Australia and South Africa.

##### a) Chapter 2.2.13.

The Code Commission considered a request to incorporate the concept of compartmentalisation in this chapter. The Code Commission is on the opinion that the word "compartment" cannot simply be inserted after "country" or "zone" in each chapter dealing with vector born diseases. Rather, the concept needs to be introduced on the basis of proper consideration of the epidemiology of the disease.-

##### b) Guidelines on surveillance for bluetongue (Appendix 3.8.10.)

#### Community comments:

**The Community can support the draft changes, but asks the TAHSC to take into account a few specific comments in Annex X.**

The Code Commission accepted the concept of compartmentalisation for bluetongue insofar as this applies to an individual establishment (Article 3.8.10.3. was modified). However, the Code Commission saw the need for specific advice how the compartmentalisation could be applied in practice in more than one establishment.

A Member's recommendation to make reference to the density of the vector population in Article 2.2.13.2. was referred to the Scientific and Technical Department on the basis that it raises a new scientific question and should be studied by appropriate experts.

The Code Commission recommended to the Director General of the OIE to reconvene an *ad hoc* group on proposing more details on the use of vaccination.

The revised appendix, which is presented at Annex X, is provided to Members for comment.

#### 11. Bovine brucellosis (Chapter 2.3.1.)

The Code Commission reviewed comments from the *ad hoc* Group on Brucellosis on the text previously circulated, which contained extensive comments from Australia, Canada, Chinese Taipei, the EU, New Zealand, Switzerland and the USA.

The Code Commission noted that a new *ad hoc* Group will be convened to review Members' comments and update the chapter accordingly.

#### 12. Bovine tuberculosis (Chapter 2.3.3.)

The Code Commission addressed comments from Australia, New Zealand and the USA.

#### Community comments:

**The Community cannot support the proposed changes. A new chapter for TB in deer should be drafted.**

The request of two Members to modify references to diagnostic testing for tuberculosis were referred to the Biological Standards Commission.

In regard to a Member's comment about the role of wildlife reservoirs, the Code Commission noted that the role of wildlife as animal disease reservoirs will be addressed by the OIE Working Group on Wildlife Diseases. However, the Code Commission proposed to make a number of amendments throughout Chapter 2.3.3., including the addition of farmed deer (multiple species) in the scope of the chapter. The comment from a Member regarding the need for a free country to conduct ongoing tuberculin testing and a comment regarding acceptable disease prevalence were addressed via appropriate amendments to Article 2.3.3.2. The proposal to refer to the importing country's free status in introducing the import measures to be applied was not accepted. The Code Commission instead reminded Members that countries are not expected to apply import measures in regard to diseases that occur within their territories and that are not the subject of official control or eradication programmes.

In response to a comment from a Member, Article 2.3.3.10 was added to the chapter providing measures in regard to the importation of antler velvet of farmed deer. The time/temperature specified is a current industry standard for processing of antler velvet and was supported by the advice of an expert.

Article 2.3.3.2. was modified in response to comments of several Members, to reflect a more stringent approach to surveillance. The rationale for this change is that freedom is not equivalent to 'low prevalence'. It is recognised that the sensitivity of surveillance systems means that surveillance can yield negative results but not be sufficiently sensitive to detect very low prevalence of infection. For this reason, such statements as Article 2.3.3.2. 3. should be phrased in terms of surveillance sensitivity. If the surveillance programme detects a case of infection, when confirmed, 'free status' will be lost and must be regained through the appropriate steps, as is currently the case for other diseases such as FMD and CSF.

The revised chapter, which is presented at [Annex XI](#), is provided to Members for comment.

### 13. Bovine spongiform encephalopathy

The Code Commission considered comments from Canada, the EU, Japan, New Zealand and the USA. Members of the Scientific and Technical Department participated in the discussion.

#### a) Chapter 2.3.13.

##### Comments of the Community:

**The Community would like the Code Commission to take into account its previous and new comments.**

The Code Commission corrected an anomaly that had been found in Article 2.3.13.4. with an appropriate text modification. Article 2.3.13.15. (2) on the production of gelatine was modified to remove the reference to vertebrae (exclusion of skulls from cattle over 12 months of age was maintained in the text) and paragraph 3 was removed completely.

Article 2.3.13.16. was modified by splitting the sections dealing with tallow and dicalcium phosphate, to reflect the different risk management considerations for the two commodities (see Grobber *et al.*, [2006] Inactivation of transmissible spongiform encephalopathy agents during the manufacture of dicalcium phosphate from bone. *Veterinary Record*, **158**, 361–366).

#### b) Risk assessment recommendations (Appendix 3.8.5.)

Members' comments on Appendix 3.8.5. (risk assessment for BSE) were not addressed. The preferred approach would be to combine Appendix 3.8.5. with the BSE risk assessment questionnaire as discussed with the Scientific Commission. The Code Commission noted that an *ad hoc* Group will be convened to review all relevant BSE texts, including Members' comments prior to developing single questionnaire and guidelines on the categorisation of countries.

The principle of combining the questionnaire with recommendations on risk assessment should also apply to FMD, rinderpest and CBPP.

The revised chapter and appendix, which are presented at [Annex XII](#), are provided to Members for comment.

#### 14. Equine influenza (Chapter 2.5.5.)

In response to a Member's request for the rationale supporting 21 days residency requirement (Articles 2.5.5.6. and 2.5.5.7.), the Code Commission commented that there is no new scientific evidence, and recalled that the issue had been raised in May 2007, at which time it requested input from Members on this point. No such input has been received and therefore the Code Commission sees no reason to modify the recommendation.

**The Community reiterates its request for data justifying the change that was made in May 2007, from 14 to 21 days in articles 6 and 7 if "there is no new scientific evidence". The explanation above is not satisfactory and should be reverse: it is not up to the Member Countries to justify their question; it's up to the TAHSC to give them answers.**

The notation 'under study' was removed from Article 2.5.5.4. (semen) in light of expert advice, endorsed by the Scientific Commission, that semen is not a vehicle for the transmission of equine influenza.

The revised chapter, which is presented at [Annex XIII](#), is provided to Members for comment.

#### 15. Equine diseases (other than equine influenza and AHS)

##### a) Equine rhinopneumonitis (Chapter 2.5.7.)

**Community comments:**

**The Community can approve the proposed change.**

See discussion under Meeting with Biological Standards Commission.

##### b) Equine viral arteritis (Chapter 2.5.10.)

The Code Commission reviewed comments from a Member. The Code Commission recognised the need for isolation for live horses and made appropriate changes to the chapter as shown in Appendix 2.5.14. The Code Commission also incorporated a modification to Articles 2.5.10.2 and 2.5.10.3. to indicate that testing of a stallion should be conducted while he was in isolation.

**Community comments:**

**The Community can approve the proposed changes but reiterates its former comments, while giving the OIE proposals for modifications in Annex XIV.**

The revised chapters, which are presented at [Annex XIV](#), are provided to Members for comment.

#### 16. African horse sickness

##### a) Chapter 2.5.14.

**Community comments:**

**The Community supports the proposed changes, but still cannot accept the chapter unless its only but essential comment is taken into account.**

The Code Commission reviewed comments from Australia, the EU, New Zealand, South Africa, Switzerland and the USA. Appropriate changes were made in the chapter.

Comments from two Members questioning the feasibility of a seasonally free zone were forwarded to the Scientific Commission for expert opinion.

##### b) Guidelines on surveillance for African horse sickness (Appendix 3.8.X.)

The Code Commission reviewed comments from the EU, New Zealand, South Africa, Switzerland and the USA and made changes to the text accordingly.

The Code Commission amended text in the introduction of Appendix 3.8.X. referring to the issue of demonstrating country status rather than applying for recognition of free status. This change will also be applied to the bluetongue, CSF and AI chapters.

The revised chapter and appendix, which are presented at [Annex XV](#), are provided to Members for comment.

#### 17. African swine fever (Chapter 2.6.6.)

The Code Commission reviewed comments from the EU, New Zealand, South Africa and the USA.

The Code Commission amended text of several articles to provide the text in full rather than rely upon cross references to other articles and to make the format of this chapter consistent with that of the CSF Chapter.

##### Community comments:

**The Community can approve the proposed changes, but requests the TAHSC to take into account its comment in article 7. Furthermore, it should be defined what is meant by "adjacent country". Guidelines should be developed for the surveillance of African Swine Fever, and of its vectors.**

The revised chapter, which is presented at [Annex XVI](#), is provided to Members for comment.

#### 18. Classical swine fever (also see discussion with the Biological Standards Commission)

##### a) Chapter 2.6.7.

##### Community comments:

**The Community cannot approve the proposed changes unless its comments are taken into account. The answer given by the TAHSC to the Community former comments is not satisfactory at all, because it focuses on theory and not practice. It is clearly stated in the paragraph A of this report: "The OIE should take a practical rather than a philosophical approach and aim to develop standards that can be applied by all OIE Members". Thus maybe the chapter should be redirected to the relevant ad hoc group.**

##### b) Guidelines on surveillance for classical swine fever (Appendix 3.8.8.)

The Code Commission reviewed comments from Australia, Canada, the EU, Japan, South Africa and the USA.

The text of several articles was modified to address Members' recommendations, including on the use of vaccines for which OIE validated standards (as per Chapter I.1.3. of the *Terrestrial Manual*) are available to differentiate infected and vaccinated pigs; and on the minimum residency period in relation to health certification of live pigs. Text in Appendix 3.8.8. was amended to reflect a Member's recommendations on surveillance.

The revised chapter and appendix, which are presented at [Annex XVII](#), are provided to Members for comment.

#### 19. Avian influenza

##### a) Chapter 2.7.12.

##### b) Guidelines on the inactivation of avian influenza virus (Appendix 3.6.5.)

##### c) Guidelines on surveillance for avian influenza (Appendix 3.8.9.)

**Community comments:****The Community can support the changes but would like its comments taken on board.**

The Code Commission considered comments from the EU, Japan, South Africa, the USA and the *ad hoc* Group on Epidemiology.

In response to a Member's comment, the Code Commission reiterated that the central concept is to require reporting of LPNAI and HPNAI in poultry for trade purposes, while reporting of HPNAI in wild birds is necessary for global surveillance purposes. For practical purposes, the Code Commission has adopted a definition of poultry as including all birds used to produce eggs or meat for consumption, in addition to other commercial activities described in Article 2.7.12.1. (2). The definition was therefore not modified.

A Member raised the concern that low pathogenic AI strains other than H5 and H7 might mutate into highly pathogenic subtypes and should, therefore, be included as notifiable strains. However, examinations of all highly pathogenic isolates since 1959 show that all were either H5 or H7. Based on expert advice, the Code Commission reiterated that low pathogenic subtypes should be limited to the H5 and H7 subtypes. There is no basis to include H9 subtypes or any other H subtypes. Nevertheless, there are recommendations (Article 2.7.12.18.) for measures to mitigate risk from low pathogenic notifiable subtypes in meat.

The Code Commission did not accept the recommendation of two Members that findings of antibodies to avian influenza be considered criteria for determining infection, recalling its previous advice that further investigations should be conducted to identify the source of the antibodies. Findings of antibodies should not be considered as an occurrence of infection if further investigation fails to isolate the virus or to detect viral RNA.

In response to a Member's comment, the Code Commission did not accept that the definition for "non-poultry" had been expanded and that there is, therefore, no reason to change the measures recommended in Article 2.7.12.6. to manage the NAI risk posed by birds other than poultry.

In response to a Member's comment to remove 'under study' from Articles 2.7.12.21., 22. and 23. dealing with products of poultry origin, the Code Commission decided to refer the request to an expert for advice including the application of the application of Appendix 3.6.5. to Newcastle disease.

A request from a Member to test a statistically representative sample of birds in large consignments for avian influenza and Newcastle disease was also referred for expert advice.

In response to a Member's comment that the *Code* should specify that new containers should also be sanitized, the Code Commission advised its view that new containers would not be expected to be contaminated.

In conclusion, the Code Commission noted that no substantive new scientific issues had been raised by Members on the avian influenza chapter, nor on the appendix, suggesting that the issues raised during the last few years have been largely addressed and these texts can be considered as stabilised.

The revised chapter and appendix, which are presented at [Annex XVIII](#), are provided to Members for comment.

**20. Newcastle disease**

- a) **Chapter 2.7.13.**
- b) **Guidelines on surveillance for Newcastle disease (Appendix 3.8.X.)**
- c) **Guidelines on the inactivation of the Newcastle disease virus**

**Community comments:**



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| <p><b>The Community can support the changes but would like its comments taken on board.</b></p> |
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The Code Commission considered comments from Canada, Chinese Taipei, the EU, Japan, New Zealand, South Africa, Switzerland, the USA and the *ad hoc* Group on Epidemiology (which reviewed the chapter to make it consistent with Chapter 2.7.12. on avian influenza).

The Code Commission accepted a proposal to improve the definition of Newcastle disease and modified Article 2.7.13.1. accordingly. In the same article, the definition of ‘poultry’ was modified to align with the definition in Chapter 2.7.12. on avian influenza. Guidance was also provided on the appropriate trade response to reports of infection with vNDV.

A Member’s recommendation to modify Article 2.7.13.2. by including a reference to risk assessment was not accepted. The Code Commission considered that risk assessment is needed for avian influenza because of its zoonotic nature and the large number of epidemiological factors that need to be taken into account in determining the status of a country, zone or compartment. Members may choose to conduct a risk assessment for Newcastle disease but it is not necessary to specify that this should be done.

Article 2.7.13.7. was deleted to make the chapter congruent with the avian influenza chapter and because the Code Commission considered that trade in this commodity was unlikely to occur in practice.

The Code Commission made a number of amendments to the chapter and to Appendix 3.8.X., with a view to making these texts more consistent with equivalent texts on avian influenza.

On the inactivation of Newcastle disease virus (NDV), the Code Commission reviewed advice provided by experts and noted that it is feasible to develop time/temperature parameters for the inactivation of NDV. However, the advice would need to be further developed and formatted in a manner that is appropriate to the *Code*. The Code Commission decided to request an expert to prepare a draft text.

The revised chapter and appendix, which are presented at [Annex XIX](#), are provided to Members for comment.

## 21. West Nile fever (Chapter 2.X.XX.) (Also see discussion with Biological Standards Commission)

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| <p><b>Community comments:</b></p> |
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| <p><b>The Community acknowledges the work of the TAHSC on this chapter but cannot support this draft. The whole Chapter should remain under study, and Guidelines for surveillance should be drafted and presented at the same time. The ad hoc group should include more experts than at present, and the Community would be happy to help in this regard.</b></p> |
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The Code Commission addressed comments from Australia, Canada, the EU, Japan, New Zealand, South Africa, Switzerland and the USA.

The Code Commission accepted a Member’s recommendation to delete most of the opening Article because this information is well covered in the *Manual*. The Code Commission did not accept a proposal to include human cases as a determinant of a country’s West Nile fever (WNF) status as this approach is not taken in the *Code* for most of other zoonotic diseases. A list of commodities that are safe for trade was added at the beginning of this chapter. In response to Members’ commenting that it would be difficult to establish a compartment for WNF, as it affects equidae and is transmitted by vectors, the Code Commission noted that similar issues would be faced in establishing a compartment for other vector borne diseases, such as bluetongue and African horse sickness. A number of other amendments were made, including modifying the references to WNF vectors to read ‘likely to be competent’.

The revised chapter, which is presented at [Annex XX](#), is provided to Members for comment.

**22. Draft guidelines on the design and implementation of identification system to achieve animal traceability**

**Community comments:**

**The Community can support the changes but would like its comments taken on board.**

The Code Commission addressed comments from Canada, the EU, Japan, New Zealand and the USA.

In response to Members' proposals to include commercial and zootechnical aspects in the desired outcomes of an identification system to achieve animal traceability, the Code Commission decided to instead include the term 'animal husbandry'.

The Code Commission forwarded the amended text to the Animal Production Food Safety Working Group (APFSWG) for further consideration.

The revised appendix, which is presented at [Annex XXI](#), is provided to Members for comment.

**23. Guidelines on the control of hazards of animal health and public health importance in animal feed**

**Community comments:**

**The Community welcomes the TAHSC work in this field but believes that still more clarity is needed in particular for the definitions.**

The Code Commission addressed comments from Australia, Canada, the EU, New Zealand and the USA.

The Code Commission modified the scope of the guidelines to include all terrestrial animals, not just food producing animals, and made several other modifications in response to Members' comments.

The Code Commission forwarded the amended text to the APFSWG for further consideration, including for the APFSWG to verify any text changes required in view of the changed scope.

The revised appendix, which is presented at [Annex XXII](#), is provided to Members for comment.

**24. Guidelines on the detection, control and prevention of *Salmonella Enteritidis* and *S. Typhimurium* in poultry producing eggs for human consumption (Appendix 3.10.2.)**

**Community comments:**

**The Community welcomes the TAHSC work in this field and wishes to participate more.**

The Code Commission welcomed the comments of Australia, Canada, the EU, Japan, South Africa and the USA on these draft Guidelines.

The Code Commission considered most, but not all, Members' comments. The Code Commission did not agree with a Member's recommendation that the guidelines not contain provisions on egg hygiene and collection. Rather, the Code Commission considered that the guidelines should cover all activities on the farm, including egg hygiene and collection.

The Code Commission recommended that the *ad hoc* Group continue working on this topic and prepare a revised text, taking into account Members' comments, for the Code Commission to review at its spring meeting. The *ad hoc* Group should commence drafting guidelines on the detection, control and prevention of *Salmonella* in broilers. It should also review the *Code* Chapter on hygiene and disease security procedures in poultry breeding flocks and hatcheries to assure consistency between the texts.

The Code Commission forwarded the Members' comments to the APFSWG for further consideration, prior to forwarding it to the *ad hoc* Group.

## 25. Animal welfare

### Community position:

The Community thanks the OIE Code Commission for its work that improves the clarity and applicability of the Guidelines on the transport, slaughter and humane killing of animals and appreciates that many of the previous Community comments have been taken into account in the revised appendices.

Furthermore, the Community welcomes the improvements of the text of the draft guidelines on dog population control and wishes to present further comments as inserted in revised Annex.

The Community strongly supports the OIE work and initiatives in the development of new standards.

- a) Guidelines on the transport of animals by sea and land
- b) *Ad hoc* Group on slaughter and humane killing
- c) Draft guidelines on dog population control
- d) Update on 2<sup>nd</sup> OIE Global Conference on Animal Welfare 2008
- e) Update from PAWWG meeting 5-7 September 2007
  - animal production systems
  - control of dog populations
  - laboratory animals
  - wildlife harvest

The Code Commission reviewed Members' comments on current and proposed texts and the recommendations of the PAWWG in response to these comments. Comments had been provided on existing *Code* appendices by Australia, the EU and South Africa and on the discussion paper on animal production systems by Canada and the USA.

The Code Commission generally supported the PAWWG's recommendations and made some additional amendments.

**Draft guidelines on dog population control** (comments received from Canada, the EU, Japan, New Zealand and the USA.)

Dr Thiermann informed the Code Commission of the process used to develop the guidelines, including the important role played by the PAWWG. The guidelines fall within the OIE mandates for protection of animal health, public health and animal welfare. One of the primary objectives of the guidelines is to help developing countries deal with the serious human health risks posed by free ranging dogs carrying rabies and other zoonoses. The Code Commission considers it particularly important that these guidelines should address issues faced by developing countries and regretted that no comments on the draft texts had been received from any such countries. The Code Commission strongly urges developing Members to offer comment on the revised text, as it is in those countries where there is the greatest need for intervention in the control of dog populations.

The revised appendices, which is presented at [Annex XXIII](#), is provided to Members for comment. The report of the fifth meeting of the Working Group on Animal Welfare is presented at [Annex XXVIII](#) for information.

## 26. Infectious bursal disease (IBD)

A Member requested that the Code Commission reconsider the submission of the revised IBD Chapter that had been presented at the 69<sup>th</sup> General Session in 2001. The Code Commission decided not to resubmit the chapter, in the absence of new scientific information on the transmissibility of IBD virus through poultry meat, as had been requested in the Code Commission report of December 2003. The Code Commission decided that only in the event of new scientific information supporting a lack of the transmission of IBD virus through meat would this matter be re-examined.

## 27. Small hive beetle

### Community comments:

**The Community welcomes this draft Chapter and can support this proposal provided some comments are taken on board.**

Dr Thiermann outlined the history to this longstanding issue. Draft chapters had been provided by Members in 2005 and in 2006. In addition, a Member had provided a risk assessment on small hive beetle in 2005. The Code Commission considered that the two draft chapters were not significantly different and decided to propose the original text for consideration of Members.

The draft chapter, which is presented at [Annex XXIV](#), is provided to Members for comment.

## 28. Leptospirosis (Chapter 2.2.4.)

The Code Commission reviewed comments provided by Australia and New Zealand.

In regard to leptospirosis, the Code Commission noted that this is an important disease in some Members and presents a risk to human health. However, the development of a chapter at this time is not a priority because the disease is virtually ubiquitous and international trade is not considered to increase the risks to human or animal health. Rather than leave a title and no chapter in the *Code*, the Code Commission decided to delete the title.

## 29. Paratuberculosis (Chapter 2.2.6.)

The Code Commission asked the Biological Standards Commission to monitor scientific developments on diagnostic testing for paratuberculosis. Once the testing methodology is improved the Code Commission will ask the Scientific Commission to prepare a chapter on paratuberculosis for inclusion in the *Code*.

## D. OTHER ISSUES

## 30. Commodity-based measures in the *Code* (also see discussions with the Director General and with the Scientific Commission)

**Community comments: The Community strongly welcomes the OIE work in this field and wishes to participate.**

In response to Members' comments and mindful of the recommendation made at the OIE/AU-IBAR/FAO Seminar of OIE Delegates from the OIE's Regional Commissions for Africa and for the Middle East: "Implementation of Animal Health Standards: the Quest for Solutions" Cairo, 11-13 October 2004, the Code Commission noted that further development of commodity-based measures for trade is a priority for the OIE.

The Code Commission discussed the need to devote more attention to making more visible and expanding the commodity specific recommendations in the *Code*. Specific recommendations on the safety of commodities, including from countries/zones that are not free of certain diseases, can be found in the *Code*. One example of this approach is the provision of a list of safe commodities, as currently found in Article 2.3.13.1. (BSE). However, the Code Commission concluded that an effort needs to be placed on the development of additional recommendations as appropriate.

While the eradication of diseases is the ultimate goal, there are diseases and country situations where this is not feasible in the short term. Therefore the intention of the Code Commission is to work with experts and with the Scientific Department in identifying all relevant scientific information available to expand on the recommendation of measures to render commodities safe for trade when originating from countries or zones that are not free of disease. Notwithstanding the importance of developing commodity standards, the quality and credibility of Veterinary Services and disease surveillance remain paramount.

The Code Commission reviewed a paper prepared by an OIE expert and agreed to place the document on the OIE internet site for guidance of Members. It is presented at [Annex XXV](#) for information.

As a next step, the Code Commission will ask the Director General to convene an expert group to provide advice on trading deboned, matured and pH tested beef, and other commodities, from countries/zones that are not free of FMD and other serious diseases.

### 31. Division of the *Code* into two volumes

**Community comments: The Community welcomes the TAHSC work in this field.**

The Code Commission noted the progress report prepared by the Secretariat and advice provided by an expert. The Code Commission endorsed the proposed approach and recommended some improvements. An outline of the planned approach to the restructuring of the *Code* may be found at [Annex XXVI](#).

### 32. Report of OIE/FAO *ad hoc* meeting on the Guide to Good Farming Practice

**Community comments: The Community welcomes the TAHSC work in this field.**

The Code Commission welcomed the report of the OIE/FAO *ad hoc* Group meeting on the Guide to Good Farming Practice. The Code Commission advised that this document should not be included in the *Code*; rather, it should be published jointly by OIE and FAO. The document was forwarded to the APFSWG for further consideration. The report of the *ad hoc* Group is presented at [Annex XXX](#) for information.

### 33. Other documents:

#### a) The Role of the Veterinary Services in Food Safety

**Community comments: The Community welcomes the TAHSC work in this field.**

The Code Commission welcomed this concise and explanatory document and forwarded it to the APFSWG for further consideration.

#### b) Report of the OIE *ad hoc* Group on the Notification of Terrestrial Animal Diseases/Pathogenic Agents

The Code Commission was provided with the report of the 5<sup>th</sup> meeting of this *ad hoc* Group, but did not have time to review it. The Code Commission will review the report at its March meeting.

The report is appended for Members' information and comments at [Annex XXXI](#).

### 34. Future work programme

**Community comments: The Community thanks the OIE for this very useful document. .**

The updated work programme is shown in [Annex XXVII](#).

### 35. Others

The next meeting of the Code Commission is scheduled for 10–14 March 2008.

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**MEETING OF THE OIE  
TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION  
Paris, 17–28 September 2007**

1. Welcome-President of the Commission
2. Meeting with Director General
3. Joint meetings of commissions
  - Meeting of the Code Commission and the Scientific Commissions
  - Meeting of the Code Commission and the Biological Standards Commission
4. Examination of Member Countries' comments and work of relevant Expert Groups
  - Item 1 General definitions
    - a) General definitions (Chapter 1.1.1.)
    - b) Status report on incorporation of new definitions (Veterinary authority, etc.)
    - c) New definition proposed by Permanent Animal Welfare Working Group (PAWWG)
  - Item 2 Model Certificates
    - a) General obligations (Chapter 1.2.1.)
    - b) Notes for Guidance on Veterinary Certificates for International Trade in Live Animals, Hatching Eggs and Products of Animal Origin (Appendix X.X.X)
    - c) Other horizontal chapters
  - Item 3 Evaluation of Veterinary Services
    - a) Chapter 1.3.3., Chapter 1.3.4.
    - b) Report of the *ad hoc* Group on the Evaluation of Veterinary Services
    - c) OIE Tool for the Evaluation of Performance of Veterinary Services (OIE PVS Tool)
  - Item 4 Zoning and compartmentalisation
    - a) Chapter 1.3.5.
    - b) General guidelines on the application of compartmentalisation (Appendix X.X.X)
    - c) Checklist on the practical application of compartmentalisation for avian influenza and Newcastle disease
    - d) Use of the compartmentalisation concept for vector borne diseases
  - Item 5 Rabies (Chapter 2.2.5.)
  - Item 6 Foot and mouth disease
    - a) Chapter 2.2.10
    - b) Guidelines on Surveillance for foot and mouth disease (Appendix 3.8.7)
    - c) Virus inactivation procedures (Appendix 3.6.2)
  - Item 7 Rinderpest
    - a) Chapter 2.2.12.
    - b) Guidelines on surveillance for rinderpest (Appendix 3.8.2.)
  - Item 8 Contagious bovine pleuropneumonia (Chapter 2.3.15. and Appendix 3.8.3.)
  - Item 9 General guidelines on animal health surveillance (Appendix 3.8.1.)

- Item 10 Bluetongue
  - a) Chapter 2.2.13.
  - b) Guidelines on surveillance for bluetongue (Appendix 3.8.10.)
- Item 11 Bovine brucellosis (Chapter 2.3.1.)
- Item 12 Bovine tuberculosis (Chapter 2.3.3.)
- Item 13 Bovine spongiform encephalopathy
  - a) Chapter 2.3.13.
  - b) Risk assessment recommendations (Appendix 3.8.5.)
- Item 14 Equine influenza (Chapter 2.5.5.)
- Item 15 Equine diseases (other than equine influenza and AHS)
  - a) Equine rhinopneumonitis (Chapter 2.5.7.)
  - b) Equine viral arteritis (Chapter 2.5.10.)
- Item 16 African horse sickness
  - a) Chapter 2.5.14.
  - b) Guidelines on surveillance for African horse sickness (Appendix 3.8.X.)
- Item 17 African swine fever (Chapter 2.6.6.)
- Item 18 Classical swine fever
  - a) Chapter 2.6.7.
  - b) Guidelines on surveillance for classical swine fever (Appendix 3.8.8.)
- Item 19 Avian influenza
  - a) Chapter 2.7.12.
  - b) Guidelines on the inactivation of avian influenza virus (Appendix 3.6.5.)
  - c) Guidelines on surveillance for avian influenza (Appendix 3.8.9.)
- Item 20 Newcastle disease
  - a) Chapter 2.7.13.
  - b) Guidelines on surveillance for Newcastle disease (Appendix 3.8.X.)
  - c) Guidelines on the inactivation of the Newcastle disease virus
- Item 21 West Nile fever (Chapter 2.X.XX.)
- Item 22 Draft guidelines on the design and implementation of identification system to achieve animal traceability
- Item 23 Guidelines on the control of hazards of animal health and public health importance in animal feed
- Item 24 Guidelines on the detection, control and prevention of *Salmonella Enteritidis* and *S. Typhimurium* in poultry producing eggs for human consumption (Appendix 3.10.2.)
- Item 25 Animal welfare
  - a) Guidelines on the transport of animals by sea and land
  - b) *Ad hoc* Group on slaughter and humane killing
  - c) Draft guidelines on dog population control
  - d) Update on 2<sup>nd</sup> OIE Global Conference on Animal Welfare 2008
  - e) Update from PAWWG meeting 5-7 September 2007
    - animal production systems

- control of dog populations
- laboratory animals
- wildlife harvest

Item 26 Infectious bursal disease (IBD)

Item 27 Small hive beetle

Item 28 Leptospirosis (Chapter 2.2.4.)

Item 29 Paratuberculosis (Chapter 2.2.6.)

5. Other issues

Item 30 Commodity based measures in the *Code*

Item 31 Division of the *Code* into two volumes

Item 32 Report of OIE/FAO *ad hoc* Group meeting on Guide to Good Farming Practice

Item 33 Other documents

a) The Role of the Veterinary Services in Food Safety

b) Report of the OIE *ad hoc* Group on the Notification of Terrestrial Animal Diseases / Pathogenic Agents

Item 34 Future work programme

Item 35 Others

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**MEETING OF THE OIE**  
**TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION**  
**Paris, 17–28 September 2007**

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## CHAPTER 1.1.1.

### GENERAL DEFINITIONS

#### Community comments:

The Community can only support the draft changes, if the specific comments below are taken into account. It would point out that the OiE should try to avoid inconsistencies when the general definitions are changed with regard to the definitions in specific chapters. The Community does not believe that just copy and pasting from an epidemiology book achieves clear, correct and practically applicable definitions.

#### Article 1.1.1.1.

For the purposes of the *Terrestrial Code*:

#### *Animal welfare*

means the state of animal as regards its attempts to cope with its environment and includes both the extent of failure to cope and the ease or difficulty in coping.

#### Community comments:

The Community welcomes the definition of animal welfare and suggests further reflections as to consider the critical link between animal welfare and animal health, the mental state of the animals and their behavioural needs.

#### ~~*Approved abattoir*~~

~~means premises used for the slaughter of *animals* for human consumption or animal feeding and approved by the *Veterinary Authority* for export purposes.~~

#### ~~*Area of direct transit*~~

~~means a special area established in a *transit country*, approved by the relevant *Veterinary Authority* and placed under its immediate control, where *animals* stay for a short time pending further transport to their final destination.~~

#### ~~*Breeding birds*~~

~~means birds kept for the purpose of producing *hatching eggs*.~~

#### ~~*Collecting centre*~~

~~means a premise or a place where *animals for breeding or rearing* or *animals for slaughter* from different *establishments* or *markets* are collected together.~~

#### Community comments:

The definition of *collecting centre* should not be deleted at any cost. It can be a very important critical point as regards disease epidemiology, surveillance and control, and it cannot be assimilated with a market as in the majority of these centres there is no commercial activity.

#### *Commodity*

means live animals, products of animal origin, animal genetic material, ~~intended for human consumption, for animal feeding, for pharmaceutical or surgical use or for agricultural or industrial use, semen, embryos/ova,~~ biological products and *pathological material*.

***Flock of birds***

means any group of birds continuously housed in one building or part of a building separated from other parts of that building by a solid partition and having its own ventilation system, or, in the case of free range birds, any group of birds having common access to one or more buildings or More than one flock of birds may exist in one *establishment*.

***Flock***

means a number of animals of one kind kept together under human control or a congregation of gregarious wild animals. For the purposes of the *Terrestrial Code*, a flock is usually regarded as an *epidemiological unit*.

***Herd***

means a number of animals of one kind kept together under human control or a congregation of gregarious wild animals. For the purposes of the *Terrestrial Code*, a herd ~~or flock~~ is usually regarded as an *epidemiological unit*.

**Community comments:**

**The same definition applies for flock and herd, so they should be in the same paragraph:**

***Flock or Herd***

**means a number of animals of one kind kept together under human control or a congregation of gregarious wild animals. For the purposes of the *Terrestrial Code*, a flock or herd is usually regarded as an *epidemiological unit*.**

***Infected country***

means a country in which the absence of the *disease* under consideration has not been demonstrated by the requirements specified in the *Terrestrial Code* being met.

**Community comments:**

**The Community cannot support this proposal as this definition seems overly severe, especially in the case of vector borne diseases, emerging diseases or any diseases for which no guidelines for surveillance have been adopted in the *Terrestrial Code*. The Community proposes the following wording:**

***Infected country***

**means a country in which an *infection* of the *disease* under consideration has been confirmed according to the OIE terrestrial Code or Manual.**

**There should still be the possibility of an "unknown status" when you have a country which has not proved its freedom but has not confirmed disease either.**

***Infection***

means the ~~presence of the pathogenic agent in the host~~ entry and development or multiplication of an infectious agent in the body of men or animals.

**Community comments:**

The Community, although the above definition may be correct, feels that there are some practical problems. For example one could find the agent by PCR with no obvious multiplication or can find FMD virus in probang samples in simple carrier animals; nevertheless, in susceptible animals, this would be considered as a case of infection. While the Community agrees that in principle development or multiplication is consubstantial with infection, this may be difficult to prove very quickly, and will affect definition of case and also infection in specific disease chapters.

The current definition, by using the word "host", links the susceptible animal to the specific agent and thus implies that the agent "lives" i.e. multiplies. By changing it to try to improve matters, the reverse could be achieved.

The Community's opinion is to keep the current definition, or to add to the new definition the following words: ", detected in accordance with the OIE Manual of Standards".

***Laying birds***

means birds kept for the purpose of producing eggs not intended for hatching.

***Monitoring***

means the ~~continuous investigation of~~ intermittent performance and analysis of routine measurements, aimed at changes in the environment or health status of a given population or subpopulation, and its environment, to detect changes in the *prevalence* of a *disease* or characteristics of a pathogenic agent.

**Community comments:**

This definition in English seems very unclear and should be revised. At least, the word "detecting" should be added after "aimed at" and the words "and/or observations" should be added after the word "measurements".

***Official veterinary control***

means that the *Veterinary Services* knows the location of the *animals* and the identity of their owner or responsible keeper and is able to apply appropriate animal health measures, as required.

**Community comments:**

A definition of *control* should remain, even if amended, in order to define the disease control strategy.

***Quarantine station***

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

**Community comments:**

If the word "facility" might be too precise, the word "place" is too vague. The word "premises" could be a good alternative.

***Risk***

means the likelihood of the occurrence and the likely magnitude of the consequences of an adverse event to animal or human health in the *importing country* during a specified time period, ~~as a result of a hazard~~.

***Risk assessment***

means the evaluation of the likelihood and the biological and economic consequences of entry, establishment, ~~or~~ and spread of a ~~pathogenic agent~~ hazards within the territory of an *importing country*.

**Community comments:**

**The word "or" should not be deleted, as it is possible to assess the risk of introduction only for example. The word "hazard" should be written without "s" and in italic.**

***Sanitary measure***

means ~~any~~ a measure applied, such as those described in various chapters of the *Terrestrial Code*, designed to protect animal or human health or life within the territory of the Member ~~Country~~ from ~~risks~~ arising from the entry, establishment or spread of a *hazard*. ~~[Note: A detailed definition of sanitary measure may be found in the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization.~~

***Surveillance***

means ~~the investigation of a given population or subpopulation to detect the presence of a pathogenic agent or disease; the frequency and type of surveillance will be determined by the epidemiology of the pathogenic agent or disease, and the desired outputs~~ 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.

***Veterinary Services***

means the governmental and non-governmental organisations that implement animal health and welfare measures and other standards and guidelines in the *Terrestrial Code* in the country. The Veterinary Services are under the overall control and direction of the *Veterinary Authority*. Private sector organisations or veterinarians are normally accredited or approved to deliver functions by the *Veterinary Authority*.

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## CHAPTER 1.2.1.

### GENERAL OBLIGATIONS

#### Community comments:

**The Community can support the draft changes, but asks the TAHSC to take into account one specific comment in article 1.2.1.3.**

#### Article 1.2.1.1.

Safety of ~~I~~ international trade in animals and animal products depends on a combination of factors which should be taken into account to ensure unimpeded trade, without incurring unacceptable risks to human and animal health.

Because of differences between countries in their the likely variations in animal health situations, various options are offered by the *Terrestrial Code*. The animal health situation in the *exporting country*, in the *transit country* or *countries* and in the *importing country* should be considered before determining the requirements which have to be met for trade. To maximise harmonisation of the sanitary aspects of *international trade*, *Veterinary Authorities* of Members Countries should base their import requirements on the OIE standards, and guidelines and recommendations.

These requirements should be included in the model certificates approved by the OIE which form are included in Part 4 of the *Terrestrial Code*.

Certification requirements should be exact and concise, and should clearly convey the wishes of the *importing country*. For this purpose, prior consultation between *Veterinary Authorities* of *importing* and *exporting countries* is useful and may be necessary. It enables the setting out of the exact requirements so that the signing *veterinarian* can, if necessary, be given a note of guidance explaining the understanding between the *Veterinary Authorities* involved.

When Members officials of a *Veterinary Authority* wish to visit another country for matters of professional interest to the *Veterinary Authority* of the other country, the latter should be informed.

#### Article 1.2.1.2.

#### Responsibilities of the importing country

1. The import requirements included in the *international veterinary certificate* should assure that *commodities* introduced into the *importing country* comply with the national level of protection that it has chosen for animal and human health. *Importing countries* should restrict their requirements to those justified for such level of protection. If these are stricter than the OIE standards, they should be based on an import risk analysis. The *international veterinary certificate* should not include requirements for the exclusion of pathogens or animal *diseases* which are present within the territory of in the *importing country* and are not subject to any *official control programme*. The requirements applying to pathogens or diseases subject



to official control programmes in a country or zone should not provide a higher level of protection on imports than that provided for the same pathogens or diseases by the measures applied within that country or zone. The measures imposed on imports to manage the risks posed by a specific pathogen or disease should not require a higher level of protection than that provided by measures applied as part of the official control programme operating within the importing country.

2. The *international veterinary certificate* should not include requirements for disease agents measures against pathogens or *diseases* which are not OIE listed, unless the *importing country* has identified the disease agent as presenting a significant risk for that country, after conducting a scientifically based import risk analysis according to the guidelines in Section 1.3 demonstrated through import risk analysis, carried out in accordance with Section 1.3., that the pathogen or disease poses a significant risk to the importing country.
3. The transmission by the *Veterinary Authority* of certificates or the communication of import requirements to persons other than the *Veterinary Authority* of another country, necessitates that copies of these documents are also sent to the *Veterinary Authority*. This important procedure avoids delays and difficulties which may arise between traders and *Veterinary Authorities* when the authenticity of the certificates or permits is not established.

This information is usually the responsibility of *Veterinary Authorities*. However, it can be issued by private sector *veterinarians* at the place of origin of the *animals* when this practice is the subject of appropriate approval and authentication by the *Veterinary Authority*.

#### Article 1.2.1.3.

### Responsibilities of the exporting country

1. An *exporting country* should, on request, be prepared to supply the following information to *importing countries* on request:
  - a) information on the animal health situation and national animal health information systems to determine whether that country is free or has *free zones* of *listed diseases*, including the regulations and procedures in force to maintain its free status;

#### Community comments:

**Where this information on the animal health situation has been provided to the OIE for an official recognition of status, this should be enough for the importing country to avoid unnecessary duplication of work.**

- b) regular and prompt information on the occurrence of transmissible notifiable *diseases*;
  - c) details of the country's ability to apply measures to control and prevent the relevant *listed diseases*;
  - d) information on the structure of the *Veterinary Services* and the authority which they exercise;
  - e) technical information, particularly on biological tests and vaccines applied in all or part of the national territory.
2. *Veterinary Authorities* of *exporting countries* should:

- a) have official procedures for authorisation of certifying *veterinarians*, defining their functions and duties as well as conditions covering possible suspension and termination of the appointment;
  - b) ensure that the relevant instructions and training are provided to certifying *veterinarians*;
  - c) monitor the activities of the certifying *veterinarians* to verify their integrity and impartiality.
3. The Head of the *Veterinary Service* of the *exporting country* is ultimately accountable for veterinary certification used in *international trade*.

#### Article 1.2.1.4.

#### Responsibilities in case of an incident ~~occurring after~~ related to importation

1. *International trade* involves a continuing ethical responsibility. Therefore, if within the recognised *incubation periods* of the various *diseases* subsequent to an export taking place, the *Veterinary Authority* becomes aware of the appearance or reappearance of a *disease* which has been specifically included in the *international veterinary certificate*, there is an obligation for the Administration to notify the *importing country*, so that the imported stock may be inspected or tested and appropriate action be taken to limit the spread of the *disease* should it have been inadvertently introduced.
2. Equally, if a *disease* condition appears in imported stock within a time period after importation consistent with the recognised *incubation period* of the *disease*, the *Veterinary Authority* of the *exporting country* should be informed so as to enable an investigation to be made, since this may be the first available information on the occurrence of the *disease* in a previously free herd. The *Veterinary Authority* of the *importing country* should be informed of the result of the investigation since the source of *infection* may not be in the *exporting country*.
3. In case of suspicion, on reasonable grounds, that an official certificate may be fraudulent, the *Veterinary Authority* of the *importing country* and *exporting country* should conduct an investigation. Consideration should also be given to notifying any third country(ies) that may have been implicated. All associated consignments should be kept under official control, pending the outcome of the investigation. The *Veterinary Authorities* of all countries involved should fully cooperate with the investigation. If the certificate is found to be fraudulent, every effort should be made to identify those responsible so that appropriate action can be taken according to the relevant legislation.

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## CHAPTER 1.3.2.

## GUIDELINES FOR IMPORT RISK ANALYSIS

**Community comments:**

**The Commission supports the addition of compartmentalisation in the Figure 1, but the words "zoning and" should not be deleted, as both zoning and compartmentalisation are essential. This must be corrected.**

Article 1.3.2.1.

**Introduction**

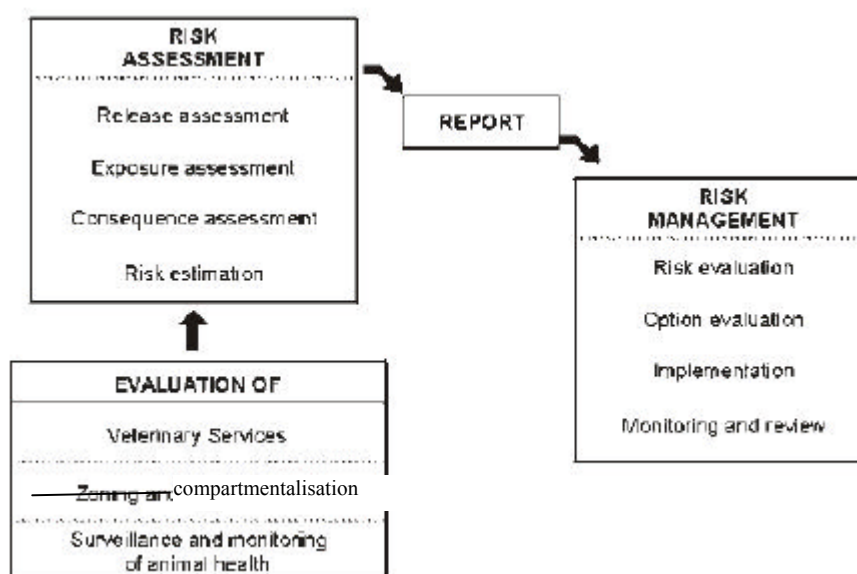
An import risk analysis begins with a description of the *commodity* proposed for import and the likely annual quantity of trade. It must be recognised that whilst an accurate estimate of the anticipated quantity of trade is desirable to incorporate into the risk estimate, it may not be readily available, particularly where such trade is new.

*Hazard identification* is an essential step which must be conducted before the *risk assessment*.

The *risk assessment* process consists of four interrelated steps. These steps clarify the stages of the *risk assessment*, describing them in terms of the events necessary for the identified potential *risk(s)* to occur, and facilitate understanding and evaluation of the outputs. The product is the *risk assessment* report which is used in *risk communication* and *risk management*.

The relationships between *risk assessment* and *risk management* processes are outlined in Figure 1.

*Fig. 1. The relationship between risk assessment and risk management processes*



Annex IV (contd)

## Article 1.3.2.2.

**Hazard identification**

The *hazard identification* involves identifying the pathogenic agents which could potentially produce adverse consequences associated with the importation of a *commodity*.

The potential *hazards* identified would be those appropriate to the species being imported, or from which the *commodity* is derived, and which may be present in the *exporting country*. It is then necessary to identify whether each potential *hazard* is already present in the *importing country*, and whether it is a *notifiable disease* or is subject to control or eradication in that country and to ensure that import measures are not more trade restrictive than those applied within the country.

*Hazard identification* is a categorisation step, identifying biological agents dichotomously as potential *hazards* or not. The *risk assessment* may be concluded if *hazard identification* fails to identify potential *hazards* associated with the importation.

The evaluation of the *Veterinary Services*, surveillance and control programmes and zoning and compartmentalisation systems are important inputs for assessing the likelihood of *hazards* being present in the animal population of the *exporting country*.

An *importing country* may decide to permit the importation using the appropriate sanitary standards recommended in the *Terrestrial Code*, thus eliminating the need for a *risk assessment*.

## Article 1.3.2.3.

**Principles of risk assessment**

1. *Risk assessment* should be flexible to deal with the complexity of real life situations. No single method is applicable in all cases. *Risk assessment* must be able to accommodate the variety of animal *commodities*, the multiple *hazards* that may be identified with an importation and the specificity of each *disease*, detection and surveillance systems, exposure scenarios and types and amounts of data and information.
2. Both *qualitative risk assessment* and *quantitative risk assessment* methods are valid.
3. The *risk assessment* should be based on the best available information that is in accord with current scientific thinking. The assessment should be well-documented and supported with references to the scientific literature and other sources, including expert opinion.
4. Consistency in *risk assessment* methods should be encouraged and *transparency* is essential in order to ensure fairness and rationality, consistency in decision making and ease of understanding by all the interested parties.
5. *Risk assessments* should document the *uncertainties*, the assumptions made, and the effect of these on the final risk estimate.
6. *Risk* increases with increasing volume of *commodity* imported.
7. The *risk assessment* should be amenable to updating when additional information becomes available.

## Article 1.3.2.4.

**Risk assessment steps**1. Release assessment

Release assessment consists of describing the biological pathway(s) necessary for an importation activity to 'release' (that is, introduce) pathogenic agents into a particular environment, and estimating the probability of that complete process occurring, either qualitatively (in words) or quantitatively (as a numerical estimate). The release assessment describes the probability of the 'release' of each of the potential *hazards* (the pathogenic agents) 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. Examples of the kind of inputs that may be required in the release assessment are:

## a) Biological factors

- species, age and breed of animals
- agent predilection sites
- vaccination, testing, treatment and quarantine.

## b) Country factors

- incidence/prevalence
- evaluation of *Veterinary Services*, surveillance and control programmes and zoning systems of the *exporting country*.

## c) Commodity factors

- quantity of *commodity* to be imported
- ease of contamination
- effect of processing
- effect of storage and transport.

If the release assessment demonstrates no significant *risk*, the *risk assessment* conclude.

2. Exposure assessment

Exposure assessment consists of describing the biological pathway(s) necessary for exposure of animals and humans in the *importing country* to the *hazards* (in this case the pathogenic agents) released from a given *risk* source, and estimating the probability of the exposure(s) occurring, either qualitatively (in words) or quantitatively (as a numerical estimate).

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 (e.g. ingestion, inhalation, or insect bite), and the number, species and other characteristics of the animal and human

populations exposed. Examples of the kind of inputs that may be required in the exposure assessment are:

- a) Biological factors
  - properties of the agent.
- b) Country factors
  - presence of potential vectors
  - human and animal demographics
  - customs and cultural practices
  - geographical and environmental characteristics.
- c) Commodity factors
  - quantity of *commodity* to be imported
  - intended use of the imported animals or products
  - disposal practices.

If the exposure assessment demonstrates no significant *risk*, the *risk assessment* may conclude at this step.

### 3. Consequence assessment

Consequence assessment consists of describing the relationship between specified exposures to a biological agent 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. This estimate may be either qualitative (in words) or quantitative (a numerical estimate).

Examples of consequences include:

- a) Direct consequences
  - animal *infection, disease*, and production losses
  - public health consequences.
- b) Indirect consequences
  - surveillance and control costs
  - compensation costs
  - potential trade losses

- adverse consequences to the environment.

#### 4. Risk estimation

Risk estimation consists of integrating the results from the release assessment, exposure assessment, and consequence assessment to produce overall measures of *risks* associated with the *hazards* identified at the outset. Thus risk estimation takes into account the whole of the risk pathway from *hazard* identified to unwanted outcome.

For a quantitative assessment, the final outputs may include:

- estimated numbers of herds, flocks, animals or people likely to experience health impacts of various degrees of severity over time;
- probability distributions, confidence intervals, and other means for expressing the *uncertainties* in these estimates;
- portrayal of the variance of all model inputs;
- a sensitivity analysis to rank the inputs as to their contribution to the variance of the risk estimation output;
- analysis of the dependence and correlation between model inputs.

#### Article 1.3.2.5.

### Principles of risk management

1. *Risk assessment* is the process of deciding upon and implementing measures to achieve the Member Country's appropriate level of protection, whilst at the same time ensuring that negative effects on trade are minimised. The objective is to manage *risk* appropriately to ensure that a balance is achieved between a country's desire to minimise the likelihood or frequency of *disease* incursions and their consequences and its desire to import *commodities* and fulfil its obligations under *international trade* agreements.
2. The international standards of the OIE are the preferred choice of *sanitary measures* for *risk management*. The application of these *sanitary measures* should be in accordance with the intentions in the standards.

#### Article 1.3.2.6.

### Risk management components

1. Risk evaluation - the process of comparing the *risk* estimated in the *risk assessment* with the Member Country's appropriate level of protection.
2. Option evaluation - the process of identifying, evaluating the efficacy and feasibility of, and selecting measures in order to reduce the *risk* associated with an importation in line with the Member Country's appropriate level of protection. The efficacy is the degree to which an option reduces the likelihood and/or magnitude of adverse health and economic consequences. Evaluating the efficacy of the options selected is an iterative process that involves their incorporation into the *risk assessment* and then comparing the resulting level of *risk* with that considered acceptable. The evaluation for feasibility normally focuses on technical, operational and economic factors affecting the implementation of the *risk management* options.



3. Implementation - the process of following through with the *risk management* decision and ensuring that the *risk management* measures are in place.
4. Monitoring and review - the ongoing process by which the *risk management* measures are continuously audited to ensure that they are achieving the results intended.

Article 1.3.2.7.

**Principles of risk communication**

1. *Risk communication* is the process by which information and opinions regarding *hazards* and *risks* are gathered from potentially affected and interested parties during a *risk analysis*, and by which the results of the *risk assessment* and proposed *risk management* measures are communicated to the decision-makers and interested parties in the *importing* and *exporting countries*. It is a multidimensional and iterative process and should ideally begin at the start of the *risk analysis* process and continue throughout.
2. A *risk communication* strategy should be put in place at the start of each *risk analysis*.
3. The *communication of the risk* should be an open, interactive, iterative and transparent exchange of information that may continue after the decision on importation.
4. The principal participants in *risk communication* include the authorities in the *exporting country* and other stakeholders such as domestic and foreign industry groups, domestic livestock producers and consumer groups.
5. The assumptions and *uncertainty* in the model, model inputs and the risk estimates of the *risk assessment* should be communicated.
6. Peer review is a component of *risk communication* in order to obtain scientific critique and to ensure that the data, information, methods and assumptions are the best available.

## CHAPTER 1.4.1.

**ANIMAL HEALTH MEASURES APPLICABLE  
BEFORE AND AT DEPARTURE****Community comments:**

**The Community can support the draft changes, but has one comment.**

## Article 1.4.1.1.

1. Countries should only authorise the exportation from their territory of *animals for breeding, rearing or slaughter* which are correctly identified and which meet the requirements of the *importing country*.
2. Biological tests and/or vaccinations required by the *importing country* should be carried out in accordance with the recommendations in the *Terrestrial Code* and *Terrestrial Manual*, as well as *disinfection* and *disinfestation* procedures.
3. Observation of the *animals* before leaving the country may be carried out either in the *establishment* where they were reared, or in a *quarantine station*. When they have been found to be clinically healthy and free from *diseases listed by the OIE* by an *Official Veterinarian* during the period of observation, the *animals* should be transported to the *place of shipment* in specially constructed *vehicles*, previously cleansed and disinfected. This must be done without delay and without the *animals* coming into contact with other susceptible animals, unless these animals have animal health guarantees similar to those of the transported *animals*.
4. The transportation of the *animals for breeding or rearing* or *animals for slaughter* from the *establishment* of origin to the point of departure from the *exporting country* shall be carried out in conformity with the conditions agreed between the *importing country* and *exporting country*.

## Article 1.4.1.2.

Countries should only undertake the export from its territory of:

- a) semen,
- b) embryos/ova,
- c) *hatching eggs*,

from *artificial insemination centres, collection centres* or farms which meet the requirements of the *importing country*.

## Article 1.4.1.3.

Countries exporting *animals*, semen, embryos/ova or *hatching eggs* should inform the country of destination and where necessary the *transit countries* if, after exportation, a *disease listed by the OIE* occurs within the *incubation period* of that particular *disease*, in the *establishment* of origin, or in an animal which was in a *collecting centre* where *animals* for breeding or rearing or *animals* for slaughter from different establishments or markets are collected together, or in a *market*, at the same time as the exported *animals*.

**Community comments:**

**After the word “*market*,” the words “semen, embryo or ova collection centre or hatchery,” should be added.**

**As the definition for collecting centres has been deleted, the words should not be in italics.**

Article 1.4.1.4.

Before the departure of *animals*, semen, embryos/ova, *hatching eggs* and brood-combs of bees, an *Official Veterinarian* should, within the 24 hours prior to shipment, provide an *international veterinary certificate* conforming with the models approved by the OIE (as shown in Part 4 of the *Terrestrial Code*) and worded in the languages agreed upon between the *exporting country* and the *importing country*, and, where necessary, with the *transit countries*.

Article 1.4.1.5.

1. Before the departure of an *animal* or a consignment of *animals* on an international journey, the *Veterinary Authority* of the port, airport or district in which the *border post* is situated may, if it is considered necessary, carry out a clinical examination of the *animal* or consignment. The time and place of the examination shall be arranged taking into account customs and other formalities and in such a way as not to impede or delay departure.
2. The *Veterinary Authority* referred to in point 1 above shall take necessary measures to:
  - a) prevent the shipment of *animals* affected or suspected of being affected with any *disease listed by the OIE* or with any other infectious *disease*;
  - b) avoid entry into the *vehicle* of possible vectors or causal agents of *infection*.

Article 1.4.1.6.

1. Countries should only authorise the export from their territory of *meat* and products of animal origin intended for human consumption, which are fit for human consumption. They must be accompanied by an *international veterinary certificate* conforming with the models approved by the OIE (as shown in Part 4. of the *Terrestrial Code*). These must be worded in the languages agreed upon between the *exporting country* and the *importing country*, and, where necessary, with the *transit countries*.
2. Products of animal origin intended for use in animal feeding, or for pharmaceutical or surgical or agricultural or industrial use, should be accompanied by an *international veterinary certificate* conforming with the models approved by the OIE (as shown in Part 4. of the *Terrestrial Code*).

## CHAPTER 1.4.3.

**BORDER POSTS AND QUARANTINE STATIONS IN  
THE IMPORTING COUNTRY****Community comments:**

**The Community can support the draft changes if the proposed changes below are taken on board.**

## Article 1.4.3.1.

1. Countries and their *Veterinary Authorities* shall, wherever possible, take the necessary action to ensure that the *border posts* and *quarantine stations* in their territory shall be provided with an adequate organisation and sufficient equipment for the application of the measures recommended in the *Terrestrial Code*.
2. Each *border post* and *quarantine station* shall be provided with facilities for the feeding and watering of animals.

## Article 1.4.3.2.

When justified by the amount of *international trade* and by the epidemiological situation, *border posts* and *quarantine stations* shall be provided with a *Veterinary Service* comprising personnel, equipment and premises as the case may be and, in particular, means for:

- a) making clinical examinations and obtaining specimens of material for diagnostic purposes from live animals or carcasses of animals affected or suspected of being affected by an epizootic *disease*, and obtaining specimens of animal products suspected of contamination;
- b) detecting and isolating animals affected by or suspected of being affected by an epizootic *disease*;
- c) carrying out *disinfection* and possibly *disinfestation* of *vehicles* used to transport animals and animal products.

In addition to this, each port and international airport should ideally be provided with equipment for the sterilisation or incineration of swill or any other material dangerous to animal health.

## Article 1.4.3.3.

When required for the transit of *commodities* in *international trade*, airports shall be provided, as soon as possible, with *areas of direct transit*. These must, however, comply with the conditions required by *Veterinary Authorities*, especially to prevent the risk of introducing *diseases* transmitted by insects.

## Article 1.4.3.4.

Each *Veterinary Authority*, when requested, shall make available for the *Central Bureau* and any interested country on request:

- a) a list of *border posts, quarantine stations, approved abattoirs* and storage depots in its territory which are approved for *international trade*;
- b) the period of time required for notice to be given for the application of the arrangements contained in point 2 of Articles 1.4.4.1. to 1.4.4.4.;
- c) a list of airports in its territory which are provided with an *area of direct transit, approved by the relevant Veterinary Authority and placed under its immediate control, where animals stay for a short time pending further transport to their final destination.*

**Community comments:**

**The Community proposes to add at the end of the sentence the following words to ensure clarity: “in another country”.**

## CHAPTER 1.3.5.

**ZONING AND COMPARTMENTALISATION****Community comments:**

**The Community can approve the draft changes, but asks the TAHSC to take into account its former comments on articles 1.3.5.2 and 1.3.5.3 paragraph 5, and two new comments in the article 1.3.5.3 on proposed principles for defining a containment zone.**

## 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 a Member in establishing and maintaining a *subpopulation* with a distinct health status within its territory. *Subpopulations* may be separated by natural or artificial geographical barriers or, in certain situations, by the application of appropriate management practices.

Zoning and compartmentalisation are procedures implemented by a country under the provisions of this chapter with a view to defining *subpopulations* of distinct health status within its territory for the purpose of *disease* control and/or *international trade*. While zoning applies to an animal *subpopulation* defined primarily on a geographical basis (using natural, artificial or legal boundaries), compartmentalisation applies to an animal *subpopulation* defined primarily by management and husbandry practices related to biosecurity. In practice, spatial considerations and good management including *biosecurity plans* play important roles in the application of both concepts.

A particular application of the concept of zoning is the establishment of a *containment zone*. In the event of a limited *outbreak* of a specified *disease* within an otherwise free country or *zone*, a single *containment zone*, which includes all *cases*, can be established for the purpose of minimizing the impact on the entire country or *zone*.

This chapter is to assist OIE Members wishing to establish and maintain different *subpopulations* within their territory using the principles of compartmentalisation and zoning. These principles should be applied in accordance with the measures recommended in the relevant *disease* chapter(s). This chapter also outlines a process through which trading partners may recognise such *subpopulations*. This process is best implemented by trading partners through establishing parameters and gaining agreement on the necessary measures prior to *disease outbreaks*.

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

As well as contributing to the safety of *international trade*, zoning and compartmentalisation may assist *disease* control or eradication within Members Countries. Zoning may encourage the more efficient use of resources within certain parts of a country and compartmentalisation may allow the functional separation

of a *subpopulation* from other domestic or wild animals through biosecurity measures, which a *zone* (through geographical separation) would not achieve. Following a *disease outbreak*, the use of compartmentalization may allow a Member to take advantage of epidemiological links among *subpopulations* or common practices relating to biosecurity, despite diverse geographical locations, to facilitate *disease* control and/or the continuation of trade.

Zoning and compartmentalisation cannot be applied to all *diseases* but separate requirements will be developed for each *disease* for which the application of zoning or compartmentalisation is considered appropriate.

To regain free status following a *disease outbreak* in a *zone* or *compartment*, Members should follow the recommendations in the relevant *disease* chapter in the *Terrestrial Code*.

#### Article 1.3.5.2.

### General considerations

The *Veterinary Services* of an *exporting country* which is establishing a *zone* or *compartment* within its territory for *international trade* purposes should clearly define the *subpopulation* in accordance with the recommendations in the relevant chapters in the *Terrestrial Code*, including those on surveillance, and the identification and traceability of live animals. The *Veterinary Services* of an *exporting country* should be able to explain to the *Veterinary Services* of an *importing country* the basis for its claim of a distinct *animal health status* for the *zone* or *compartment* in such terms.

The procedures used to establish and maintain the distinct *animal health status* of a *zone* or *compartment* should be appropriate to the particular circumstances, and will depend on the epidemiology of the *disease*, environmental factors and applicable biosecurity measures.

The authority, organisation and infrastructure of the *Veterinary Services*, including laboratories, must be clearly documented in accordance with the chapter on the evaluation of *Veterinary Services* of the *Terrestrial Code*, to provide confidence in the integrity of the *zone* or *compartment*. The final authority of the *zone* or *compartment*, for the purposes of domestic and *international trade*, lies with the *Veterinary Authority*.

In the context of maintaining the animal health status of a population, references to ‘import’, ‘importation’ and ‘imported animals/products’ found in the *Terrestrial Code* apply both to importation into a country and to the movement of animals and their products into *zones* and *compartments*. Such movements should be the subject of appropriate measures to preserve the health status of the *zone/compartment*.

The *exporting country* should be able to demonstrate, through detailed documentation provided to the *importing country*, that it has implemented the recommendations 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* when the appropriate measures recommended in the *Terrestrial Code* are applied and the *Veterinary Authority* of the *exporting country* certifies that this is the case.

The *exporting country* should conduct an 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*) including *disease* surveillance and diagnosis.

Biosecurity and surveillance are essential components of zoning and compartmentalisation, and the arrangements should be developed through cooperation of industry and *Veterinary Services*.

Industry’s responsibilities include the application of biosecurity measures, documenting and recording movements of animals, quality assurance schemes, monitoring the efficacy of the measures, documenting

corrective actions, conducting surveillance, rapid reporting and maintenance of records in a readily accessible form.

**Community comments:**

**The words "and personnel" should be added after "of animals".**

The *Veterinary Services* should provide movement certification, and carry out documented periodic inspections of facilities, biosecurity measures, records and surveillance procedures. *Veterinary Services* should conduct or audit surveillance, reporting and laboratory diagnostic examinations.

Article 1.3.5.3.

**Principles for defining a zone or compartment, including containment zone**

In conjunction with the above considerations, the following principles should apply when Members define a *zone* or a *compartment*.

1. The extent of a *zone* and its geographical limits should be established by the *Veterinary Authority* on the basis of natural, artificial and/or legal boundaries, and made public through official channels.
2. Establishment of a *containment zone* should be based on a rapid response including appropriate standstill of movement of animals and *commodities* upon notification of suspicion of the specified *disease* and the demonstration that the *outbreak* is contained within this *zone* through epidemiological investigation (trace-back, trace-forward) after confirmation of *infection*. The primary *outbreak* and likely source of the *outbreak* should be identified and all *cases* shown to be epidemiologically linked. For the effective establishment of a *containment zone*, it is necessary to demonstrate that there have been no new *cases* in the *containment zone* within a minimum of two *incubation periods* from the last detected *case*.

**Community comments:**

**The Community finds the above very restrictive as it seems to refer to only one outbreak and then, where cases are referred to this, it actually means secondary outbreaks. The use of outbreak and cases should be reviewed in the above text to ensure clarity.**

**The Community thus proposes to replace the words "that the outbreak is" by "that outbreaks are".**

**On the other hand, in order to be sure of the efficiency of such a containment zone, the Community thinks that the following sentence should be added: "The containment zone should be large enough to contain all the linked outbreaks and comprise both a restricted/protection zone and a larger surveillance zone."**

A *stamping-out policy* or another effective control strategy should be applied and the susceptible animal population within the *containment zones* should be clearly identifiable as belonging to the *containment zone*. Increased passive and targeted surveillance in accordance with Appendix 3.8.7. in the rest of the country or *zone* should be carried out and has not detected any evidence of *infection*. Measures to prevent spread of the *infection* from the *containment zone* to the rest of the country or *zone*, including ongoing surveillance in the *containment zone*, should be in place.

**Community comments:**



**The Community proposes to add the words "with the aim to eradicate the disease" after the words "effective control strategy", in order to clearly state that the containment zone is not aimed at being a long term infected zone.**

The free status of the areas outside the *containment zone* would be suspended pending the establishment of the *containment zone*. The suspension of free status of these areas could be lifted, once the *containment zone* is clearly established, irrespective of the provisions of the *disease specific chapter*.

The recovery of the free status of the *containment zone* should follow the provisions of the *disease specific chapter*.

23. The factors defining a *compartment* should be established by the *Veterinary Authority* on the basis of relevant criteria such as management and husbandry practices related to biosecurity, and made public through official channels.
34. Animals and herds belonging to such *subpopulations* need to be recognisable as such through a clear epidemiological separation from other animals and all things presenting a *disease* risk. For a *zone* or *compartment*, the *Veterinary Authority* should document in detail the measures taken to ensure the identification of the *subpopulation* and the establishment and maintenance of its *animal health status* through a *biosecurity plan*. The measures used to establish and maintain the distinct *animal health status* of a *zone* or *compartment* should be appropriate to the particular circumstances, and will depend on the epidemiology of the *disease*, environmental factors, the health status of animals in adjacent areas, applicable biosecurity measures (including movement controls, use of natural and artificial boundaries, the spatial separation of animals, and commercial management and husbandry practices), and surveillance.
45. Relevant animals within the *zone* or *compartment* should be identified in such a way that their history can be audited. Depending on the system of production, identification may be done at the herd, flock lot or individual animal level. Relevant animal movements into and out of the *zone* or *compartment* should be well documented, controlled and supervised. The existence of a valid animal identification system is a prerequisite to assess the integrity of the *zone* or *compartment*.

**The Community reiterates its former comments: In order to better stress the importance of documentation in traceability, the Community proposes to:**

- Add the words "and their movements documented" in the first sentence after the word "identified";
- Add the words "and documentation" in the second sentence after the word "identification".

56. For a *compartment*, the *biosecurity plan* should describe the partnership between the relevant industry and the *Veterinary Authority*, and their respective responsibilities. It should also describe the routine operating procedures to provide clear evidence that the surveillance conducted, the live animal identification and traceability system, and the management practices are adequate to meet the definition of the *compartment*. In addition to information on animal movement controls, the plan should include herd or flock production records, feed sources, surveillance results, birth and death records, visitor logbook, morbidity and mortality history, medications, vaccinations, documentation of training of relevant personnel and any other criteria necessary for evaluation of risk mitigation. The information required may vary according to the species and *disease(s)* under consideration. The *biosecurity plan* should also describe how the measures will be audited to ensure that the risks are regularly re-assessed and the measures adjusted accordingly.

Article 1.3.5.4.

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

There is no single sequence of steps which should be followed in establishing a *zone* or a *compartment*. The steps that the *Veterinary Services* of the *importing country* and the *exporting country* choose and implement will generally depend on the circumstances existing within the countries and at their borders, and their trading history. 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.
- b) The *exporting country* describes in the *biosecurity plan* for the *zone* the measures which are being, or will be, applied to distinguish such an area epidemiologically from other parts of its territory, in accordance with the recommendations in the *Terrestrial Code*.
- c) The *exporting country* provides:
  - i) the above information to the *importing country*, with an explanation of why the area can be treated as an epidemiologically separate *zone* for *international trade* purposes;
  - ii) access to enable the procedures or systems that establish the *zone* to be examined and evaluated upon request by the *importing country*.
- d) The *importing country* determines whether it accepts 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 its determination and the underlying reasons, within a reasonable period of time, being:
  - i) recognition of the *zone*; or
  - 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 over recognition of the *zone*, either in the interim or finally, by using an agreed mechanism to reach consensus such as the OIE in-house

procedure for settlement of disputes (Article 1.3.1.3.)

- g) The *Veterinary Authorities* of the *importing* and *exporting countries* should enter into a formal agreement recognizing the *zone*.

## 2. For compartmentalisation

- a) Based on discussions with the relevant industry, the *exporting country* identifies within its territory a *compartment* of one or more *establishments* or other premises which operates under common management practices related to biosecurity and which contains an identifiable animal *subpopulation* with a distinct health status with respect to a specific *disease/specific diseases*; the *exporting country* describes how this status is maintained through a partnership between the relevant industry and the *Veterinary Authority* of the *exporting country*.
- b) The *exporting country* examines the *compartment's biosecurity plan* and confirms through an audit that:
- i) the *compartment* is epidemiologically closed throughout its routine operating procedures as a result of effective implementation of its *biosecurity plan*; and
  - ii) the surveillance and monitoring programme in place is appropriate to verify the status of such *establishment(s)* with respect to such *disease(s)*.
- c) The *exporting country* describes the *compartment*, in accordance with the recommendations in the *Terrestrial Code*.
- d) The *exporting country* provides:
- i) the above information to the *importing country*, with an explanation of why such an *establishment(s)* can be treated as an epidemiologically separate *compartment* for *international trade* purposes; and
  - ii) access to enable the procedures or systems that establish the *compartment* to be examined and evaluated upon request by the *importing country*.
- e) The *importing country* determines whether it accepts such *establishment(s)* as a *compartment* 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.
- f) The *importing country* notifies the *exporting country* of its determination and the underlying reasons, within a reasonable period of time, being:

- i) recognition of the *compartment*; or
  - ii) request for further information; or
  - iii) rejection of such *establishment(s)* as a *compartment* for international trade purposes.
- g) An attempt should be made to resolve any differences over recognition of the *compartment*, either in the interim or finally, by using an agreed mechanism to reach consensus such as the OIE in-house procedure for settlement of disputes (Article 1.3.1.3).
- h) The *Veterinary Authorities* of the *importing* and *exporting countries* should enter into a formal agreement recognizing the *compartment*.

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## APPENDIX 3.x.x.

## GENERAL GUIDELINES ~~FOR~~ ON THE APPLICATION OF COMPARTMENTALISATION

**Community comments:**

**The Community can approve the proposed changes, but asks the TAHSC to take into account its former comments on article 3.x.x.3, and new comments in article 3.x.x.1 and 3.x.x.7.**

**The Community will soon send to the OIE the outcome of its on-going work on the compartmentalisation concept and its practical implementation for trade.**

Article 3.x.x.1.

**Introduction and objectives**

The guidelines in this ~~appendix~~ Appendix provide a structured framework for the application and recognition of *compartments* within countries or *zones*, based on the provisions of Chapter 1.3.5. with the objective to facilitate trade in *animals* and products of animal origin and as a tool for *disease* management.

Establishing and maintaining a disease-free status for an entire country may be difficult, especially in the case of *diseases* that can easily cross international boundaries. For many *diseases*, OIE Members ~~Countries~~ have traditionally applied the concept of zoning to establish and maintain an animal *subpopulation* with a different animal health status within national boundaries.

Chapter 1.1.1. defines a *compartment* as “one or more *establishments* under a common biosecurity management system containing an animal *subpopulation* with a distinct health status with respect to a specific *disease* or specific *diseases* for which required surveillance, control and biosecurity measures have been applied for the purpose of *international trade*.”

The essential difference between zoning and compartmentalisation is that the recognition of *zones* is based on geographical boundaries whereas the recognition of *compartments* is based of management practices and biosecurity. However, spatial considerations and good management practices play a role in the application of both concepts.

**Community comments:**

**In order to be more precise, the Community proposes to add the words "geographical or other epidemiological" between the words "However" and "spatial considerations".**

Compartmentalisation is not a new concept for *Veterinary Services*; in fact, it has been applied for a long time in many *disease* control programmes that are based on the concept of *disease-free* herds/flocks.

The fundamental requirement for compartmentalisation is the implementation of management and biosecurity measures to create a functional separation of *establishments* and allows the *Veterinary Services* to make a clear epidemiological differentiation ~~to be made~~ between *subpopulations* of differing health status.

**Community comments:**

**The Community proposes to add the words "documentation and" after the words "The fundamental requirement for compartmentalisation is the".**

For example, a ~~confinement operation~~ for poultry or swine operation in an infected country or *zone* might have biosecurity measures and management practices that result in negligible risk from *diseases* or agents. The concept of a *compartment* extends the application of a 'risk boundary' beyond that of a geographical interface and considers all epidemiological factors that can help to create an effective disease-specific separation between *subpopulations*.

In *disease-free* countries or *zones*, *compartments* preferably should be defined prior to the occurrence of a *disease outbreak*. In the event of an *outbreak* or in ~~endemic~~ infected countries or *zones*, compartmentalisation may be used to facilitate trade.

**Community comments:**

**The Community proposes to delete the words "preferably". Indeed, the compartmentalisation should not be used as a way to replace regionalisation, the control and/or eradication of the disease being always the final objective.**

For the purpose of *international trade*, *compartments* must be under the ~~direct control and~~ responsibility of the *Veterinary Administration Authority* in the country. For the purposes of this ~~appendix~~ Appendix, compliance by the Members with Chapters 1.1.2. and 1.3.3. ~~are~~ is an essential prerequisite.

Article 3.x.x.2.

**Principles for defining a compartment**

A *compartment* may be established with respect of a specific *disease* or *diseases*. A *compartment* must be clearly defined, indicating the location of all its components including *establishments*, as well as related functional units (such as feed mills, *slaughterhouses*, rendering plants, etc.), their interrelationships and their contribution to an epidemiological separation between the animals in a *compartment* and *subpopulations* with a different health status. The definition of *compartment* may revolve around *disease* specific epidemiological factors, animal production systems, biosecurity practices infrastructural factors and surveillance, ~~and similar functional demarcations~~.

Article 3.x.x.3.

**Separation of a compartment from potential sources of infection**

The management of a *compartment* must provide to the *Veterinary Administration Authority* documented evidence on the following:

a) Physical or spatial factors that affect the status of biosecurity in a compartment

While a *compartment* is primarily based on management and biosecurity measures, a review of geographical factors is needed to ensure that the functional boundary provides adequate separation of a *compartment* from adjacent animal populations with a different health status. The following factors should be taken into consideration in conjunction with biosecurity measures and, in some instances, may alter the degree of confidence achieved by general biosecurity and surveillance measures:

- i) *disease* status in adjacent areas and in areas epidemiologically linked to the *compartment*;
- ii) location, *disease* status and biosecurity of the nearest *epidemiological units* or other epidemiologically relevant premises. Consideration should be given to the distance and physical separation from:
  - flocks or herds with a different health status in close proximity to the *compartment*, including wildlife and migratory routes;
  - *slaughterhouses*, rendering plants or feed mills;
  - markets, fairs, agricultural shows, sporting events, zoos, circuses and other points of animal concentration.

b) Infrastructural factors

Structural aspects of the *establishments* within a *compartment* contribute to the effectiveness of its biosecurity. Consideration should be given to:

- i) fencing or other effective means of physical separation;
- ii) facilities for people entry including access control, changing area and showers;
- iii) *vehicle* access including washing and *disinfection* procedures;
- iv) *unloading* and *loading* facilities;
- v) isolation facilities for introduced animals;
- vi) infrastructure to store feed and veterinary products;
- vii) disposal of carcasses, manure and waste;
- viii) water supply;
- ix) physical measures to prevent exposure to living mechanical or biological vectors such as insects, rodents and wild birds;

**Community comments:**

**Physical is too limiting as other measures can be used e.g. chemical etc. So the Community proposes to delete the word "physical".**

x) air supply;

xi) feed supply/source.

More detailed recommendations for certain *establishments* can be found in Sections 3.2., 3.3. and 3.4. of the *Terrestrial Code*.

c) Biosecurity plan

The integrity of the *compartment* relies on effective biosecurity. The management of the *compartment* should develop, implement and monitor a comprehensive *biosecurity plan*.

The *biosecurity plan* should describe in detail:



- i) potential pathways for introduction and spread into the *compartment* of the agents for which the *compartment* was defined, including animal movements, rodents, fauna, aerosols, arthropods, *vehicles*, people, biological products, equipment, fomites, feed, waterways, drainage or other means. Consideration should also be given to the survivability of the agent in the environment;
- ii) the critical control points for each pathway;
- iii) measures to mitigate exposure for each critical control point;
- iv) standard operating procedures including:
  - implementation, maintenance, monitoring of the measures;
  - application of corrective actions;
  - verification of the process;
  - record keeping;
- v) contingency plan in the event of a change in the level of exposure;
- vi) reporting procedures to the *Veterinary Administration Authority*;
- vii) the programme for educating and training workers to ensure that all persons involved are knowledgeable and informed on biosecurity principles and practices;
- viii) the surveillance programme in place.

In any case, sufficient evidence should be submitted to assess the efficacy of the biosecurity plan in accordance with the level of *risk* for each identified pathway. The biosecurity risk of all operations of the *compartment* should be regularly re-assessed. Based on the outcome of the assessment, concrete and documented mitigation steps should be taken to reduce the likelihood of introduction of the *disease* agent into the *compartment*.

#### **Community comments:**

**In order to get compartmentalisation accepted internationally, Veterinary Services need to assess the biosecurity plan of an establishment in an internationally accepted standardised way. It is important that countries apply more or less the same procedure and a procedure that they are familiar with, HACCP being the most. Therefore the Community suggests making clear reference to HACCP as the means to make the assessment.**

**Thus the following sentence should be added after the first sentence of the above paragraph: "This evidence shall be structured in line with the international recognised guidance provided for the application of the Hazard Analysis and Critical Control Point (HACCP) system".**

#### d) Traceability system

A prerequisite for assessing the integrity of a *compartment* is the existence of a valid traceability system. All animals within a *compartment* should be individually identified and registered in such a way that their history and movements can be documented and audited. In cases where individual identification may not be feasible, such as broilers and day-old chicks, the *Veterinary Administration Authority* should provide sufficient assurance of traceability.

All animal movements into ~~and out of~~ the *compartment* should be certified by the *Veterinary Administration Authority* and recorded at the *compartment* level. Movements within the *compartment* need not be certified but should be recorded at the *compartment* level.

#### Community comments:

**The *Veterinary Authority* shall recognise and audit the compartment but cannot expressly certify movements of animals, even those into the compartment. Recognition by the veterinary authorities implies that the compartment has a functioning system of traceability. The role of the Veterinary Authority is not to certify every movement, except if a risk assessment implies a temporary stricter control.**

**The first sentence above should be replaced by the following: "All animal movements into and out of the compartment should be recorded at the compartment level and, when needed based on a risk assessment, certified by the *Veterinary Services*."**

#### Article 3.x.x.4.

#### Documentation ~~of factors critical to the definition of a compartment~~

Documentation must provide clear evidence that the biosecurity, surveillance, traceability and management practices defined for a *compartment* are effectively and consistently applied. In addition to animal movement information, the necessary documentation should include herd or flock production records, feed sources, laboratory tests, birth and death records, the visitor logbook, morbidity history, medication and vaccination records, *biosecurity plans*, training documentation and any other criteria necessary for the evaluation of *disease* exclusion.

The historical status of a *compartment* for the *disease(s)* for which it was defined should be documented and demonstrate compliance with the requirements for freedom in the relevant *Terrestrial Code* chapter.

In addition, a *compartment* seeking recognition should submit to the *Veterinary Administration Authority* a baseline animal health report indicating the presence or absence of OIE *listed diseases*. This report should be regularly updated to reflect the current animal health situation of the *compartment*.

Vaccination records including the type of vaccine and frequency of administration must be available to enable interpretation of surveillance data.

The time period for which all records should be kept may vary according to the species and *disease(s)* for which the *compartment* was defined.

All relevant information must be recorded in a transparent manner and be easily accessible so as to be auditable by the *Veterinary Administration Authority*.

#### Article 3.x.x.5.

#### Surveillance for the agent or disease

The surveillance system should comply with Appendix 3.8.1. on General Guidelines for Surveillance and the specific guidelines for surveillance for the *disease(s)* for which the *compartment* was defined, if available.

If there is an increased risk of exposure to the agent for which the *compartment* has been defined, the detection level of the internal surveillance and the level of biosecurity should be raised.

a) Internal surveillance

Surveillance should involve the collection and analysis of *disease/infection* data ~~such~~ so that the ~~Veterinary Administration Authority~~ can certify that the animals in all the *establishments* comply with the defined status of that *compartment*. A surveillance system that is able to ensure early detection in the event that the agent enters an *establishment* is essential. Depending on the *disease(s)* for which the *compartment* was defined, different surveillance strategies may be applied to achieve the desired confidence in *disease* freedom.

b) External surveillance

The biosecurity measures applied in a *compartment* must be appropriate to the level of exposure of the *compartment*. External surveillance will help identify a significant change in the level of exposure for the identified pathways for *disease* introduction into the *compartment*.

An appropriate combination of active and passive surveillance is necessary to achieve the goals described above. Based on the recommendations of ~~appendix~~ Appendix 3.8.1., targeted surveillance based on an assessment of risk factors may be the most efficient surveillance approach. Targeted surveillance should in particular include *epidemiological units* in close proximity to the *compartment* or those that have a potential epidemiological link with it.

**Community comments:**

**The last sentence above could possibly lead to financial and legal complications, and should be subject to more in depth discussions.**

Article 3.x.x.6.

**Diagnostic capabilities and procedures**

Officially-designated laboratory facilities complying with the OIE standards for quality assurance, as defined in Chapter I.1.2. of the *Terrestrial Manual*, should be available for sample testing. All laboratory tests and procedures should comply with the recommendations of the *Terrestrial Manual* for the specific *disease*. Each laboratory that conducts testing should have systematic procedures in place for rapid reporting of *disease* results to the ~~Veterinary Administration Authority~~. Where appropriate, results should be confirmed by an OIE Reference Laboratory.

Article 3.x.x.7.

**Emergency response and notification**

Early detection, diagnosis and notification of *disease* are critical to minimise the consequences of *outbreaks*.

In case of ~~a suspicion or an~~ an occurrence of any OIE *listed disease* not present according to the baseline animal health report of the *compartment* referred to in ~~article~~ Article 3.x.x.4., the management of the *compartment* should notify the ~~Veterinary Administration Authority~~, as this may indicate a breach in the biosecurity measures. The ~~Veterinary Administration Authority~~ should immediately ~~suspend export certification and should notify the importing countries~~ re-assess the biosecurity of the compartment and if a significant breach is detected, export certification should be suspended. Trade may only be resumed after the *compartment* has adopted the necessary measures to re-establish the biosecurity level and the ~~Veterinary Administration Authority~~ re-approves the *compartment* for trade.

**Community comments:**

**In order to deal with all possible situations, the Community proposes the following paragraph is added:**

**"In the event of a compartment or one of the establishments in a compartment, coming within an infected zone established as a result of an outbreak of disease for which the compartment was defined, the Veterinary Authority should reassess without delay the biosecurity status of the compartment to ensure that its integrity has been maintained. During this period export certification should be temporarily suspended".**

In the event of suspicion of occurrence of the *disease* for which the *compartment* was defined, export certification should be immediately suspended. If confirmed, the status of the *compartment* should be immediately revoked and *importing countries* should be notified following the provisions of Chapter 1.1.2.

~~Positive findings of the disease(s) for which the compartment has been defined, should be immediately notified following the provisions of Chapter 1.1.2.~~

Article 3.x.x.8.

**Supervision and control of a compartment**

The authority, organisation, and infrastructure of the *Veterinary Services*, including laboratories, must be clearly documented in accordance with the chapter on the evaluation of *Veterinary Services* of the OIE *Terrestrial Code*, to provide confidence in the integrity of the *compartment*.

The *Veterinary Administration Authority* has the final authority in granting, suspending and revoking the status of a *compartment*. The *Veterinary Administration Authority* should continuously supervise compliance with all the requirements critical to the maintenance of the *compartment* status described in this ~~appendix~~ Appendix and ensure that all the information is readily accessible to the *importing countries*. Any significant change should be notified to the *importing country*.

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— text deleted



## CHAPTER 2.2.5.

**RABIES****Community comments:**

**The Community can approve the proposed changes, but wishes that its comments in articles 2.2.5.5 and 2.2.5.9 are taken into account.**

## Article 2.2.5.1.

For the purposes of the *Terrestrial Code*, the *incubation period* for rabies shall be 6 months, and the *infective period* in domestic carnivores starts 15 days before the onset of the first clinical signs and ends when the animal dies.

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

## Article 2.2.5.2.

**Rabies free country**

A country may be considered free from rabies when:

1. the *disease* is notifiable;
2. an effective system of *disease* surveillance is in operation;
3. all regulatory measures for the prevention and control of rabies have been implemented including effective importation procedures;
4. no *case* of indigenously acquired rabies *infection* has been confirmed in man or any animal species during the past 2 years; however, this status would not be affected by the isolation of an Australian or European Bat Lyssavirus (EBL1 or EBL2);
5. no imported *case* in carnivores has been confirmed outside a *quarantine station* for the past 6 months.

## Article 2.2.5.3.

When importing from rabies free countries, *Veterinary Authorities* should require:

for domestic mammals, and wild mammals reared under confined conditions

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

1. showed no clinical sign of rabies on the day of shipment;
2. were kept since birth or for the 6 months prior to shipment in a rabies free country or were imported in conformity with the regulations stipulated in Articles 2.2.5.5., 2.2.5.6. or 2.2.5.7.

## Article 2.2.5.4.

When importing from rabies free countries, *Veterinary Authorities* should require:

for wild mammals not reared under confined conditions

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

1. showed no clinical sign of rabies on the day of shipment;
2. have been captured in a rabies free country, at a sufficient distance from any infected country. The distance should be defined according to the species exported and the reservoir species in the infected country.

## Article 2.2.5.5.

When importing from countries considered infected with rabies, *Veterinary Authorities* should require:

for dogs and cats

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

1. showed no clinical sign of rabies within 48 hours of shipment;

AND EITHER

2. were vaccinated against rabies:
  - a) not less than 6 months and not more than one year prior to shipment in the case of a primary vaccination, which should have been carried out when the animals were at least 3 months old;
  - b) not more than one year prior to shipment in the case of a booster vaccination;
  - c) with an inactivated virus vaccine or with a recombinant vaccine expressing the rabies virus glycoprotein and were identified by a permanent mark (including a microchip) before the vaccination (their identification number shall be stated in the certificate);
3. were subjected not less than 3 months and not more than 24 months prior to shipment to an antibody test as prescribed in the *Terrestrial Manual* with a positive result equivalent to at least 0.5 IU/ml;

OR

4. have not been vaccinated against rabies or do not meet all the conditions set out in points 1, 2 and 3 above; in such cases, the *importing country* may require the placing of the animals in a *quarantine station* located on its territory, in conformity with the conditions stipulated in its animal health legislation.

**Community comments:****The identification of the animals should be better highlighted:**

**There should be another point 2: "were identified by a permanent mark (including a microchip) and their identification number shall be stated in the certificate;"**

**Point 2 would become point 3, of which indent c) would end by the word "glycoprotein";**

**Point 3 and 4 would become 4 and 5, in which "1, 2, and 3" would be replaced by "2, 3, and 4".**

## Article 2.2.5.6.

When importing from countries considered infected with rabies, *Veterinary Authorities* should require:

for domestic ruminants, equines and pigs

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

1. showed no clinical sign of rabies on the day of shipment;
2. was maintained and where no *case* of rabies was reported for at least 12 months prior to shipment.

## Article 2.2.5.7.

When importing from countries considered infected with rabies, *Veterinary Authorities* should require:

for laboratory reared rodents and lagomorphs, and lagomorphs or wild mammals (other than non-human primates) reared under confined conditions

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

1. showed no clinical sign of rabies on the day of shipment;
2. were kept since birth, or for the 12 months prior to shipment, in an *establishment* where no *case* of rabies was reported for at least 12 months prior to shipment.

## Article 2.2.5.8.

When importing from countries considered infected with rabies, *Veterinary Authorities* should require:

for wild mammals not belonging to the orders of primates or carnivores and not reared under confined conditions

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

1. showed no clinical sign of rabies on the day of shipment;
2. were kept in a *quarantine station* for the 6 months prior to shipment.

## Article 2.2.5.9.

When importing from countries considered infected with rabies, *Veterinary Authorities* should require:

for frozen semen of dogs

the presentation of an *international veterinary certificate* attesting that the donor animals showed no clinical sign of rabies during the 15 days following collection of the semen.

**Community comments:**

**The Community would ask the OiE to look at the scientific justification for this article as the Community is not aware of any scientific papers indicating rabies can be spread via semen of dogs.**



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— text deleted

## CHAPTER 2.2.10.

**FOOT AND MOUTH DISEASE****Community comments:**

**The Community can only approve the proposed changes, if the comments regarding Articles 2, 7 and 21 are taken on board.**

## Article 2.2.10.1.

For the purposes of this *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 ribonucleic acid (RNA) specific to one or more of the serotypes of FMDV has been identified in samples from one or more animals, whether showing clinical signs consistent with FMD or not, 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**

Susceptible animals in the FMD free country should be separated from neighbouring infected countries by a *buffer zone*, or physical or geographical barriers, and animal health measures that effectively prevent the entry of the virus should be implemented.

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;
  - d) no vaccinated animal has been introduced since the cessation of vaccination;
3. supply documented evidence that:
  - a) surveillance for both FMD and FMDV *infection* in accordance with Appendix 3.8.7. is in operation;
  - b) regulatory measures for the prevention and control of FMD have been implemented.

The country will be included in the list only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information in points 2 and 3a) above be re-submitted annually and changes in the epidemiological situation or other significant events should be reported promptly to the OIE.

#### **Community comments:**

**The Community cannot approve the proposed change. Once a country has established its free status, the surveillance is adapted to the risk of reintroduction of the virus, and the elements to be gathered and transmitted to the OIE should not include all of that described in Appendix 3.8.7.**

**Thus, in the sentence above the words "3a)" should be replaced by "3b)"; and in the point 3b) above the words "early warning," should be inserted between the words "regulatory measures for the" and the words "prevention and control of FMD have been implemented".**

Article 2.2.10.3.

#### **FMD free country where vaccination is practised**

Susceptible animals in the FMD free country where vaccination is practised should be separated from neighbouring infected countries by a *buffer zone* or by physical/geographical barriers, and animal health measures that effectively prevent the entry of the virus should be implemented.

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. Retention on the list requires that the information in point 2 above be re-submitted annually and changes in the epidemiological situation or other significant events should be reported promptly to 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 then notify the OIE 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. In defining such *zones* the principles of Chapter 1.3.5. should be followed. Susceptible animals in the FMD free *zone* should be separated by a *buffer zone* or by physical/geographical barriers from the rest of the country and from neighbouring countries if they are of a different health status, and animal health measures that effectively prevent the entry of the virus should be implemented.

A country in which an FMD free *zone* where vaccination is not practised is to be established should:

1. have a record of regular and prompt animal *disease* reporting;
2. send a declaration to the OIE stating that it wishes to establish an FMD free *zone* where vaccination is not practised and that within the proposed FMD free *zone*:
  - a) there has been no *outbreak* of FMD during the past 12 months;
  - b) no evidence of FMDV *infection* has been found during the past 12 months;
  - c) no vaccination against FMD has been carried out during the past 12 months;
  - d) no vaccinated animal has been introduced since the cessation of vaccination, except in accordance with Article 2.2.10.9.;
  - e) documented evidence shows that surveillance in accordance with Appendix 3.8.7. is in operation for both FMD and FMDV *infection*;
3. describe in detail:
  - a) regulatory measures for the prevention and control of both FMD and FMDV *infection*,
  - b) the boundaries of the proposed FMD free *zone* and, if applicable, the *buffer zone* or physical or geographical barriers,

- c) the system for preventing the entry of the virus (including the control of the movement of susceptible animals) into the proposed FMDV free *zone* (in particular if the procedure described in Article 2.2.10.9. is implemented),

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

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

The information required in points 2 and 3c) above should be re-submitted annually as well as and any relevant changes in the epidemiological situation or other significant events including those relevant to under points 3a) and 3b) should be reported promptly to the OIE.

#### Article 2.2.10.5.

#### **FMD free zone where vaccination is practised**

An FMD free *zone* where vaccination is practised can be established in either an FMD free country where vaccination is not practised or in a country of which parts are infected. In defining such *zones* the principles of Chapter 1.3.5. should be followed. Susceptible animals in the FMD free *zone* where vaccination is practised should be separated by a *buffer zone* or by physical/geographical barriers from the rest of the country and from neighbouring countries if they are of a different health status, and animal health measures that effectively prevent the entry of the virus should be implemented.

A country in which an FMD free *zone* where vaccination is 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 and that within the proposed FMD free *zone*:
  - a) there has been no *outbreak* of FMD for the past 2 years;
  - b) no evidence of FMDV circulation for the past 12 months;
  - c) documented evidence shows that surveillance in accordance with Appendix 3.8.7. is in operation for FMD and FMDV circulation;
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 proposed FMD free *zone* where vaccination is practised and, if applicable, the *buffer zone* or physical or geographical barriers,
  - c) the system for preventing the entry of the virus into the proposed FMD free *zone* (in particular if the procedure described in Article 2.2.10.9. is implemented),

and supply evidence that these are properly implemented and supervised.

The proposed free *zone* will be included in the list of FMD free *zones* where vaccination is practised only after the submitted evidence has been accepted by the OIE. The information required in points 2, 3 and 4c) above should be re-submitted annually as well as and any relevant changes in the epidemiological situation or other significant events including those relevant to under points 4a) and 4b) should be reported promptly to the OIE.

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

#### Article 2.2.10.6.

#### **FMD infected country or zone**

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

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

#### Article 2.2.10.7.

#### **Establishment of a containment zone within an FMD free country or zone**

In the event of a limited *outbreak* within an FMD free country or *zone* with or without vaccination, a single *containment zone*, which includes all *cases*, can be established for the purpose of minimizing the impact on the entire country or *zone*. For this to be achieved, the *Veterinary Authority* should provide documented evidence that:

#### **Community comments:**

**In consistence with its comment on the "Zoning and Compartmentalisation" chapter, the Community proposes to replace the beginning of the above paragraph by the following wording: "In the event of a limited number of *outbreaks* " etc.**

**Indeed, cases may be linked but in the same time be the cause of more than one outbreak, and this is what is covered by the points 1.e) and f) below. Thus the following changes should be made:**

- the words "the *outbreak* is" in point 1 below should be replaced by the words "the *outbreaks* are";**
- the second word "*outbreak*" in point 1.e) below should be replaced by the word "*outbreaks*".**

1. the *outbreak* is limited based on the following factors:
  - a) immediately on suspicion, a rapid response including notification has been made;
  - b) standstill of animal movements has been imposed, and effective controls on the movement of other *commodities* mentioned in this chapter are in place;
  - c) epidemiological investigation (trace-back, trace-forward) has been completed;

- d) the *infection* has been confirmed;
  - e) the primary outbreak and likely source of the *outbreak* has been identified;
  - f) all *cases* have been shown to be epidemiologically linked;
  - g) no new cases have been found in the containment zone within a minimum of two incubation periods as defined in Article 2.2.10.1. from the last detected case.
2. ~~surveillance in accordance with Appendix 3.8.7. demonstrates that there are no undetected cases in the containment zone;~~
32. a stamping-out policy or another effective control strategy has been applied;

**Community comments:**

**In consistence with its comment on the "Zoning and Compartmentalisation" chapter, the Community proposes that the words "aimed at eradication of the disease" are added after the words "control strategy" in point 2 above.**

- 3. the susceptible animal population within the containment zones should be clearly identifiable as belonging to the containment zone.
- 4. increased passive and targeted surveillance in accordance with Appendix 3.8.7. in the rest of the country or *zone* has been carried out and has not detected any evidence of *infection*;
- 5. measures to prevent spread of the *infection* from the *containment zone* to the rest of the country or *zone*, including ongoing surveillance in the *containment zone*, are in place.

**Community comments:**

**In order to be sure of the efficiency of such a containment zone, the Community thinks that a point 6 should be added:**

**"6. the containment zone should be large enough to contain all the linked outbreaks and comprise both a restricted/protection zone and a larger surveillance zone."**

The free status of the areas outside the *containment zone* would be suspended pending the establishment of the *containment zone*. The suspension of free status of these areas could be lifted irrespective of the provisions of Article 2.2.10.8., once the *containment zone* is clearly established, by complying with points 1 to 5 above.

The recovery of the FMD free status of the *containment zone* should follow the provisions of Article 2.2.10.8.

Article 2.2.10.8.

**Recovery of free status**

- 1. When an FMD *outbreak* or FMDV *infection* occurs in an FMD free country or *zone* where vaccination is not practised, one of the following waiting periods is required to regain the status of FMD free country or *zone* where vaccination is not practised:
  - a) 3 months after the last *case* where a *stamping-out policy* and serological surveillance are applied in accordance with Appendix 3.8.7.; or

- b) 3 months after the *slaughter* of all vaccinated animals where a *stamping-out policy*, emergency vaccination and serological surveillance are applied in accordance with Appendix 3.8.7.; or
- c) 6 months after the last *case* or the last vaccination (according to the event that occurs the latest), where a *stamping-out policy*, emergency vaccination not followed by the slaughtering of all vaccinated animals, and serological surveillance are applied in accordance with Appendix 3.8.7., provided that a serological survey based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of *infection* in the remaining vaccinated population.

Where a *stamping-out policy* is not practised, the above waiting periods do not apply but either Article 2.2.10.2. or Article 2.2.10.4. applies.

2. When an FMD *outbreak* or FMDV *infection* occurs in an FMD free country or *zone* where vaccination is practised, one of the following waiting periods is required to regain the status of FMD free country or *zone* where vaccination is practised:
  - a) 6 months after the last *case* where a *stamping-out policy*, emergency vaccination and serological surveillance in accordance with Appendix 3.8.7. are applied, provided that the serological surveillance based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of virus circulation; or
  - b) 18 months after the last *case* where a *stamping-out policy* is not applied, but emergency vaccination and serological surveillance in accordance with Appendix 3.8.7. are applied, provided that the serological surveillance based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of virus circulation.

#### Article 2.2.10.9.

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

FMD susceptible animals should only leave the infected *zone* if moved by mechanised transport to the nearest designated *abattoir* located in the *buffer zone* directly to *slaughter*.

In the absence of an *abattoir* in the *buffer zone*, live FMD susceptible animals can be transported to the nearest *abattoir* in a free *zone* directly to *slaughter* only under the following conditions:

1. no FMD susceptible animal has been introduced into the *establishment* of origin and no animal in the *establishment* of origin has shown clinical signs of FMD for at least 30 days prior to movement;
2. the animals were kept in the *establishment* of origin for at least 3 months prior to movement;
3. FMD has not occurred within a 10-kilometre radius of the *establishment* of origin for at least 3 months prior to movement;
4. the animals must be transported under the supervision of the *Veterinary Authority* in a *vehicle*, which was cleansed and disinfected before *loading*, directly from the *establishment* of origin to the *abattoir* without coming into contact with other susceptible animals;
5. such an *abattoir* is not approved for the export of *fresh meat* during the time it is handling the meat of animals from the infected *zone*;
6. *vehicles* and the *abattoir* must be subjected to thorough cleansing and *disinfection* immediately after use.

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



Animals moved into a free *zone* for other purposes must be moved under the supervision of the *Veterinary Authority* and comply with the conditions in Article 2.2.10.12.

Article 2.2.10.10.

When importing from FMD free countries where vaccination is not practised or FMD free *zones* where vaccination is not practised, *Veterinary Authorities* 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;
3. have not been vaccinated.

Article 2.2.10.11.

When importing from FMD free countries where vaccination is practised or from FMD free zones where vaccination is practised, *Veterinary Authorities* 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 or *zone* 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 2.2.10.12.

When importing from FMD infected countries or *zones*, *Veterinary Authorities* 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 ten-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, that 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 ten-kilometer radius of the *establishment* during that period; or

4. were kept in a *quarantine station* for the 30 days prior to shipment, that 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 ten-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 2.2.10.13.

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

##### for fresh semen of domestic ruminants and pigs

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

1. the donor animals:
  - a) showed no clinical sign of FMD on the day of collection of the semen;
  - b) were kept in an FMD free country or *zone* where vaccination is not practised for at least 3 months prior to collection;
2. the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.1. or Appendix 3.2.2., as relevant.

#### Article 2.2.10.14.

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

##### for frozen semen of domestic ruminants and pigs

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

1. the donor animals:
  - a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;
  - b) were kept in an FMD free country or *zone* where vaccination is not practised for at least 3 months prior to collection;
2. the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.1. or Appendix 3.2.2., as relevant.

#### Article 2.2.10.15.

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

##### for semen of domestic ruminants and pigs

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

1. the donor animals:
  - a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;
  - b) were kept in a country or *zone* free from FMD for at least 3 months prior to collection;
  - c) if destined to an FMD free country or *zone* where vaccination is not practised:
    - i) have not been vaccinated and were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMD virus, with negative results; or
    - ii) had been vaccinated at least twice, with the last vaccination not more than 12 and not less than one month prior to collection;
2. no other animal present in the *artificial insemination centre* has been vaccinated within the month prior to collection;
3. the semen:
  - a) was collected, processed and stored in conformity with the provisions of Appendix 3.2.1. or Appendix 3.2.2., as relevant;
  - b) was stored in the country of origin for a period of at least one month following collection, and during this period no animal on the *establishment* where the donor animals were kept showed any sign of FMD.

Article 2.2.10.16.

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

for semen of domestic ruminants and pigs

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

1. the donor animals:
  - a) showed no clinical sign of FMD on the day of collection of the semen;
  - b) were kept in an *establishment* where no animal had been added in the 30 days before collection, and that FMD has not occurred within 10 kilometres for the 30 days before and after collection;
  - c) have not been vaccinated and were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMD virus, with negative results; or
  - d) had been vaccinated at least twice, with the last vaccination not more than 12 and not less than one month prior to collection;
2. no other animal present in the *artificial insemination centre* has been vaccinated within the month prior to collection;
3. the semen:
  - a) was collected, processed and stored in conformity with the provisions of Appendix 3.2.1. or Appendix 3.2.2., as relevant;

- b) was subjected, with negative results, to a test for FMDV *infection* if the donor animal has been vaccinated within the 12 months prior to collection;
- c) was stored in the country of origin for a period of at least one month following collection, and during this period no animal on the *establishment* where the donor animals were kept showed any sign of FMD.

Article 2.2.10.17.

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

Article 2.2.10.18.

When importing from FMD free countries where vaccination is not practised or FMD free *zones* where vaccination is not practised, *Veterinary Authorities* 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 2.2.10.13., 2.2.10.14., 2.2.10.15. or 2.2.10.16., 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 2.2.10.19.

When importing from FMD free countries where vaccination is practised or from FMD free *zones* where vaccination is practised, *Veterinary Authorities* 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 2.2.10.13., 2.2.10.14., 2.2.10.15. or 2.2.10.16., 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 2.2.10.20.

When importing from FMD free countries where vaccination is not practised or FMD free *zones* where vaccination is not practised, *Veterinary Authorities* 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 2.2.10.10., Article 2.2.10.11. or Article 2.2.10.12.;
2. have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results.

Article 2.2.10.21.

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

for fresh meat of cattle and buffalo (*Bubalus bubalis*) (excluding feet, head and viscera)

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

1. have been kept in the FMD free country or *zone* where vaccination is practised since birth, or which have been imported in accordance with Article 2.2.10.10., Article 2.2.10.11. or Article 2.2.10.12.;
2. have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results.

**Community comment**

**The Community reiterates its comment regarding risk mitigation measures to be taken when importing cattle and buffalo meat from a country where vaccination is practised. In such cases de-boning and maturation of the meat should be recommended, especially in the case of the implementation of the *containment zone* principle.**

**Thus the Community proposes to add a point 3: "3. if the principle of containment zone has been used, comply with article 2.2.10.23 point 2 a and b".**

Article 2.2.10.22.

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

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

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

1. have been kept in the FMD free country or *zone* where vaccination is practised since birth, or which have been imported in accordance with Article 2.2.10.10., Article 2.2.10.11. or Article 2.2.10.12.;
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 2.2.10.23.

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

for fresh meat of cattle and buffalo (*Bubalus bubalis*) (excluding feet, head and viscera)

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

1. comes from animals which:
  - a) have remained in the *exporting country* for at least 3 months prior to *slaughter*;
  - b) have remained, during this period, in a part of the country where cattle are regularly vaccinated against FMD and where official controls are in operation;
  - c) have been vaccinated at least twice with the last vaccination not more than 12 months and not less than one month prior to *slaughter*;
  - d) were kept for the past 30 days in an *establishment*, and that FMD has not occurred within a ten-kilometre radius of the *establishment* during that period;
  - e) have been transported in a *vehicle*, which was cleansed and disinfected before the cattle were loaded, directly from the *establishment* of origin to the *approved abattoir* without coming into contact with other animals which do not fulfil the required conditions for export;
  - f) have been slaughtered in an *approved abattoir*:
    - i) which is officially designated for export;
    - ii) in which no FMD has been detected during the period between the last *disinfection* carried out before *slaughter* and the shipment for export has been dispatched;
  - g) have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results within 24 hours before and after *slaughter*;
2. comes from deboned carcasses:
  - a) from which the major lymphatic 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 2.2.10.24.

When importing from FMD infected countries or *zones*, *Veterinary Authorities* 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 2.2.10.25.

When importing from FMD free countries or *zones* (where vaccination either is or is not practised), *Veterinary Authorities* 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 2.2.10.10., Article 2.2.10.11. or Article 2.2.10.12.

## Article 2.2.10.26.

When importing from FMD infected countries or *zones* where an official control programme exists, *Veterinary Authorities* 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 2.2.10.27.

When importing from FMD infected countries, *Veterinary Authorities* 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 2.2.10.28.

When importing from FMD infected countries, *Veterinary Authorities* 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 Article 3.6.2.2., Article 3.6.2.3. and Article 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 Authorities* 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 2.2.10.29.

When importing from FMD infected countries or *zones*, *Veterinary Authorities* 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 2.2.10.30.

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

for skins and trophies derived from FMD susceptible wild animals

the presentation of an *international veterinary certificate* attesting that these products are derived from animals that have been killed in such a country or *zone*, or which have been imported from a country or *zone* free of FMD (where vaccination either is or is not practised).

## Article 2.2.10.31.

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



for skins and trophies derived from FMD susceptible wild animals

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

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## APPENDIX 3.8.7.

**GUIDELINES FOR ON THE SURVEILLANCE OF FOR  
FOOT AND MOUTH DISEASE****Community comments:**

**The Community can approve the proposed changes except the deletion of the word "approved": even if the definition of *laboratory* implies official approval, it should be clearly brought to the attention of the Members who read the chapters. Thus it is much preferable to retain the former wording.**

**This comment applies to all the other similar proposals of deletion of "approved" in the other chapters.**

Article 3.8.7.1.

**Introduction**

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

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

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

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

## Article 3.8.7.2.

**General conditions and methods**

1. A surveillance system in accordance with Appendix 3.8.1. should be under the responsibility of the *Veterinary Authority*. A procedure should be in place for the rapid collection and transport of samples from suspect cases of FMD to a laboratory for FMD diagnoses as described in the *Terrestrial Manual*.
2. The FMD surveillance programme should:
  - a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers who have day-to-day contact with livestock, as well as diagnosticians, should report promptly any suspicion of FMD. They should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. All suspect cases of FMD should be investigated immediately. Where suspicion cannot be resolved by epidemiological and clinical investigation, samples should be taken and submitted to an ~~approved~~ laboratory. This requires that sampling kits and other equipment are available for those responsible for surveillance. Personnel responsible for surveillance should be able to call for assistance from a team with expertise in FMD diagnosis and control;
  - b) implement, when relevant, regular and frequent clinical inspection and serological testing of high-risk groups of animals, such as those adjacent to an FMD infected country or *zone* (for example, bordering a game park in which infected wildlife are present).

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

## Article 3.8.7.3.

**Surveillance strategies**1. Introduction

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

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

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

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

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

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

## 2. Clinical surveillance

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

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

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

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

## 3. Virological surveillance

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

- a) to monitor at risk populations;

- b) to confirm clinically suspect cases;
- c) to follow up positive serological results;
- d) to test “normal” daily mortality, to ensure early detection of *infection* in the face of vaccination or in *establishments* epidemiologically linked to an *outbreak*.

#### 4. Serological surveillance

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

- a) natural *infection* with FMDV;
- b) vaccination against FMD;
- c) maternal antibodies derived from an immune dam (maternal antibodies in cattle are usually found only up to 6 months of age but in some individuals and in some species, maternal antibodies can be detected for considerably longer periods);
- d) heterophile (cross) reactions.

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

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

The discovery of clustering of seropositive reactions should be foreseen. It may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or the presence of field strain *infection*. As clustering may signal field strain *infection*, the investigation of all instances must be incorporated in the survey design. If vaccination cannot be excluded as the cause of positive serological reactions, diagnostic methods should be employed that detect the presence of antibodies to nonstructural proteins (NSPs) of FMDVs as described in the *Terrestrial Manual*.

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

#### Article 3.8.7.4.

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

In addition to the general conditions described in Chapter 2.2.10., a Member applying for recognition of FMD freedom for the country or a *zone* where vaccination is not practised should provide evidence for the existence of an effective surveillance programme. The strategy and design of the surveillance programme will depend on the prevailing epidemiological circumstances and will be planned and implemented according to general conditions and methods in this Appendix, to demonstrate absence of FMDV *infection*, during the preceding 12 months in susceptible populations. This requires the support of a national or

other laboratory able to undertake identification of FMDV *infection* through virus/antigen/genome detection and antibody tests described in the *Terrestrial Manual*.

#### Article 3.8.7.5.

### **Countries or zones applying for freedom from FMD where vaccination is practised**

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

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

#### Article 3.8.7.6.

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

In addition to the general conditions described in Chapter 2.2.10., a country re-applying for country or *zone* freedom from FMD where vaccination is practised or not practised should show evidence of an active surveillance programme for FMD as well as absence of FMDV *infection/circulation*. This will require serological surveillance incorporating, in the case of a country or a *zone* practising vaccination, tests able to detect antibodies to NSPs as described in the *Terrestrial Manual*.

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

1. *slaughter* of all clinically affected and in-contact susceptible animals;
2. *slaughter* of all clinically affected and in-contact susceptible animals and vaccination of at-risk animals, with subsequent *slaughter* of vaccinated animals;
3. *slaughter* of all clinically affected and in-contact susceptible animals and vaccination of at-risk animals, without subsequent *slaughter* of vaccinated animals;
4. vaccination used without *slaughter* of affected animals or subsequent *slaughter* of vaccinated animals.

The time periods before which an application can be made for re-instatement of freedom from FMD depends on which of these alternatives is followed. The time periods are prescribed in Article 2.2.10.8.

In all circumstances, a Member re-applying for country or *zone* freedom from FMD with vaccination or without vaccination should report the results of an active surveillance programme implemented according to general conditions and methods in this Appendix.

### The use and interpretation of serological tests (see Figure 1)

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

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

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

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

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

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

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

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

In case of vaccinated populations, one has to exclude that positive test results are indicative of virus

circulation. To this end, the following procedure should be followed in the investigation of positive serological test results derived from surveillance conducted on FMD vaccinated populations.

The investigation should examine all evidence that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were not due to virus circulation. All the epidemiological information should be substantiated, and the results should be collated in the final report.

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

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

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

- b) Following clinical examination, serum samples should be collected from representative numbers of cattle that were in physical contact with the primary sampling unit. The magnitude and prevalence of antibody reactivity observed should not differ in a statistically significant manner from that of the primary sample if virus is not circulating.
- c) Following clinical examination, epidemiologically linked herds should be serologically tested and satisfactory results should be achieved if virus is not circulating.
- d) Sentinel animals can also be used. These can be young, unvaccinated animals or animals in which maternally conferred immunity has lapsed and belonging to the same species resident within the positive initial sampling units. They should be serologically negative if virus is not circulating. If other susceptible, unvaccinated ruminants (sheep, goats) are present, they could act as sentinels to provide additional serological evidence.

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

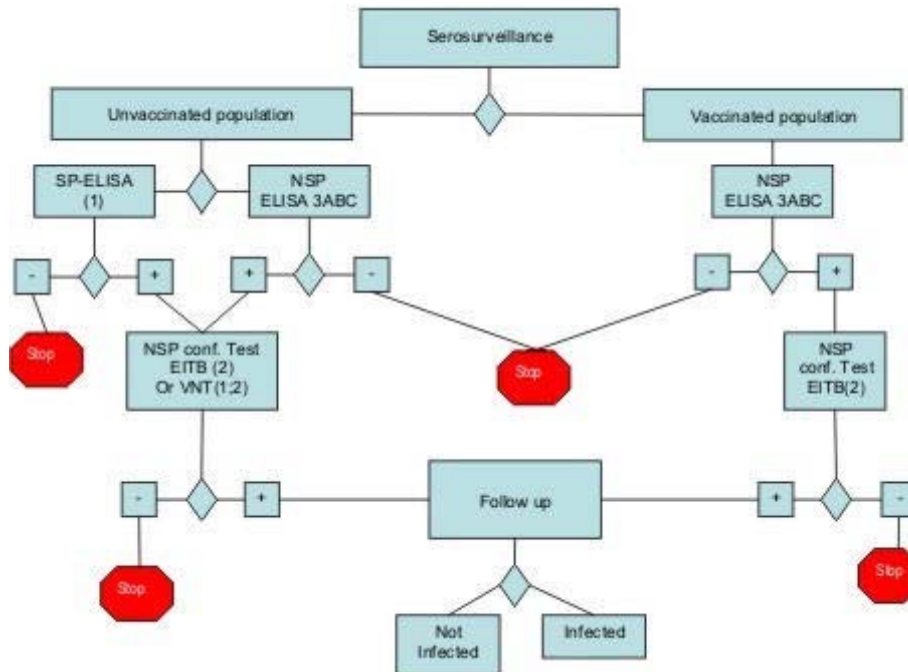
- characterization of the existing production systems;
- results of clinical surveillance of the suspects and their cohorts;
- quantification of vaccinations performed on the affected sites;
- sanitary protocol and history of the *establishments* with positive reactors;
- control of animal identification and movements;
- other parameters of regional significance in historic FMDV transmission.

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



## Annex VII (contd)

*Fig. 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) |
| SP    | Structural protein test  |
| S     | No evidence of FMDV  |

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## APPENDIX 3.6.2.

**FOOT AND MOUTH DISEASE VIRUS  
INACTIVATION PROCEDURES****Community comments:****The Community can approve the proposed changes.**

## Article 3.6.2.1.

**Meat**

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

1. Canning

Meat is subjected to heat treatment in a hermetically sealed container to reach an internal core temperature of at least 70°C for a minimum of 30 minutes or to any equivalent treatment which has been demonstrated to inactivate the FMD virus.

2. Thorough cooking

Meat, previously deboned and defatted, shall be subjected to heating so that an internal temperature of 70°C or greater is maintained for a minimum of 30 minutes.

After cooking, it shall be packed and handled in such a way that it cannot be exposed to a source of virus.

3. Drying after salting

When *rigor mortis* is complete, the meat must be deboned, salted with cooking salt (NaCl) and completely dried. It must not deteriorate at ambient temperature.

'Drying' is defined in terms of the ratio between water and protein which must not be greater than 2.25:1.

## Article 3.6.2.2.

**Wool and hair**

For the inactivation of viruses present in wool and hair for industrial use, one of the following procedures should be used:

1. industrial washing, which consists of the immersion of the wool in a series of baths of water, soap and sodium hydroxyde (soda) or potassium hydroxyde (potash);
2. chemical depilation by means of slaked lime or sodium sulphide;

3. fumigation in formaldehyde in a hermetically sealed chamber for at least 24 hours. The most practical method is to place potassium permanganate in containers (which must NOT be made of plastic or polyethylene) and add commercial formalin; the amounts of formalin and potassium permanganate are respectively 53 ml and 35 g per cubic metre of the chamber;
4. industrial scouring which consists of the immersion of wool in a water-soluble detergent held at 60-70°C;
5. storage of wool at 18°C for 4 weeks, or 4°C for 4 months, or 37°C for 8 days.

Article 3.6.2.3.

### **Bristles**

For the inactivation of viruses present in bristles for industrial use, one of the following procedures should be used:

1. boiling for at least one hour;
2. immersion for at least 24 hours in a 1% solution of formaldehyde prepared from 30 ml commercial formalin per litre of water.

Article 3.6.2.4.

### **Raw hides and skins**

For the inactivation of viruses present in raw hides and skins for industrial use, the following procedure should be used: salting for at least 28 days in sea salt containing 2% sodium carbonate.

Article 3.6.2.5.

### **Milk and cream for human consumption**

For the inactivation of viruses present in *milk* and cream for human consumption, one of the following procedures should be used:

1. a sterilisation process applying a minimum temperature of 132°C for at least one second (ultra-high temperature [UHT]), or
2. if the milk has a pH less than 7.0, a sterilisation process applying a minimum temperature of 72°C for at least 15 seconds (high temperature - short time pasteurisation [HTST]), or
3. if the milk has a pH of 7.0 or over, the HTST process applied twice.

Article 3.6.2.6.

### **Milk for animal consumption**

For the inactivation of viruses present in *milk* for animal consumption, one of the following procedures should be used:

1. the HTST process applied twice;
2. HTST combined with another physical treatment, e.g. maintaining a pH 6 for at least one hour or

additional heating to at least 72°C combined with dessication;

3. UHT combined with another physical treatment referred to in point 2 above.

#### Article 3.6.2.7.

#### **Skins and trophies from wild animals susceptible to foot and mouth disease**

For the inactivation of viruses present in skins and trophies from wild animals susceptible to FMD, one of the following procedures should be used prior to complete taxidermal treatment:

1. boiling in water for an appropriate time so as to ensure that any matter other than bone, horns, hooves, claws, antlers or teeth is removed;
2. gamma irradiation at a dose of at least 20 kiloGray at room temperature (20°C or higher);
3. soaking, with agitation, in a 4% (w/v) solution of washing soda (sodium carbonate - Na<sub>2</sub>CO<sub>3</sub>) maintained at pH 11.5 or above for at least 48 hours;
4. soaking, with agitation, in a formic acid solution (100 kg salt [NaCl] and 12 kg formic acid per 1,000 litres water) maintained at below pH 3.0 for at least 48 hours; wetting and dressing agents may be added;
5. in the case of raw hides, salting for at least 28 days with sea salt containing 2% washing soda (sodium carbonate - Na<sub>2</sub>CO<sub>3</sub>).

#### Article 3.6.2.8.

#### **Casings of small ruminants and pigs**

For the inactivation of viruses present in casings of small ruminants and pigs, the following procedures should be used: salting for at least 30 days either with dry salt (NaCl) or with saturated brine (Aw < 0.80), and kept at room temperature during this entire period.



## CHAPTER 2.2.12.

### RINDERPEST

#### **Community comments:**

**The Community cannot approve the proposed changes. Once a country has established its free status, the surveillance is adapted to the risk of reintroduction of the virus, and the elements to be gathered and transmitted to the OIE should not include all of that described in Appendix 3.8.2.**

#### Article 2.2.12.1.

For the purposes of the *Terrestrial Code*, the *incubation period* for rinderpest (RP) shall be 21 days.

For the purpose of this chapter, a *case* includes an animal infected with rinderpest virus (RPV).

For the purpose of this chapter, susceptible animals apply to both domestic and wild artiodactyls.

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

Ban on vaccination against rinderpest means a ban on administering a RP vaccine to any susceptible animal and a heterologous vaccine against RP to any large ruminants or pigs.

1. Animal not vaccinated against RP means:

- a) for large ruminants and pigs: an animal that has received neither a RP vaccine nor a heterologous vaccine against RP;
- b) for small ruminants: an animal that has not received a RP vaccine.

2. The following defines the occurrence of RPV *infection*:

- a) RPV has been isolated and identified as such from an animal or a product derived from that animal; or
- b) viral antigen or viral ribonucleic acid (RNA) specific to RP has been identified in samples from one or more animals showing one or more clinical signs consistent with RP, or epidemiologically linked to an *outbreak* of RP, or giving cause for suspicion of association or contact with RP; or
- c) antibodies to RPV antigens which are not the consequence of vaccination, have been identified in one or more animals with either epidemiological links to a confirmed or suspected *outbreak* of RP in susceptible animals, or showing clinical signs consistent with recent *infection* with RP.

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

#### Article 2.2.12.2.

#### **RP free country**

To qualify for inclusion in the existing list of RP free countries, 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 RP during the past 24 months,
  - b) no evidence of RPV *infection* has been found during the past 24 months,
  - c) no vaccination against RP has been carried out during the past 24 months,

and supply documented evidence that surveillance for both RP and RPV *infection* in accordance with Appendix 3.8.2. is in operation and that regulatory measures for the prevention and control of RP have been implemented;

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

The country will be included in the list only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information in points 2 and 3 above be re-submitted annually and changes in the epidemiological situation or other significant events should be reported promptly to the OIE.

#### **Community comments:**

**The words "points 2 and 3 above" should be replaced by "points 2.a), 2.b), 2.c), and 3 above".**

Article 2.2.12.3.

#### **Recovery of free status**

When a RP *outbreak* or RPV *infection* occurs in a RP free country, one of the following waiting periods is required to regain the status of RP free country:

1. 3 months after the last *case* where a *stamping-out policy* and serological surveillance are applied in accordance with Appendix 3.8.2.; or
2. 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 3.8.2.; or
3. 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 *slaughter* of all vaccinated animals, and serological surveillance are applied in accordance with Appendix 3.8.2.

Where a *stamping-out policy* is not practised, the above waiting periods do not apply but Article 2.2.12.2. applies.

Article 2.2.12.4.

#### **Infected country**

When the requirements for acceptance as a RP free country are not fulfilled, a country shall be considered as RP infected.

Article 2.2.12.5.

When importing from RP free countries, *Veterinary Authorities* should require:

for RP susceptible animals

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

1. showed no clinical sign of RP on the day of shipment;
2. remained in a RP free country since birth or for at least 30 days prior to shipment.

## Article 2.2.12.6.

When importing from RP infected countries, *Veterinary Authorities* should require:

for RP susceptible animals

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

1. RP is the subject of a national surveillance programme according to Appendix 3.8.2.;
2. RP has not occurred within a 10-kilometre radius of the *establishment* of origin of the animals destined for export for at least 21 days prior to their shipment to the *quarantine station* referred to in point 3b) below;
3. the animals:
  - a) showed no clinical sign of RP on the day of shipment;
  - b) were kept in the *establishment* of origin since birth or for at least 21 days before introduction into the *quarantine station* referred to in point c) below;
  - c) have not been vaccinated against RP, were isolated in a *quarantine station* for the 30 days prior to shipment, and were subjected to a diagnostic test for RP on two occasions with negative results, at an interval of not less than 21 days;
  - d) were not exposed to any source of *infection* during their transportation from the *quarantine station* to the place of shipment;
4. RP has not occurred within a ten-kilometre radius of the *quarantine station* for 30 days prior to shipment.

## Article 2.2.12.7.

When importing from RP free countries, *Veterinary Authorities* should require:

for semen of RP susceptible animals

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

1. the donor animals:
  - a) showed no clinical sign of RP on the day of collection of the semen;
  - b) were kept in a RP free country for at least 3 months prior to collection;
2. the semen was collected, processed and stored in conformity with the provisions of either Appendix 3.2.1. or Appendix 3.2.2., as relevant.

## Article 2.2.12.8.



When importing from RP infected countries, *Veterinary Authorities* should require:

for semen of RP susceptible animals

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

1. RP is the subject of a national surveillance programme according to Appendix 3.8.2.;
2. the donor animals:
  - a) showed no clinical sign of RP on the day of collection of the semen;
  - b) were kept in an *establishment* where no RP susceptible animals had been added in the 21 days before collection, and that RP has not occurred within 10 kilometres of the *establishment* for the 21 days before and after collection;
  - c) were vaccinated against RP at least 3 months prior to collection; or
  - d) have not been vaccinated against RP, and were subjected to a diagnostic test on two occasions with negative results, at an interval of not less than 21 days within the 30 days prior to collection;
3. the semen was collected, processed and stored in conformity with the provisions of either Appendix 3.2.1. or Appendix 3.2.2., as relevant.

**Article 2.2.12.9.**

When importing from RP free countries, *Veterinary Authorities* should require:

for *in vivo* derived embryos of RP susceptible animals

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

1. the donor females were kept in an *establishment* located in a RP free country at the time of collection;
2. the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.1. or Appendix 3.3.3., as relevant.

**Article 2.2.12.10.**

When importing from RP infected countries, *Veterinary Authorities* should require:

for *in vivo* derived embryos of RP susceptible animals

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

1. RP is the subject of a national surveillance programme according to Appendix 3.8.2.;
2. the donor females:
  - a) and all other animals in the *establishment* showed no clinical sign of RP at the time of collection and for the following 21 days;
  - b) were kept in an *establishment* where no RP susceptible animals had been added in the 21 days before collection of the embryos;
  - c) were vaccinated against RP at least 3 months prior to collection; or

- d) have not been vaccinated against RP, and were subjected to a diagnostic test for RP on two occasions with negative results, at an interval of not less than 21 days within the 30 days prior to collection;
3. the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.1. or Appendix 3.3.3., as relevant.

Article 2.2.12.11.

When importing from RP free countries, *Veterinary Authorities* should require:

for fresh meat or meat products of susceptible animals

the presentation of an *international veterinary certificate* attesting that the entire consignment comes from animals which have been kept in the country since birth or for at least 3 months prior to *slaughter*.

Article 2.2.12.12.

When importing from RP infected countries, *Veterinary Authorities* should require:

for fresh meat (excluding offal) of susceptible animals

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

1. comes from a country where RP is the subject of a national surveillance programme according to Appendix 3.8.2.;
2. comes from animals which:
  - a) showed no clinical sign of RP within 24 hours before *slaughter*;
  - b) have remained in the country for at least 3 months prior to *slaughter*;
  - c) were kept in the *establishment* of origin since birth or for at least 30 days prior to shipment to the approved *abattoir*, and that RP has not occurred within a ten-kilometre radius of the *establishment* during that period;
  - d) were vaccinated against RP at least 3 months prior to shipment to the approved *abattoir*;
  - e) had been transported, in a *vehicle* which was cleansed and disinfected before the animals 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) were slaughtered in an approved *abattoir* in which no RP has been detected during the period between the last *disinfection* carried out before *slaughter* and the date on which the shipment has been dispatched.

Article 2.2.12.13.

When importing from RP infected countries, *Veterinary Authorities* should require:

for meat products of susceptible animals

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

1. only *fresh meat* complying with the provisions of Article 2.2.12.12. has been used in the preparation of the *meat products*; or

2. the *meat products* have been processed to ensure the destruction of the RPV 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 possible source of RPV.

Article 2.2.12.14.

When importing from RP free countries, *Veterinary Authorities* should require:

for *milk* and *milk products* intended for human consumption and for products of animal origin (from RP 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 since birth or for at least 3 months.

Article 2.2.12.15.

When importing from RP infected countries, *Veterinary Authorities* should require:

for *milk* and cream

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

1. these products:
  - a) originate from herds or flocks which were not subjected to any restrictions due to RP at the time of *milk* collection;
  - b) have been processed to ensure the destruction of the RPV 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 RPV.

Article 2.2.12.16.

When importing from RP infected countries, *Veterinary Authorities* should require:

for *milk products*

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

1. these products are derived from *milk* complying with the above requirements;
2. the necessary precautions were taken after processing to avoid contact of the *milk products* with a potential source of RPV.

Article 2.2.12.17.

When importing from RP infected countries, *Veterinary Authorities* should require:

for blood and meat-meals (from susceptible animals)

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 2.2.12.18.

When importing from RP infected countries, *Veterinary Authorities* should require:

for wool, hair, bristles, raw hides and skins (from susceptible animals)

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

1. these products have been processed to ensure the destruction of the RPV in conformity with one of the procedures referred to in Article 3.6.2.2., Article 3.6.2.3. and Article 3.6.2.4.;
2. the necessary precautions were taken after processing to avoid contact of the products with any potential source of RPV.

*Veterinary Authorities* 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 2.2.12.19.

When importing from RP infected countries, *Veterinary Authorities* should require:

for hooves, claws, bones and horns, hunting trophies and preparations destined for museums (from susceptible animals)

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

1. were completely dried and had no trace on them of skin, flesh or tendon; and/or
2. have been adequately disinfected.

1. [Note: International veterinary certificates for animal products coming from RP infected countries, may not be required if the products are transported in an approved manner to premises controlled and approved by the Veterinary Authority of the importing country for processing to ensure the destruction of the RPV as described in Article 3.6.2.2., Article 3.6.2.3. and Article 3.6.2.4.]

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## APPENDIX 3.8.2.

**GUIDELINES FOR ON THE SURVEILLANCE OF FOR  
RINDERPEST****Community comments:****The Community supports the proposed changes.**

## Article 3.8.2.1.

**Purposes of the document**

In order to receive OIE recognition of rinderpest freedom, a country's national authority must present for consideration a dossier of information relating to its livestock production systems, rinderpest vaccination and eradication history and the functioning of its *Veterinary Services*. The dossier must contain convincing evidence derived from an animal *disease* surveillance system that sufficient evidence has accrued to demonstrate that the presence of rinderpest virus would have been disclosed were it to be present. Guidelines for the structure and the functioning of *Veterinary Services* and diagnostic support services are provided in Chapters 1.3.3. and 1.3.4. of the *Terrestrial Code*. A Member must also be in compliance with its OIE reporting obligations (Chapter 1.1.2. of the *Terrestrial Code*).

## Article 3.8.2.2.

**Definitions**1. Rinderpest

For the purpose of this Appendix, rinderpest is defined as an *infection* of large ruminants (cattle, buffaloes, yaks, etc.), small ruminants, pigs and various wildlife species within the order Artiodactyla, caused by rinderpest virus. In small ruminants and various species of wildlife, particularly antelopes, *infection* generally passes without the development of frank clinical signs. Characteristic clinical signs and pathological lesions are described in Chapter 2.1.4. of the *Terrestrial Manual*

*Outbreaks* of rinderpest in cattle may be graded as per-acute, acute or sub-acute. Differing clinical presentations reflect variations in levels of innate host resistance (*Bos indicus* breeds being more resistant than *Bos taurus*), and variations in the virulence of the attacking strain. It is generally accepted that unvaccinated populations of cattle are likely to promote the emergence of virulent strains and associated epidemics while partially vaccinated populations favour the emergence of mild strains associated with endemic situations. In the case of per-acute cases the presenting sign may be sudden death. In the case of sub-acute (mild) cases, clinical signs are irregularly displayed and difficult to detect.

Freedom from rinderpest means freedom from rinderpest virus *infection*.

2. Rinderpest vaccines

For the purpose of this Appendix and the *Terrestrial Code*, OIE-recognised rinderpest vaccines currently in use, or likely to become so in the foreseeable future, are considered to be commercial modified live vaccines produced from attenuated rinderpest virus (referred to as 'rinderpest vaccine') produced in accordance with Chapter 2.1.4. of the *Terrestrial Manual*

## Article 3.8.2.3.

**Rinderpest surveillance**

General guidelines on animal *disease* surveillance are outlined in Appendix 3.8.1. of the *Terrestrial Code*.

Rinderpest must be a *notifiable disease* i.e. notification of *outbreaks* of rinderpest as soon as detected or suspected must be brought to the attention of the *Veterinary Authority*.

The precise surveillance information required for establishing freedom will differ from country to country depending on factors such as the former rinderpest status of the country, the regional rinderpest situation and accreditation status, the time elapsing since the last occurrence of rinderpest, livestock husbandry systems (e.g. extensive pastoralism, nomadism and transhumance versus sedentary agropastoralism) and trading patterns.

Evidence of efficiency of the surveillance system can be provided by the use of performance indicators.

Surveillance results presented will be expected to have accrued from a combination of surveillance activities including some or all of the following:

1. A routine national animal disease reporting system supported by evidence of its efficiency and follow-up – an on-going, statutory, centrally organised system of reporting

Ideally *disease* reports should be expressed in a Geographical Information System environment and analysed for clustering of observations and followed up.

2. Emergency disease reporting systems and investigation of epidemiologically significant events ('stomatitis- enteritis syndrome')

Emergency reporting systems can be devised to short-circuit normal passive reporting systems to bring suspicious events to the fore and lead to rapid investigation and tracing. All such investigations should be well documented for presentation as an outcome of the surveillance system.

3. Detection and thorough investigation of epidemiologically significant events ('stomatitis-enteritis syndrome') which raise suspicion of rinderpest supported by evidence of efficiency of the system

Laboratory examination undertaken to confirm or rule out rinderpest is given extra credibility if it is accompanied by the results of differential diagnostic examinations.

4. Searching for evidence of clinical rinderpest

Active search for *disease* might include participatory *disease* searching combined with village *disease* searching, tracing backwards and forwards, follow-up and investigation.

5. Serosurveillance

- a) Randomised serosurveys

Statistically selected samples from relevant strata within the host populations are examined to detect serological evidence of possible virus circulation.

A sampling unit for the purposes of *disease* investigation and surveillance is defined as a group of animals in sufficiently close contact that individuals within the group are at approximately equal risk of coming in contact with the virus if there should be an infectious animal within the group. In most circumstances, the sampling unit will be a herd which is managed as a unit by an individual or a community, but it may also be other epidemiologically appropriate groupings which are subject to regular mixing, such as all animals belonging to residents of a village. In the areas where nomadic or transhumant movements exist, the sampling unit can be the permanent

bore holes, wells or water points. Sampling units should normally be defined so that their size is generally between 50 and 1,000 animals.

i) Criteria for stratification of host populations

Strata are homogeneously mixing sub-populations of livestock. Any *disease* surveillance activities must be conducted on populations stratified according to the management system, and by herd size where this is variable. Herds, or other sampling units, should be selected by proper random statistical selection procedures from each stratum.

ii) Field procedures and sample sizes

Annual sample sizes shall be sufficient to provide 95% probability of detecting evidence of rinderpest if present at a prevalence of 1% of herds or other sampling units and 5% within herds or other sampling units. This can typically be achieved by examining 300 herds per stratum per year, but procedures for sampling should be in accordance with the "Guide to Epidemiological Surveillance for Rinderpest"<sup>1</sup>, or another procedure that would achieve the same probability of detection.

Where the sampling frame of herds is known, herds shall be selected for examination by the use of random number tables. Otherwise, samples of herds can be selected by taking the nearest herd to a randomly selected map reference, provided that the herds are evenly distributed. Failing this, any herd(s) within a fixed radius of randomly selected map references should be sampled. It must be compulsory for any selected herd to be examined or tested as required.

In carrying out clinical surveillance for evidence of rinderpest, all animals in selected herds or sampling units will be examined by a *veterinarian* for signs of the *disease*, especially mouth lesions. Any positive result shall be evaluated using epidemiological and laboratory methods to confirm or refute the suspicion of rinderpest virus activity. All animals born after the cessation of vaccination and more than one year old will be eligible for serological testing.

Where operational considerations require it, the number of eligible animals tested within each sampled herd may be reduced. This will reduce the probability of within-herd detection and there must be at least a compensatory increase in the number of herds sampled, so that the required 95% probability of detecting 1% between-herd prevalence is maintained.

b) Risk-focussed serosurveillance

Risk-focussed serosurveillance differs from randomised serosurveillance in that it increases detection sensitivity by obtaining samples from areas/populations determined to be at higher risk of *infection*, so as to detect serological evidence of possible virus circulation. The operational modalities for risk-based focussing of surveillance require definition (randomisation within defined focus, high risk animals, etc.). The extent to which randomisation needs to be retained in the generation of risk-focussed serosurveillance data needs to be established.

Focussing can be achieved by reference to some or all of the following:

- i) Historical *disease* patterns (prior probability mapping) - clinical, participatory and laboratory-based
- ii) Critical population size, structure and density
- iii) Livestock husbandry and farming systems



- iv) Movement and contact patterns — markets and other trade-related movements
- v) Transmission parameters (e.g. virulence of the strain, animal movements)
- vi) Wildlife and other species demography.

#### Article 3.8.2.4.

#### **Selection of cattle and buffaloes for serosurveillance**

Ageing cattle and Asian buffaloes for the purpose of serosurveillance:

Mis-ageing of cattle selected for serosurveillance is the most common source of error. Colostral immunity can persist almost up to one year of age when measured by the H c-ELISA. Thus, it is essential to exclude from sampling buffaloes and cattle less than one year of age. In addition, it is frequently necessary to be able to exclude those which are older than a certain age, for example, to select only those born after cessation of vaccination.

Accounts of the ages for eruption of the incisor teeth vary markedly and are clearly dependent on species, breed, nutritional status and nature of the feed.

Pragmatically, and solely for the purposes of serosurveillance, it can be accepted that:

- a) cattle having only one pair of erupted permanent central incisor teeth are aged between 21 and 36 months (Asian buffaloes 24-48 months);
- b) cattle having only two pairs of erupted permanent central incisor teeth are aged between 30 and 48 months (Asian buffaloes 48-60 months).

Thus selecting a cohort of cattle possessing only one pair of permanent incisors will preclude any interference from maternal immunity derived from earlier vaccination or *infection* and ensure that vaccinated cattle are not included if vaccination ceased 3 years or more previously (for Asian buffaloes 4 years or more).

Although it is stressed here that animals with milk teeth only are not suitable for surveillance based on serology, they are of particular interest and importance in surveillance for clinical *disease*. After the loss of colostral immunity, by about one year of age, these are the animals which are most likely to suffer the more severe *disease* form and in which to look for lesions indicative of rinderpest.

#### Article 3.8.2.5.

#### **Wildlife surveillance where a significant susceptible wildlife population exists**

There are some key wildlife populations, especially African buffaloes, which act as sentinels for rinderpest *infection*. Where a significant population of a susceptible wildlife species exists, serosurveillance data are required to support absence of *infection*. These populations should be monitored purposively to support the dossiers to be submitted for freedom from rinderpest virus *infection*. Detection of virus circulation in wildlife can be undertaken indirectly by sampling contiguous livestock populations.

Obtaining meaningful data from wildlife surveillance can be enhanced by close coordination of activities in the regions and countries. Both purposive and opportunistic samplings are used to obtain material for analysis in national and reference laboratories. The latter are required because most countries are unable to perform the full testing protocol for detecting rinderpest antibodies in wildlife sera.

Purposive sampling is the preferred method to provide wildlife data to evaluate the status of rinderpest *infection*. In reality, the capacity to perform purposive work in the majority of countries remains minimal. Opportunistic sampling (hunting) is feasible and it provides useful background information.

Wildlife form transboundary populations; therefore, any data from the population could be used to represent the result for the ecosystem and be submitted by more than one country in a dossier (even if the sampling was not obtained in the country submitting). It is therefore recommended that the countries represented in a particular ecosystem should coordinate their sampling programmes.

The standards for serosurveillance are different from that set for cattle because the serological tests are not fully validated for wildlife species and financial and logistic constraints of sampling prevent collection of large numbers of samples.

From the collective experience of the laboratories and experts over the years, an appropriate test protocol is based on the high expected sero-prevalence in a previously infected buffalo herd (99% seroconversion of eligible animals within a herd), which is detected using a test, which is 100% sensitive. No single test can achieve this; however, combining H c-ELISA to VNT raises sensitivity close to 100%.

In the order of 1-2% of a herd of African buffaloes must be sampled to ensure that no positive case is missed. For example in a herd of 300 buffaloes, five animals should be sampled and the above multiple test protocol followed. Where the serological history of the herd is known from previous work (as might be the case for a sentinel herd), repeat sampling need only focus on the untested age groups, born since the last known *infection*. Appropriate sampling fraction for other wildlife species are less well defined, as social organization (herd structure, likely contact rates, etc.) vary. The sample needs to be taken according to the known epidemiology of the *disease* in a given species. Opportunistic samples, which are positive, should not be interpreted without a purposive survey to confirm the validity of these results. Opportunistic sampling cannot follow a defined protocol and therefore can only provide background information.

#### Article 3.8.2.6.

### **Evaluation of applications for accreditation of freedom from rinderpest**

Evaluation of applications for the status of freedom from rinderpest will be the responsibility of the OIE Scientific Commission for Animal Diseases which can request the Director General if the OIE to appoint an *ad hoc* group in order to assist in reaching an informed decision to present to the OIE International Committee for approval.

The composition and method of selection of the *ad hoc* group shall be such as to ensure both a high level of expertise in evaluating the evidence and total independence of the group in reaching conclusions concerning the *disease* status of a particular country.

#### Article 3.8.2.7.

### **Steps to be taken to declare a country to be free from rinderpest**

Recognition of the status 'free from rinderpest' is given to a Member. Where traditionally managed livestock move freely across international borders, groups of Members may usefully associate themselves into a group for the purposes of obtaining data to be used for mutually supportive applications for individual country accreditation.

For the purpose of this Appendix, the following assumptions are made:

- a) that within most previously infected countries, rinderpest vaccine will have been used to control the rate of *infection*;

- b) that within an endemically infected population there will be a large number of immune hosts (both vaccines and recovered animals);
- c) that the presence of a proportion of immune hosts within a vaccinated population could have led to a slowing of the rate of virus transmission and possibly the concomitant emergence of strains of reduced virulence, difficult to detect clinically;
- d) that the virulence of the virus (and therefore the ease of clinical detection) may or may not increase as the herd immunity declines following withdrawal of vaccination; however, continuing transmission will generate serological evidence of their persistence.

Before accreditation can be considered, countries which have controlled the *disease* by the use of rinderpest vaccine must wait until an unvaccinated cohort is available to allow meaningful serological surveillance to be conducted.

The OIE has concluded that the majority of countries have stopped vaccinating for a sufficient length of time for it now to be feasible that a single submission of evidence gained over 2 years of appropriate surveillance shall be sufficient to gain rinderpest free accreditation.

A Member accredited as free from rinderpest must thereafter submit annual statements to the Director General of the OIE indicating that surveillance has failed to disclose the presence of rinderpest, and that all other criteria continue to be met.

A country previously infected with rinderpest which has not employed rinderpest vaccine for at least 25 years and has throughout that period detected no evidence of rinderpest virus *disease* or *infection* may be accredited as free from rinderpest by the OIE based on historical grounds, provided that the country:

- has had throughout at least the last 10 years and maintains permanently an adequate animal *disease* surveillance system along with the other requirements outlined in Article 3.8.1.6.;
- is in compliance with OIE reporting obligations (Chapter 1.1.2.).

The *Veterinary Authorities* of the Member must submit a dossier containing evidence supporting their claim to be free from rinderpest on a historical basis to the Director General of the OIE for evaluation by the OIE Scientific Commission for Animal Diseases and accreditation by the OIE International Committee. The dossier should contain at least the following information:

- a description of livestock populations, including wildlife;
- the history of rinderpest occurrence in the country and its control;
- an affirmation that rinderpest has not occurred for 25 years, that vaccine has not been used during that time, and that rinderpest is a *notifiable disease*;
- evidence that in the last 10 years the *disease* situation throughout the Member has been constantly monitored by a competent and effective veterinary infrastructure that has operated a national animal *disease* reporting system submitting regular (monthly) *disease* occurrence reports to the *Veterinary Authority*;
- the structure and functioning of the *Veterinary Services*;
- the Member operates a reliable system of *risk analysis* based importation of livestock and livestock products.

Evidence in support of these criteria must accompany the Member's accreditation application dossier. In the event that satisfactory evidence is not forthcoming, the OIE may seek clarification or refer the dossier

back to the originators, giving its reasons for so doing. Under such circumstances a fresh dossier would be entertained in due course.

OR

A Member having eradicated rinderpest within the last 25 years, wishing to be accredited free from rinderpest and having ended rinderpest vaccination must initiate a two-year surveillance programme to demonstrate freedom from rinderpest whilst banning further use of rinderpest vaccine. The step of accreditation as free from rinderpest is subject to meeting stringent criteria with international verification under the auspices of the OIE.

A country historically infected with rinderpest but which has convincing evidence that the *disease* has been excluded for at least two years and is not likely to return, may apply to OIE to be accredited as free from rinderpest. The conditions which apply include that an adequate animal *disease* surveillance system has been maintained throughout at least that period.

The *Veterinary Authority* of the Member must submit a dossier containing evidence supporting their claim to be free from rinderpest to the Director General of the OIE for evaluation by the OIE Scientific Commission for Animal Diseases and accreditation by the OIE International Committee showing that they comply with:

- the provisions outlined in Chapter 2.2.12. of the *Terrestrial Code*,
- OIE reporting obligations outlined in Chapter 1.1.2. of the *Terrestrial Code*.

Other conditions that apply are:

- The Member affirms that rinderpest has not occurred for at least 2 years, that vaccine has not been used during that time, and that rinderpest is a *notifiable disease*.
- The *Veterinary Authority* has issued orders curtailing the distribution and use of rinderpest vaccine in livestock.
- The *Veterinary Authority* has issued orders for the recall and destruction of rinderpest vaccine already issued.
- The *Veterinary Authority* has issued orders restricting the importation of rinderpest vaccine into, or the further manufacture of rinderpest vaccine within, the territory under his jurisdiction. An exception can be made for establishing a safeguarded rinderpest emergency vaccine bank under the control of the Chief Veterinary Officer who can demonstrate that no calls have been made on that vaccine bank.
- The *Veterinary Authority* has set in place a rinderpest contingency plan.
- Over the previous 2 years at least, the *disease* situation throughout the Member has been constantly monitored by a competent and effective infrastructure that has operated a national animal *disease* reporting system submitting regular (monthly) *disease* occurrence reports to the *Veterinary Authority*.
- All *outbreaks of disease* with a clinical resemblance to rinderpest have been thoroughly investigated and routinely subjected to laboratory testing by an OIE recognised rinderpest-specific test within the national rinderpest laboratory or at a recognised reference laboratory.

The dossier shall contain:

- the results of a continuous surveillance programme, including appropriate serological surveys conducted during at least the last 24 months, providing convincing evidence for the absence of rinderpest virus circulation;
- a description of livestock populations including wildlife;
- the history of rinderpest occurrence in the country and its control;
- an affirmation that rinderpest has not occurred for at least 2 years, that vaccine has not been used during that time, and that rinderpest is a *notifiable disease*;
- evidence that in the last 2 years the *disease* situation throughout the Member has been constantly monitored by a competent and effective veterinary infrastructure that has operated a national animal *disease* reporting system submitting regular (monthly) *disease* occurrence reports to the *Veterinary Authority*;
- the structure and functioning of the *Veterinary Services*;
- the Member operates a reliable system of *risk analysis* based importation of livestock and livestock products.

In the event that satisfactory evidence in support of the application is not forthcoming, the OIE may seek clarification or refer the dossier back to the originators, giving its reasons for so doing. Under such circumstances a fresh dossier would be entertained in due course.

#### Article 3.8.2.8.

#### **Rinderpest outbreaks after the accreditation process and recovery of rinderpest free status**

Should there be an *outbreak*, or *outbreaks*, of rinderpest in a Member at any time after recognition of rinderpest freedom, the origin of the virus strain must be thoroughly investigated. In particular it is important to determine if this is due to the re-introduction of virus or re-emergence from an undetected focus of *infection*. The virus must be isolated and compared with historical strains from the same area as well as those representatives of other possible sources. The *outbreak* itself must be contained with the utmost rapidity using the resources and methods outlined in the Contingency Plan.

After elimination of the *outbreak*, a Member wishing to regain the status 'free from rinderpest' must undertake serosurveillance to determine the extent of virus spread.

If investigations show the *outbreak* virus originated from outside the country, provided the *outbreak* was localised, rapidly contained and speedily eliminated, and provided there was no serological evidence of virus spread outside the index infected area, accreditation of freedom could proceed rapidly. The country must satisfy the OIE Scientific Commission for Animal Diseases that the *outbreaks* were contained, eliminated and did not represent endemic *infection*.

An application to regain the status free from rinderpest shall not generally be accepted until both clinical and serological evidence shows that there has been no virus transmission for at least 3 or 6 months, depending on whether or not stamping-out or vaccination respectively has been applied.

1 JAMES A.D. (1998). Guide to epidemiological surveillance for rinderpest. *Rev. Sci. Tech.* **17** (3), 796-824.

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## CHAPTER 2.3.15.

**CONTAGIOUS BOVINE PLEUROPNEUMONIA****Community comments:**

**The Community can only support the proposed changes if the following point is taken on board: once a country has established its free status, the surveillance is adapted to the risk of reintroduction of the virus, and the elements to be gathered and transmitted to the OIE should not include all of that described in Appendix 3.8.3.**

## Article 2.3.15.1.

For the purposes of the *Terrestrial Code*, the *incubation period* for contagious bovine pleuropneumonia (CBPP) shall be 6 months.

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

## Article 2.3.15.2.

**CBPP free country**

To be declared free from either *disease* or *infection* by the OIE, a country should meet the requirements contained in Appendix 3.8.3.

The country will be included in the list of free country only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information above be re-submitted annually and changes in the epidemiological situation or other significant events should be reported promptly to the OIE.

## Article 2.3.15.3.

**CBPP free zone**

To be declared free from either *disease* or *infection* by the OIE, a *zone* defined according to the provisions of Chapter 1.3.5. should meet the requirements contained in Appendix 3.8.3.

The zone will be included in the list of free zone only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information above be re-submitted annually and changes in the epidemiological situation or other significant events should be reported promptly to the OIE.

## Article 2.3.15.4.

**CBPP infected country or zone**

When the requirements for acceptance as a CBPP free country or zone are not fulfilled, a country or zone shall be considered as infected.

## Article 2.3.15.5.

*Veterinary Authorities* of CBPP free countries may prohibit importation or transit through their territory,

from countries considered infected with CBPP, of domestic and wild bovidae.

**Article 2.3.15.6.**

When importing from CBPP free countries, *Veterinary Authorities* should require:

for domestic bovidae

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

1. showed no clinical sign of CBPP on the day of shipment;
2. were kept in a CBPP free country since birth or for at least the past 6 months.

**Article 2.3.15.7.**

When importing from CBPP free countries, *Veterinary Authorities* should require:

for wild bovidae

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

1. showed no clinical sign of CBPP on the day of shipment;
2. come from a CBPP free country;

if the country of origin has a common border with a country considered infected with CBPP:

3. were kept in a *quarantine station* for the 6 months prior to shipment.

**Article 2.3.15.8.**

When importing from CBPP infected countries, *Veterinary Authorities* should require:

for bovidae for breeding

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

1. showed no clinical sign of CBPP on the day of shipment;
2. were subjected to the complement fixation test for CBPP with negative results, on two occasions, with an interval of not less than 21 days and not more than 30 days between each test, the second test being performed within 14 days prior to shipment;
3. were isolated from other domestic bovidae from the day of the first complement fixation test until shipment;
4. were kept since birth, or for the past 6 months, in an *establishment* where no *case* of CBPP was officially reported during that period, and that the *establishment* was not situated in a CBPP *infected zone*;
5. have not been vaccinated against CBPP; or
6. were vaccinated using a vaccine complying with the standards described in the *Terrestrial Manual* not more than 4 months prior to shipment. In this case, the condition laid down in point 2 above is not required.

**Article 2.3.15.9.**

When importing from CBPP infected countries, *Veterinary Authorities* should require:

for bovidae for slaughter

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

1. showed no clinical sign of CBPP on the day of shipment;
2. were kept since birth, or for the past 6 months, in an *establishment* where no *case* of CBPP was officially reported during that period, and that the *establishment* was not situated in a CBPP *infected zone*.

Article 2.3.15.10.

When importing from CBPP infected countries, *Veterinary Authorities* should require:

for wild bovidae

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

1. showed no clinical sign of CBPP on the day of shipment;
2. were kept, for the 180 days prior to shipment, in a *quarantine station* where no *case* of CBPP was officially reported during that period, and that the *quarantine station* was not situated in a CBPP *infected zone*;
3. have not been vaccinated against CBPP; or
4. were vaccinated using a vaccine complying with the standards described in the *Terrestrial Manual* not more than 4 months prior to shipment. In this case, the condition laid down in point 2 above is not required.

Article 2.3.15.11.

When importing from CBPP infected countries, *Veterinary Authorities* should require:

for fresh meat of bovidae

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

1. which showed no lesion of CBPP;
2. which have been slaughtered in an approved *abattoir* and have been subjected to ante-mortem and post-mortem inspections for CBPP with favourable results.

Article 2.3.15.12.

When importing from CBPP free countries, *Veterinary Authorities* should require:

for *in vivo* derived or *in vitro* produced embryos/oocytes of bovidae

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

1. the donor animals:
  - a) showed no clinical sign of CBPP on the day of collection of the embryos/oocytes;



- b) were kept in a CBPP free country since birth or for at least the past 6 months;
- 2. the oocytes were fertilised with semen meeting the conditions referred to in points a) and b) above and in Appendix 3.2.1.;
- 3. the embryos/oocytes were collected, processed and stored in conformity with the provisions of Appendix 3.3.1., Appendix 3.3.2. or Appendix 3.3.3., as relevant.

Article 2.3.15.13.

When importing from CBPP infected countries, *Veterinary Authorities* should require:

for *in vivo* derived or *in vitro* produced embryos/oocytes of bovidae

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

- 1. the donor animals:
  - a) showed no clinical sign of CBPP on the day of collection of the embryos/oocytes;
  - b) were subjected to the complement fixation test for CBPP with negative results, on two occasions, with an interval of not less than 21 days and not more than 30 days between each test, the second test being performed within 14 days prior to collection;
  - c) were isolated from other domestic bovidae from the day of the first complement fixation test until collection;
  - d) were kept since birth, or for the past 6 months, in an *establishment* where no *case* of CBPP was reported during that period, and that the *establishment* was not situated in a CBPP *infected zone*;
  - e) have not been vaccinated against CBPP; or
  - f) were vaccinated using a vaccine complying with the standards described in the *Terrestrial Manual* not more than 4 months prior to collection; in this case, the condition laid down in point b) above is not required;
- 2. the oocytes were fertilised with semen meeting the conditions referred to in points a) to f) above and in Appendix 3.2.1.;
- 3. the embryos/oocytes were collected, processed and stored in conformity with the provisions of Appendix 3.3.1., Appendix 3.3.2. or Appendix 3.3.3., as relevant.

## APPENDIX 3.8.3.

## GUIDELINES ON SURVEILLANCE FOR **CONTAGIOUS BOVINE PLEUROPNEUMONIA**

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|----------------------------|
| <b>Community comments:</b> |
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| <b>The Community supports the proposed changes.</b> |
|---|

**1. Introduction**

The Ad hoc Group on Contagious Bovine Pleuropneumonia (CBPP) Surveillance Systems held a meeting on 7-9 June 1993 with the purpose of formulating these standards, which describe surveillance systems suited to the declaration of countries and *zones* free of *disease* and free of *infection*. Background information is contained in the report of the meeting. In order to write these standards, the Group reviewed the following:

- a) epidemiological and non-*disease* factors influencing the choice of CBPP surveillance systems;
- b) sampling and surveillance strategies;
- c) diagnostic methods applicable to CBPP surveillance systems;
- d) the implications of CBPP vaccination for surveillance systems.

This last point was the subject of lengthy discussions during the meeting of the OIE Committee in May 1994. A revised text was submitted at the following meeting of the Committee (May 1995), which requested that a small group of experts formulate revised proposals. The present text is the product of their consensus.

**2. Definition and purposes of surveillance**

*Disease* surveillance is necessary to provide evidence that a country or *zone* is free from a *disease* or *infection*. *Disease* surveillance should be implemented by both:

- a) a system of reporting any signs of *disease* activity which come to the notice of *Veterinary Services* or livestock owners; and
- b) an active programme of examination of statistically selected samples from host populations in order to detect clinical signs or other indications of the occurrence of *disease* or transmission of *infection*.

In either case, suspicion of *disease* activity should be followed by quarantine, confirmatory diagnostic work and any necessary *disease* control measures. Surveillance thus implies that official action will follow from the discovery of evidence of *disease* or *infection*. It can be contrasted with monitoring, in which the gathering of data from the field takes place similarly, but no official action based on the findings is implied in the data-gathering activity.

Within the context of pleuropneumonia, specific measures need to be implemented, such as an exhaustive inspection of all lungs of bovines throughout the country or *zone*.

### 3. Steps to be taken to declare a country free from contagious bovine pleuropneumonia

The current goal in CBPP control is to achieve freedom from *disease* in particular countries and later of entire world regions, with the ultimate aim of achieving global eradication. It is therefore necessary to institute a system for verifying the steps towards these short and long-term aims, and to assist countries which wish to trade in livestock or livestock products, but face difficulties due to the presence or past occurrence of CBPP.

In conformity with the general principles for assessing *disease* status developed by the OIE, a four-stage process should be applied:

- intention to eradicate pleuropneumonia: the longest phase, depending on prevalence of the *disease* in the country or zone, geographical, socio-economic and administrative conditions, and the capacity of the animal health infrastructure;
- once a country is free from CBPP and that *disease* is unlikely to be re-introduced, the country can declare itself provisionally free from *disease*, provided it meets the criteria listed below;
- declaration of freedom from clinical CBPP, after international verification carried out under the auspices of the OIE;
- declaration of freedom from CBPP, where a country meets more stringent surveillance and control criteria.

The last three stages are strictly covered by the epidemiological surveillance methods of the OIE.

The sequence of operations differs both in terms of tactics and duration depending on whether or not the country wishing to eradicate CBPP practises vaccination.

'*Disease*' in the context of declaration of freedom means that the particular pathogenic agent is present and causes significant pathological effects on animals which become infected with the agent. Thus 'freedom from *disease*' means that there is no evidence in animals within the country or *zone* of any pathological effects occurring (including clinical signs) due to the presence of the agent, and from all the evidence pathogenic strains of the particular agent have been eliminated.

## COUNTRIES PRACTISING VACCINATION

The process is summarised in the following chart:

The specific criteria proposed for each stage of this process are as follows:

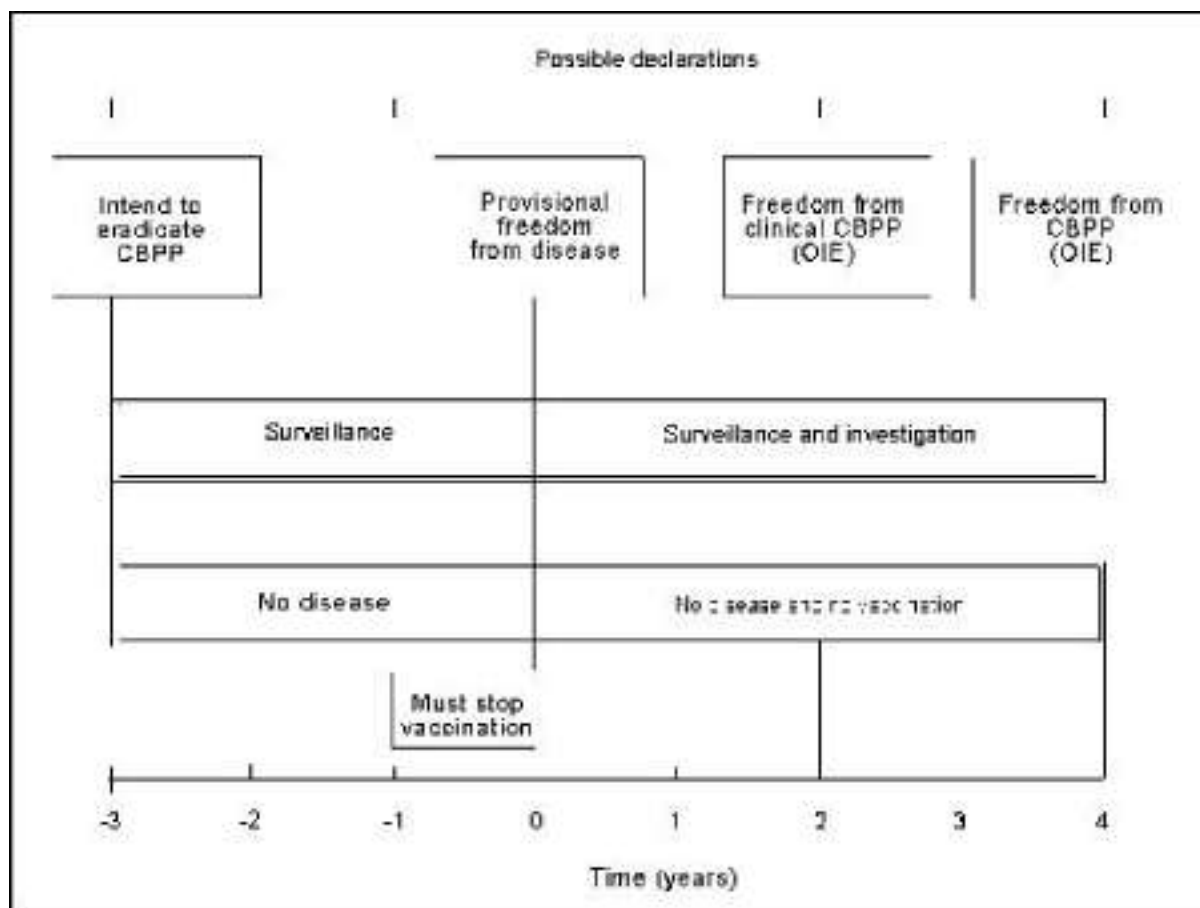
#### a) Provisional freedom from disease

For a country to declare the whole or a *zone* of its territory provisionally free from *disease*, it must fulfil certain conditions, which are:

- i) no clinical or pathological evidence of CBPP should have been detected for at least 3 years;
- ii) there is an effective *Veterinary Service* which is able to monitor the animal health situation in the country;

- iii) there is effective meat inspection at *approved abattoirs*, and effective surveillance of populations in which significant numbers of slaughtered susceptible livestock are not subject to meat inspection;

**Fig. 1. Requirements for the declaration of freedom from disease and freedom from CBPP**



- iv) all evidence suggestive of CBPP is investigated by field and laboratory methods (including serological and microbiological assessment) to refute a possible diagnosis of CBPP;
- v) there is an effective reporting system, both from the field to the central veterinary authority, and by that body to the OIE;
- vi) there is an effective system to prevent the introduction of *infection*, including appropriate border control, quarantine, etc.;
- vii) if vaccination has been used, all vaccination against CBPP has ceased by the date of declaration; the OIE and neighbouring countries having been notified in writing, giving the date from which vaccination was discontinued.
- b) Freedom from clinical CBPP

A country which has declared itself or a *zone* to be provisionally free from *disease* may be declared by the OIE free from clinical CBPP, provided that the following criteria are met:

- i) no clinical or pathological evidence of CBPP has been detected for at least 5 years;

- ii) no CBPP vaccination has taken place for at least 2 years;
- iii) the country operates surveillance and *disease* reporting systems for CBPP adequate to detect *disease* if it were present, and ensures that veterinary staff are adequately trained in the recognition of CBPP;
- iv) all susceptible livestock at recognised *abattoirs* are subject to meat inspection procedures adequate to detect lung lesions, with diagnostic procedures to refute a possible diagnosis of CBPP;
- v) there has been a programme of surveillance (using serological, pathological and microbiological techniques) for at least 2 years on any populations of susceptible domestic livestock where more than 10% of slaughtering is not subject to adequate meat inspection procedures;
- vi) all evidence suggestive of CBPP is investigated by field and laboratory methods (including serological and microbiological assessment) to refute a possible diagnosis of CBPP;
- vii) there are effective measures in force to prevent re-introduction of the *disease*.

On meeting these criteria, a country may apply to the OIE for all, or a *zone*, of its territory to be declared free from clinical CBPP.

An Expert Panel for the Verification of Disease Status of the OIE will evaluate the application and decide whether or not to approve it. In coming to its decision, the Expert Panel will consider evidence presented by the country and will gather information on the extent to which the criteria are met. This information-gathering will usually include sending members of the Panel to make a field visit to the country. The Expert Panel will report its findings to the OIE Scientific Commission for Animal Diseases. The Commission will report its conclusions annually to the International Committee for endorsement.

To maintain this status, a country must continue to meet these requirements until it is declared free from CBPP, and must report to the OIE an annual summary of developments.

Should there be a localised temporary *outbreak of disease* due to re-introduction of CBPP to a country which has met, or is within 2 years of meeting, the requirements for a declaration of freedom from clinical CBPP, that country should implement a *stamping-out policy*, which may be supported by intensive perifocal vaccination, to eradicate the *outbreak*. In such circumstances if no vaccination was carried out, it will then require at least one year from the date of the last case before the country becomes eligible to apply for a declaration of freedom from clinical CBPP. If vaccination was used, this period is extended to 2 years from the date of the last *case* or the last vaccination (whichever occurs later). In making an application under these special circumstances, it must be shown that the *outbreak* did not represent endemic *infection*, and that the *disease* has been eradicated by the actions taken.

The declaration of *zones* to be free from clinical CBPP will not remove the requirement for the country subsequently to meet the criteria for declaration of freedom from clinical CBPP for the country as a whole; if it wishes to achieve that status, it will have to meet all of the requirements specified above before it can apply for a declaration of freedom from clinical CBPP for the entire country.

c) Freedom from CBPP

A country or a *zone* of its territory which has within the last 10 years either vaccinated against CBPP, or found clinical or pathological evidence of CBPP, may be declared by the OIE to be free from CBPP if the following criteria are met:

- i) it has been declared free from clinical CBPP at least 2 years earlier, and continues to meet the requirements for this status;
- ii) there has been effective *abattoir* surveillance for at least 4 years, covering all susceptible domestic livestock;
- iii) use has been made of diagnostic procedures capable of differentiating *Mycoplasma mycoides* from other bovine *Mycoplasma* infections in the investigation of respiratory *disease*, and the findings are consistent with freedom from *M. mycoides infection*;
- iv) there has been a programme of surveillance, including serological, pathological and microbiological components, for at least 3 years on any populations of susceptible domestic livestock where more than 10% of slaughter stock are not subject to adequate meat inspection procedures.

On satisfying these criteria, a country may apply to the OIE to be declared free from CBPP.

An Expert Panel for the Verification of Disease Status of the OIE will evaluate the application and decide whether or not to approve it. In coming to its decision, the Expert Panel will consider evidence presented by the country and will gather information on the extent to which the criteria are met. This information-gathering will usually include sending members of the Panel to make a field visit to the country.

The Expert Panel will report its findings to the OIE Scientific Commission for Animal Diseases. The Commission will report its conclusions annually to the International Committee for endorsement.

In the special case of a country or *zone* which has been considered to be continuously free from CBPP for at least 10 years, and meets all of the following requirements:

- v) has not vaccinated against CBPP for at least 10 years;
- vi) throughout that period found no clinical or pathological evidence of CBPP *infection*;
- vii) had throughout that period, and undertakes to maintain permanently, an adequate *disease* surveillance and reporting system, covering all susceptible domestic livestock;
- viii) in appropriate circumstances, made use of diagnostic procedures capable of differentiating *Mycoplasma mycoides*; from other bovine *Mycoplasma infections* in the investigation of respiratory *disease*, with findings consistent with freedom from *M. mycoides infection*;

the country or *zone* may be declared by the OIE to be free from CBPP without the necessity to proceed through the normal intermediate steps. This declaration will be based on the conclusions of the Expert Panel for the Verification of Disease Status.

Declaration of freedom from CBPP can be made for the country as a whole, or for zones within a country.

Should there be a localised temporary *outbreak of disease* due to re-introduction of CBPP to a country which has met, or is within one year of meeting, the requirements for a declaration of freedom from CBPP, that country may take special measures (excluding the use of vaccination) to eradicate the *outbreak*. In such circumstances, it will then require at least 2 years from the date of the last *case* before the country becomes eligible to apply for a declaration of freedom from CBPP. In making an application under these special circumstances, the country must demonstrate that the *outbreak* did not represent endemic *infection*, and that the *disease* has been eradicated by the actions taken.

In order to maintain this status, the country must continue to operate an efficient *disease* surveillance and reporting system, which would detect CBPP if it occurred.

## COUNTRIES NOT PRACTISING VACCINATION

These are generally countries with a solid animal health infrastructure (with a system for individually identifying animals) where CBPP has been accidentally introduced.

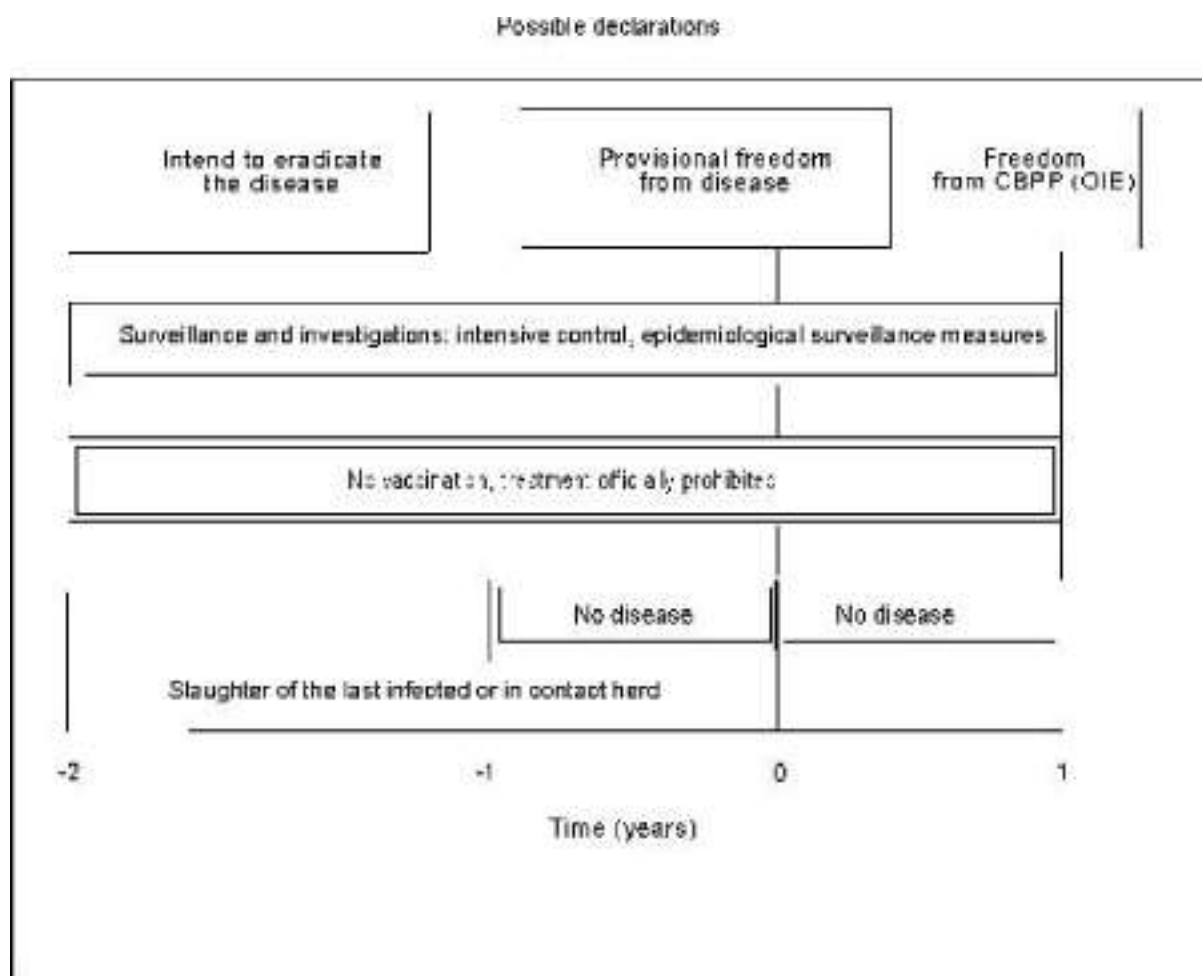
The specific criteria proposed for each stage of this process are as follows:

### a) Provisional freedom from disease

A country may declare the whole or a *zone* of its territory provisionally free from *disease* one year after the last infected herds and in-contact herds have been slaughtered, on condition that:

- i) there has been no vaccination in the country or *zone* for at least 2 years;
- ii) all treatment against CBPP is prohibited for sick animals or suspected cases;
- iii) a *stamping-out policy* is implemented after any CBPP *outbreaks*. Within the framework of the declaration, a minimum period of 12 months will be required after the last sick or in-contact herd has been slaughtered;
- iv) an epidemiological investigation, including serological tests, has been carried out to determine the prevalence of the *disease* in the country or *infected zone*. Special attention should be given to screening animals transported into or out of the infected herds during the 6 months preceding detection of the *outbreak(s)*;
- v) a system of livestock identification and movement control has been set up in the country or *zone* for the purposes of CBPP control and surveillance as follows:
  - all herds are officially registered and all animals of susceptible species aged over 12 months are individually identified;
  - before being moved, other than for immediate *slaughter*, all animals of susceptible species are to be clinically inspected and serologically tested for CBPP;
- vi) all animals of susceptible species in herds or *establishments* within a 3-km radius of an *outbreak*, and any animals with a possible epidemiological link, are individually identified, placed in quarantine for at least 6 months, and
  - all animals of susceptible species in the aforementioned herds or *establishments* are serological tested on two occasions at an interval of 2 to 8 weeks; microbiological investigations are to be carried out on any serologically positive animal;
  - during the quarantine period, animals in the aforementioned herds or *establishments* are not to be moved other than to an officially approved *abattoir*, where they are to be immediately slaughtered and subjected to sanitary inspection after slaughter;
  - microbiological tests should be carried out on animals presenting lesions suggestive of CBPP;

Fig. 2. Summary of the accelerated eradication process



- vii) surveillance is carried out in *abattoirs* in the contaminated country. Any lesion suggestive of CBPP should be examined microbiologically and, if the result is positive, the herd of origin must be found and subjected to serological testing;
- viii) the diagnostic tests used in the country or *zone* comply with OIE standards and are conducted in a nationally approved *laboratory*.

b) Freedom from contagious bovine pleuropneumonia

A country or *zone* may be declared by the OIE to be free from CBPP 2 years after the last infected and in-contact herds have been slaughtered if the conditions listed in points a)i) to a)viii) continue to be met.

4. **Epidemiological methods**

a) Surveillance systems

In demonstrating that a country or *zone* is free of *disease*, it is necessary to conduct a surveillance programme which would have a very high probability of detecting the *disease* if it were present. Surveillance for CBPP will include a combination of clinical, pathological, serological and microbiological methods, built around an epidemiological surveillance approach. The mix of procedures used will depend on the specific circumstances of the country or *zone*.



The most efficient means of detecting CBPP is through effective meat inspection procedures at *abattoirs* followed by laboratory examination of suspect lesions. Where a very high proportion of susceptible domestic livestock are slaughtered in controlled *abattoirs*, this will provide a very sensitive surveillance system covering the whole population. It is possible that structured investigation of a statistical sample of carcasses might be used to augment the routine meat inspection procedures.

Where large numbers of susceptible livestock are exported for slaughter, it may be necessary to obtain meat inspection data from the *importing country*.

Where a significant proportion of susceptible domestic livestock are not subject to meat inspection at the *abattoir*, then it will be necessary to use alternative surveillance methods based on the examination of samples of herds so as to achieve a standard probability of detection. Animals in sampled herds would be subjected to clinical examination for signs of CBPP, but not all infected animals exhibit clinical signs. Serological testing can be useful in identifying infected herds, but due to the limitations of the currently available serological tests, and the possibility that the *disease* may be present at very low prevalence, such surveillance systems are not very efficient in proving freedom from *disease*, and require large numbers of herds to be sampled.

b) Definition of sampling units

A sampling unit for the purposes of *disease* investigation and surveillance is defined as a group of animals in sufficiently close contact that individuals in the group would be at approximately equal risk of coming into contact with the *disease* agent if there were an infectious animal within the group. In most circumstances, the sampling unit would be a herd which is managed as a unit by an individual or a community, but there may be other epidemiologically appropriate groupings which are subject to regular mixing, such as all the animals belonging to residents of a village. Sampling units should normally be defined so that the majority of units contain between 50 and 1,000 animals.

c) Criteria for the stratification and sampling of host populations

'Serological surveillance would only be adopted for CBPP in circumstances where the preferred *slaughterhouse* surveillance system described in item 3(c) of this document could not be carried out on an adequate scale because too low a proportion of animals was slaughtered in a *slaughterhouse*. Thus the following system would be used as an exceptional case, rather than as the usual procedure'.

Any *disease* surveillance activities must be conducted on populations stratified according to *disease risk*, which depends principally upon the environment and management system. The cattle production systems of most countries would be categorised into between two and six strata.

Annual sample sizes must be sufficient to provide 95% probability of detecting evidence of CBPP if it were present at a prevalence of 1% of herds or other sampling units. Given perfect sensitivity of the within-herd testing procedure, this would require the examination of 300 herds from each stratum per year. However, the currently available serological tests have rather low sensitivity. The sensitivity of the test procedure at herd level is further reduced when only a sample of the herd is tested. It is possible to compensate for lower sensitivity by increasing the numbers of herds examined. The required sample size is determined by adjusting the prevalence to allow for the lack of sensitivity. For example, if there was 50% probability of detecting a sampled infected herd (sensitivity 0.5), then a true *disease* prevalence of 1% of herds would result in a detectable prevalence of 0.5%, and this detectable prevalence would be used to determine the required sample size.

Herds, or other sampling units, must be selected from each stratum by proper random methods, which are described in the *Guide to Epidemiological Surveillance for Rinderpest* published by the OIE.

Any randomly selected herd must be examined in order to achieve the required probability of detection. However, this probability can often be increased by an important but unquantifiable margin by sampling additional herds based on subjective assessment of risk, or information gained during field work.

## 5. Contagious bovine pleuropneumonia vaccines

T1 strain (and its streptomycin-resistant variant) is the recommended vaccine, and the following facts are relevant to *disease* surveillance activities:

Current vaccines do not induce life-long immunity; the duration of protection after vaccination is about one year.

A significant proportion of vaccinated animals do not develop a serological response detectable by currently used techniques, although such animals may be protected against challenge. Where the serological response to vaccination is detectable by the complement fixation test, it usually persists for less than 3 months.

As their immunity wanes, vaccinated cattle are more likely to develop chronic lesions (sequestra) after *infection*.

## 6. Diagnostic methods

The diagnosis of CBPP depends on:

- clinical signs in the live animal;
- gross pathological findings;
- serological tests;
- culture and identification of the causative organism.

### a) Clinical diagnosis

The clinical signs of CBPP may be slight or non-existent. Furthermore, the use of anti-microbial or anti-inflammatory drugs can mask the clinical expression of the *disease*. For these reasons, clinical signs are an unreliable indicator of the presence of the *disease*. However, if respiratory *disease* is observed in a livestock population, then the diagnosis of CBPP should be considered and confirmed or rejected on the basis of further pathological, microbiological or serological investigations.

### b) Gross pathology

The lung lesions of CBPP are distinctive. Consequently, *abattoir* meat inspection is the most practical single method for maintaining CBPP surveillance. The pleura and lungs should be examined by palpation and section. A mixture of acute lesions and chronic lesions (sequestra) may be found in the same herd or even the same animal. In case of chronic *infection*, post-mortem diagnosis may be the only way of detecting asymptomatic animals, which may not react to serological tests.

### c) Serological diagnosis

The serological test of choice is the complement fixation test (CFT). The specificity of this test can be as high as 99.5%, but the frequency of false positive reactions may temporarily be higher

in certain herds. The sensitivity of the test is limited, and it may fail to identify four classes of animals:

- i) animals in the very early stages of the *disease*;
- ii) animals in the very late stages of the *disease* (the CFT appears to fail to detect 30% of animals containing sequestra);
- iii) animals with massive lesions, where the antibodies produced are overwhelmed by the antigen;
- iv) animals which have been treated in the early stages of the *disease* may fail to develop a detectable serological response.

Despite these limitations, the CFT is a useful herd test.

The CFT reaction after vaccination is inconstant and short-lived (generally less than 3 months).

An indirect enzyme linked immunosorbent assay (ELISA) is under field evaluation in several countries. It is at least as sensitive as the CFT, but as with other ELISA systems, increased sensitivity can only be achieved at the expense of specificity, and vice versa. It is a useful tool to measure the efficacy of vaccination programmes, as the detectable response is more reliable than the CFT, and may persist for as long as one year after vaccination.

Monoclonal and competitive ELISA systems are being developed and should offer higher specificity.

The passive haemagglutination test, while not used routinely, may have a place in serological diagnosis. It is more sensitive than the CFT in early and late stages of *disease*, but the specificity is lower. It has a potential role as a screening test.

The slide agglutination test is simple to perform and could be used as a pen-side test. It is more sensitive than the CFT in the early stages of the *disease*, but it lacks specificity.

#### d) Culture and identification of the causative organism

It is desirable that all diagnoses are confirmed by isolation of the causative organism. It may prove difficult to isolate *Mycoplasma* from chronic lesions and also after animals have been treated with anti-microbial drugs.

The causative organism is normally identified by growth inhibition tests and/or the immunofluorescence test. Closely related *Mycoplasma* may cause cross-reactions in these tests. Several new techniques which may overcome this problem are being developed, and these include immunobinding, immunoperoxidase and polymerase chain reaction (PCR) tests. These need further evaluation.

#### e) Testing imported animals

In formulating its recommendations for a system of declaration of freedom, the Group acknowledged that existing serological tests for CBPP are quite variable in sensitivity and specificity. Hence serological methods alone are unlikely to prevent the introduction of *infection* if live animals are imported from CBPP-infected countries. The chronic course of the *disease*

may mean that diagnosis following introduction of CBPP may be delayed by a number of years. In the longer term there is a need for more sensitive and specific diagnostic tests. Pending the development of such tests, serological methods are necessary, but not sufficient to prevent introduction of the *disease* in live animals.



## APPENDIX 3.8.10.

## GUIDELINES ~~FOR~~ ON THE SURVEILLANCE ~~OF~~ FOR BLUETONGUE

**Community comments:****The Community can support the proposed changes but:**

- would ask the OiE to add bulk milk sampling;
- ELISA test should be looked at by the Biological Standards Commission;
- the same comment regarding approved laboratory applies (as in the FMD chapter).

## Article 3.8.10.1.

**Introduction**

This Appendix defines the principles and provides a guide on the surveillance for bluetongue (BT) ~~in accordance with complementary to~~ Appendix 3.8.1., applicable to countries seeking to demonstrate recognition for a declared BT status, with or without the use of vaccination. This may be for the entire country or *zone*. Guidance for countries seeking free status following an *outbreak* and for the maintenance of BT status is also provided. ~~This Appendix complements Chapter 2.2.13.~~

BT is a vector-borne *infection* transmitted by different species of *Culicoides* insects in a range of ecosystems. An important component of BT epidemiology is vectorial capacity which provides a measure of *disease risk* that incorporates vector competence, abundance, biting rates, survival rates and extrinsic *incubation period*. However, methods and tools for measuring some of these vector factors remain to be developed, particularly in a field context. Therefore, surveillance for BT should focus on transmission in domestic ruminants.

Susceptible wild ruminant populations should be included in surveillance when these animals are intended for trade.

The impact and epidemiology of BT differ widely in different regions of the world and therefore it is impossible to provide specific guidelines for all situations. It is incumbent upon Members ~~Countries~~ to provide scientific data that explain the epidemiology of BT in the region concerned and adapt the surveillance strategies for defining their *infection* status (free, seasonally free or infected country or *zone*) to the local conditions. There is considerable latitude available to Members ~~Countries~~ to justify their *infection* status at an acceptable level of confidence.

Surveillance for BT should be in the form of a continuing programme.

## Article 3.8.10.2.

**Case definition**

For the purposes of surveillance, a *case* refers to an animal infected with BT virus (BTV).

For the purposes of *international trade*, a distinction must be made between a *case* as defined below and an animal that is potentially infectious to vectors. The conditions for trade are defined in Chapter 2.2.13. of the *Terrestrial Code*.

The purpose of surveillance is the detection of virus circulation in a country or *zone* and not determination of the status of an individual animal or herds. Surveillance deals not only with the occurrence of clinical signs caused by BTV, but also with the evidence of *infection* with BTV in the absence of clinical signs.

The following defines the occurrence of BTV *infection*:

1. BTV has been isolated and identified as such from an animal or a product derived from that animal, or
2. viral antigen or viral ribonucleic acid (RNA) specific to one or more of the serotypes of BTV has been identified in samples from one or more animals showing clinical signs consistent with BT, or epidemiologically linked to a confirmed or suspected *case*, or giving cause for suspicion of previous association or contact with BTV, or
3. antibodies to structural or nonstructural proteins of BTV that are not a consequence of vaccination have been identified in one or more animals that either show clinical signs consistent with BT, or epidemiologically linked to a confirmed or suspected *case*, or give cause for suspicion of previous association or contact with BTV

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

#### Article 3.8.10.3.

##### General conditions and methods

1. A surveillance system in accordance with Appendix 3.8.1. should be under the responsibility of the *Veterinary Authority*. In particular:
  - a) a formal and ongoing system for detecting and investigating *outbreaks of disease* should be in place;
  - b) a procedure should be in place for the rapid collection and transport of samples from suspect *cases* of BT to a laboratory for BT diagnosis as described in the *Terrestrial Manual*;
  - c) a system for recording, managing and analysing diagnostic and surveillance data should be in place.
2. The BT surveillance programme should:
  - a) in a country/*zone* free or seasonally free, include an early warning system for reporting suspicious *cases*. Farmers and workers, who have day-to-day contact with domestic ruminants, as well as diagnosticians, should report promptly any suspicion of BT to the *Veterinary Authority*. They should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. An effective surveillance system will periodically identify suspicious *cases* that require follow-up and investigation to confirm or exclude that the cause of the condition is BTV. The rate at which such suspicious *cases* are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. All suspected *cases* of BT should be investigated immediately and

samples should be taken and submitted to an ~~approved~~ laboratory. This requires that sampling kits and other equipment are available for those responsible for surveillance;

- b) conduct random or targeted serological and virological surveillance appropriate to the *infection* status of the country or *zone*.

Generally, the conditions to prevent exposure of susceptible animals to BTV infected vectors will be difficult to apply. However, under specific situations, establishments such as like artificial insemination centres or quarantine stations exposure to vectors may be preventable. The testing requirements for animals kept in these facilities are described in Articles 2.2.13.11. and 2.2.13.15.

### Community comments:

**The word "in" should be added before the word "establishments".**

Article 3.8.10.4.

### Surveillance strategies

The target population for surveillance aimed at identification of *disease* and/or *infection* should cover susceptible domestic ruminants within the country or *zone*. Active and passive surveillance for BTV *infection* should be ongoing. Surveillance should be composed of random or targeted approaches using virological, serological and clinical methods appropriate for the *infection* status of the country or *zone*.

The strategy employed may be based on surveillance using randomised sampling that would demonstrate the absence of BTV *infection* at an acceptable level of confidence. The frequency of sampling should be dependent on the epidemiological situation. Random surveillance is conducted using serological tests described in the *Terrestrial Manual*. Positive serological results may be followed up with virological methods as appropriate.

Targeted surveillance (e.g. based on the increased likelihood of *infection* in particular localities or species) may be an appropriate strategy. Virological and serological methods may be used concurrently to define the BTV status of targeted populations.

A country should justify the surveillance strategy chosen as being adequate to detect the presence of BTV *infection* in accordance with Appendix 3.8.1. and the prevailing epidemiological situation. It may, for example, be appropriate to target clinical surveillance at particular species likely to exhibit clinical signs (e.g. sheep). Similarly, virological and serological testing may be targeted to species that rarely show clinical signs (e.g. cattle).

In vaccinated populations, serological and virological surveillance is necessary to detect the BTV types circulating to ensure that all circulating types are included in the vaccination programme.

If a Member wishes to declare freedom from BTV *infection* in a specific *zone*, the design of the surveillance strategy would need to be aimed at the population within the *zone*.

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



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

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

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

#### 1. Clinical surveillance

Clinical surveillance aims at the detection of clinical signs of BT at the flock/herd level. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, surveillance based on clinical inspection should not be underrated, particularly during a newly introduced *infection*. In sheep and occasionally goats, clinical signs may include oedema, hyperaemia of mucosal membranes, coronitis and cyanotic tongue.

BT suspects detected by clinical surveillance should always be confirmed by laboratory testing.

#### 2. Serological surveillance

An active programme of surveillance of host populations to detect evidence of BTV transmission is essential to establish BTV status in a country or *zone*. Serological testing of ruminants is one of the most effective methods of detecting the presence of BTV. The species tested depends on the epidemiology of BTV *infection*, and the species available, in the local area. Cattle are usually the most sensitive indicator species. Management variables that may influence likelihood of *infection*, such as the use of insecticides and animal housing, should be considered.

Surveillance may include serological surveys, for example *abattoir* surveys, the use of cattle as sentinel animals (which must be individually identifiable), or a combination of methods.

#### **Community comments:**

**The Community proposes to include bulk milk sampling and testing. This is being used with good results in the Community, using an ELISA test: it has a functional procedure, high sensitivity and specificity enough to be used as a screening tool.**

**The Community thus proposes to add the words "or bulk milk samples" after the words "for example *abattoir* surveys" in the above paragraph.**

The objective of serological surveillance is to detect evidence of BTV circulation. Samples should be examined for antibodies against BTV using tests prescribed in the *Terrestrial Manual*. Positive BTV antibody tests results can have four possible causes:

- a) natural *infection* with BTV,

- b) vaccination against BTV,
- c) maternal antibodies,
- d) positive results due to the lack of specificity of the test.

It may be possible to use sera collected for other survey purposes for BTV surveillance. However, the principles of survey design described in these guidelines and the requirements for a statistically valid survey for the presence of BTV *infection* should not be compromised.

The results of random or targeted serological surveys are important in providing reliable evidence that no BTV *infection* is present in a country or *zone*. It is, therefore, essential that the survey is thoroughly documented. It is critical to interpret the results in light of the movement history of the animals being sampled.

Serological surveillance in a free *zone* should target those areas that are at highest risk of BTV transmission, based on the results of previous surveillance and other information. This will usually be towards the boundaries of the free *zone*. In view of the epidemiology of BTV *infection*, either random or targeted sampling is suitable to select herds and/or animals for testing.

A surveillance *zone* within a free country or *zone* should separate it from a potentially *infected* country or *zone*. Serological surveillance in a free country or *zone* should be carried out over an appropriate distance from the border with a potentially *infected* country or *zone*, based upon geography, climate, history of *infection* and other relevant factors.

Serological surveillance in infected *zones* will identify changes in the boundary of the *zone*, and can also be used to identify the BTV types circulating. In view of the epidemiology of BTV *infection*, either random or targeted sampling is suitable.

### 3. Virological surveillance

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

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

- a) to identify virus circulation in at risk populations,
- b) to confirm clinically suspect cases,
- c) to follow up positive serological results,
- d) to better characterize the genotype of circulating virus in a country or *zone*.

### 4. Sentinel animals

Sentinel animals are a form of targeted surveillance with a prospective study design. They are the preferred strategy for BTV surveillance. They comprise groups of unexposed animals managed at fixed locations and sampled regularly to detect new BTV *infections*.

The primary purpose of a sentinel animal programme is to detect BTV *infections* occurring at a particular place, for instance sentinel groups may be located on the usual boundaries of *infected zones* to detect changes in distribution of BTV. In addition, sentinel animal programmes allow the timing and dynamics of *infections* to be observed.

A sentinel animal programme should use animals of known source and history of exposure, control management variables such as use of insecticides and animal housing (depending on the epidemiology of BTV in the area under consideration), and be flexible in its design in terms of sampling frequency and choice of tests.

Care is necessary in choosing the sites for the sentinel groups. The aim is to maximise the chance of detecting BTV activity at the geographical location for which the sentinel site acts as a sampling point. The effect of secondary factors that may influence events at each location, such as climate, may also be analysed. To avoid confounding factors, sentinel groups should comprise animals selected to be of similar age and susceptibility to BTV *infection*. Cattle are the most appropriate sentinels but other domestic ruminant species may be used. The only feature distinguishing groups of sentinels should be their geographical location.

Sera from sentinel animal programmes should be stored methodically in a serum bank to allow retrospective studies to be conducted in the event of new serotypes being isolated.

The frequency of sampling will depend on the reason for choosing the sampling site. In endemic areas, virus isolation will allow monitoring of the serotypes and genotypes of BTV circulating during each time period. The borders between infected and non infected areas can be defined by serological detection of *infection*. Monthly sampling intervals are frequently used. Sentinels in declared free *zones* add to confidence that BTV *infections* are not occurring unobserved. In such cases, sampling prior to and after the possible period of transmission is sufficient.

Definitive information on BTVs circulating in a country or *zone* is provided by isolation and identification of the viruses. If virus isolation is required, sentinels should be sampled at sufficiently frequent intervals to ensure that samples are collected during the period of viraemia.

#### 5. Vector surveillance

BTV is transmitted between ruminant hosts by species of *Culicoides* which vary across the world. It is therefore important to be able to identify potential vector species accurately although many such species are closely related and difficult to differentiate with certainty.

The main purpose of vector surveillance is to define high, medium and low-risk areas and local details of seasonality by determining the various species present in an area, their respective seasonal occurrence, and abundance. Vector surveillance has particular relevance to potential areas of spread. Long term surveillance can also be used to assess vector suppression measures.

The most effective way of gathering this information should take account of the biology and behavioural characteristics of the local vector species of *Culicoides* and may include the use of Onderstepoort-type light traps or similar, operated from dusk to dawn in locations adjacent to domestic ruminants, or the use of drop traps over ruminant animals.

Vector surveillance should be based on scientific sampling techniques. The choice of the number and type of traps to be used in vector surveillance and the frequency of their use should take into account the size and ecological characteristics of the area to be surveyed.

The operation of vector surveillance sites at the same locations as sentinel animals is advisable.

The use of a vector surveillance system to detect the presence of circulating virus is not recommended as a routine procedure as the typically low vector *infection* rates mean that such detections can be rare. Other surveillance strategies (e.g. the use of sentinel animals of domestic ruminants) are preferred to detect virus circulation.

#### Article 3.8.10.5.

### **Documentation of BTV infection free status**

### 1. Countries declaring freedom from BTV infection for the country or zone

In addition to the general conditions described in Chapter 2.2.13. of the *Terrestrial Code*, a Member declaring freedom from BTV *infection* for the entire country or a *zone* should provide evidence for the existence of an effective surveillance programme. The strategy and design of the surveillance programme will depend on the prevailing epidemiological circumstances and should be planned and implemented according to general conditions and methods described in this Appendix, to demonstrate absence of BTV *infection* during the preceding 24 months in susceptible domestic ruminant populations. This requires the support of a laboratory able to undertake identification of BTV *infection* through virus detection and antibody tests described in the *Terrestrial Manual*. This surveillance should be targeted to non-vaccinated animals. Clinical surveillance may be effective in sheep while serological surveillance is more appropriate in cattle.

### 2. Additional requirements for countries or zones that practise vaccination

Vaccination to prevent the transmission of BTV may be part of a *disease* control programme. The level of flock or herd immunity required to prevent transmission will depend on the flock or herd size, composition (e.g. species) and density of the susceptible population. It is therefore impossible to be prescriptive. The vaccine must also comply with the provisions stipulated for BTV vaccines in the *Terrestrial Manual*. Based on the epidemiology of BTV *infection* in the country or *zone*, it may be that a decision is reached to vaccinate only certain species or other subpopulations.

In countries or *zones* that practise vaccination, there is a need to perform virological and serological tests to ensure the absence of virus circulation. These tests should be performed on non-vaccinated subpopulations or on sentinels. The tests have to be repeated at appropriate intervals according to the purpose of the surveillance programme. For example, longer intervals may be adequate to confirm endemicity, while shorter intervals may allow on-going demonstration of absence of transmission.

#### Article 3.8.10.6.

### **The use and interpretation of serological and virus detection tests**

#### 1. Serological testing

Ruminants infected with BTV produce antibodies to structural and non-structural viral proteins, as do animals vaccinated with current modified live virus vaccines. Antibodies to the BTV serogroup antigen are detected with high sensitivity and specificity by competitive ELISA (c-ELISA) and to a lesser extent by AGID as described in the *Terrestrial Manual*. Positive c-ELISA results can be confirmed by neutralization assay to identify the infecting serotype(s); however, BTV infected ruminants can produce neutralizing antibodies to serotypes of BTV other than those to which they were exposed (false positive results), especially if they have been infected with multiple serotypes.

#### 2. Virus detection

The presence of BTV in ruminant blood and tissues can be detected by virus isolation or polymerase chain reaction (PCR) as described in the *Terrestrial Manual*.

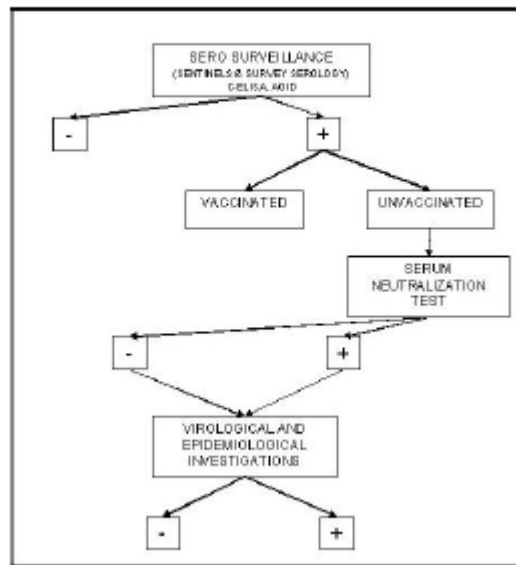
Interpretation of positive and negative results (both true and false) differs markedly between these tests because they detect different aspects of BTV *infection*, specifically (1) infectious BTV (virus isolation) and (2) nucleic acid (PCR). The following are especially relevant to interpretation of PCR assays:

- a) The nested PCR assay detects BTV nucleic acid in ruminants long after the clearance of infectious virus. Thus positive PCR results do not necessarily coincide with active *infection* of ruminants. Furthermore, the nested PCR assay is especially prone to template contamination, thus there is considerable risk of false positive results.

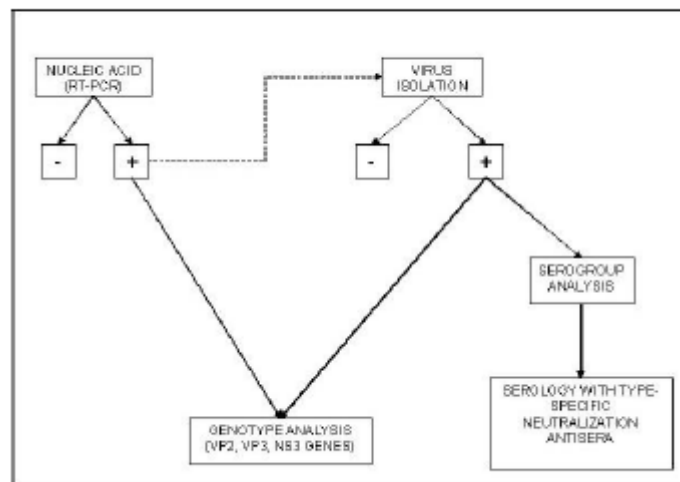
- b) PCR procedures other than real time PCR allow sequence analysis of viral amplicons from ruminant tissues, insect vectors or virus isolates. These sequence data are useful for creating data bases to facilitate important epidemiological studies, including the possible distinction of field and vaccine virus strains of BTV, genotype characterization of field strains of BTV, and potential genetic divergence of BTV relevant to vaccine and diagnostic testing strategies.

It is essential that BTV isolates are sent regularly to the OIE Reference Laboratories for genetic and antigenic characterization.

*Fig. 1. Application of laboratory tests in serological surveillance*



*Fig. 2. Application of laboratory tests in virological surveillance*



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CHAPTER 2.3.3.  
**BOVINE TUBERCULOSIS**

**Community comments:**

**The Community cannot support the proposed changes, unless the comments below are taken into account.**

**General comment: The Community suggests to maintain the text proposed by the Scientific Commission (which was unanimously adopted in May 2007) and to send the present proposed text to the ad hoc group for their deliberations.**

**Guidelines are needed for TB in species other than cattle. The EFSA is preparing an opinion on TB in farmed deer and as soon as this is available it will be sent to the OiE. The Community would be please to take part in the OiE working group.**

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 domestic (permanently captive and owned free-range) bovines including cattle (*Bos taurus*, *B. indicus* and *B. grunniens*), water buffaloes (*Bubalus bubalis*) and wood bisons (*Bison bison* and *B. bonasus*) and in farmed deer (red, wapiti, sika, samba, rusa, fallow, white-tailed, black-tailed and mule deer (*Cervus elephus*, *C. canadensis*, *C. nippon*, *C. unicolor unicolor*, *C. timorensis*, *Dama dama dama*, *Odocoileus virginianus borealis*, *Odocoileus hemionus columbianus* and *Odocoileus hemionus hemionus*).

**Community comments:**

**The Community acknowledges the work done on this chapter. However, the Community's opinion is that farmed deer should not be included in the scope of this chapter because:**

- **it was not raised by the ad hoc group nor the Scientific Commission, and has not been discussed yet at this level;**
- **farmed deer has not yet been defined;**
- **it is not consistent to include owned free range bovines and to exclude owned free deer;**
- **including deer in this chapter obliges to qualify deer herds and other deer populations;**
- **the inclusion of deer would affect the free status of countries that would need to substantiate the absence of disease in that population, without any relation to the risk associated with bovine population;**
- **it is not consistent to include deer but not goats that are highly susceptible to the disease and are of more important concern from the public health point of view.**
- **the tests in species other than bovine need to be validated.**

**Therefore the references to deer should be removed from the text, and a new Chapter concerning tuberculosis in species other than bovine should be drafted, through the relevant ad hoc group.**

When authorising import or transit of the following *commodities*, *Veterinary Authorities* 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*.
5. antler velvet.

**Community comments:**

**It was unanimously agreed that such listing of commodities for which a veterinary certificate is necessary are useless in the Code redundant and possibly confusing: the articles are sufficient themselves.**

**This paragraph should thus be deleted.**

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

Article 2.3.3.2.

Country, zone or compartment free from bovine tuberculosis

**Community comments:**

**The article 2.3.3.2 is not applicable to a compartment. The compartment is then at least a gathering of herds, and thus its status should be linked to that of the herds. A free compartment should be, among other, made out of 100% free herds. The whole concept of free compartment, if needed (the free herd should be sufficient for this disease) should necessitate a new article.**

**General comment: it is not because the concept of compartmentalisation is now accepted, that the same conditions for freedom or trade should apply systematically to compartments as to countries or zones.**

To qualify as free from bovine tuberculosis, a country, *zone* or *compartment* should satisfy the following requirements:

1. *M. bovis* infection in domestic (permanently captive and owned free-range) bovines including cattle (*Bos taurus*, *B. indicus* and *B. grunniens*), water buffalo (*Bubalus bubalis*) and wood bison (*Bison bison* and *B. bonasus*) and in farmed deer as specified in Article 2.3.3.1 is a *notifiable disease* in the country;

**Community comments:**

**The article 2.3.3.1 is sufficient for the definition of the disease.**

**The point 1 should only read: "Bovine tuberculosis as defined in article 2.3.3.1 is a notifiable disease in the country".**

2. an on-going awareness programme should be in place to encourage reporting of all cases suggestive of clinical tuberculosis;
3. surveillance programme, involving regular and periodic testing of all cattle, water buffalo, ~~and~~ wood bison ~~and farmed deer~~ herds ~~and capable of detecting infection at an annual period prevalence of 0.2% of herds and 0.1% of animals with 95% confidence~~ has failed to detect infection ~~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 *M. bovis* has not exceeded 0.1% per year for 3 consecutive years;~~

#### **Community comments:**

**A number of factors influence the required sensitivity of surveillance activities to demonstrate freedom from TB:**

- **the nature of the disease: TB is a very slow chronic disease that may be present at low or even very low herd and intra-herd prevalence;**
- **the sensitivity of the diagnostic test: for the skin test the sensitivity is known to be relatively low.**

**The relations between these factors are complex; therefore, even if the proposed sampling method can be used to substantiate freedom from other diseases, it is not adequate for TB: the probability to find the disease at a very low rate is too low and a country could be declared free with no real image of the situation. With the proposed figures, a country with 20 million cattle should have only to test 3000 animals, which will indubitably fail to find the disease at a low prevalence.**

**The Community thus considers that the epidemiological unit to be used is the herd, and that the status of a country or zone should be proven by using the herd status (which is why this status is defined in the following articles). 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 thus proposes to retain the present wording and transfer the question to the ad hoc group.**

4. a surveillance programme should be in place to detect bovine tuberculosis in the country, ~~zone or compartment~~, through ~~monitoring at slaughter~~ ante-mortem and post-mortem inspection ~~based on the inspection as~~ described in Article Appendix 2.3.3.8: 3.10.1;
5. if the surveillance programme described in points 3 and 4 above has failed to detect *M. bovis* for 3 consecutive years, surveillance may be maintained through monitoring at slaughter alone;

#### **Community comments:**

**In consistency with its comments above, as well as to be consistent with point 4, the Community proposes the following wording:**



**"5. if the regular and periodic testing of all cattle herds has shown that the country or zone meets the requirements to be qualified as free from bovine tuberculosis, surveillance may be maintained at least through ante-mortem and post-mortem inspection as described in Appendix 3.10.1".**

56. cattle, water buffalo ~~and~~, wood bison and farmed deer introduced into a country, *zone* or *compartment* free from bovine tuberculosis should be accompanied by a certificate from an *official Veterinarian* attesting that they come from a country, *zone* or *compartment* or herd free from bovine tuberculosis or comply with the relevant provisions in Article 2.3.3.4. or in Article 2.3.3.5.

#### Article 2.3.3.3.

#### Herd free from bovine tuberculosis

To qualify as free from bovine tuberculosis, a herd of cattle, water buffalo, ~~or~~ wood bisons or farmed deer should satisfy the following requirements:

1. the herd is in a country, *zone* or *compartment* free from bovine tuberculosis and is certified free by the *Veterinary Authority*; or
2. cattle, water buffalo ~~and~~, wood bison and farmed deer in the herd:
  - a) showed 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 a minimum 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; or
    - i) showed a negative result to a tuberculin test every 2 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 or zone during the last 2 years; or
    - ii) showed a negative result to a tuberculin test every 3 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 or zone during the last 4 years; or
    - iii) showed a negative result to a tuberculin test every 4 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 or zone during the last 6 years;
3. cattle, water buffalo, ~~and~~ wood bison and farmed deer introduced into the herd come from 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.

#### Article 2.3.3.4.

*Veterinary Authorities* of *importing countries* should require:

for cattle, water buffalo ~~and~~, wood bison and farmed deer 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 free from bovine tuberculosis; or
4. have been isolated and prior to entry into the herd were subjected to at least two tuberculin tests carried out at a six-month interval with negative results.

Article 2.3.3.5.

*Veterinary Authorities of importing countries* should require:

for cattle, water buffalo and, wood bison and farmed deer for slaughter

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. originated from a herd free from bovine tuberculosis or were subjected to a tuberculin test for bovine tuberculosis with negative results during the 30 days prior to shipment;
3. were not being eliminated as part of an eradication programme against bovine tuberculosis.

Article 2.3.3.6.

*Veterinary Authorities of importing countries* should require:

for semen of cattle, water buffalo and, wood bison and farmed deer

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 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 annually and were kept in a herd free from bovine tuberculosis;
2. the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.1.

Article 2.3.3.7.

*Veterinary Authorities of importing countries* should require:

for embryos/ova of cattle, water buffalo and, wood bison and farmed deer

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 embryo collection;

- 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 free from bovine tuberculosis, and were subjected to a tuberculin test for bovine tuberculosis with negative results during an isolation period of 30 days in the *establishment* of origin prior to departure to the collection centre;
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., as relevant.

**Article 2.3.3.8.**

*Veterinary Authorities of importing countries* should require:

for *fresh meat* and *meat products* of cattle, water buffalo ~~and~~, wood bison and farmed deer

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 as described in Appendix 3.10.1.

**Article 2.3.3.9.**

*Veterinary Authorities of importing countries* should require:

for *milk* and *milk products* of cattle, water buffalo and wood bison

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 pasteurization; or
3. was subjected to a combination of control measures with equivalent performance as described in the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products.

**Article 2.3.3.10.**

*Veterinary Authorities of importing countries* should require:

for *antler velvet* of farmed deer

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
1. has been cooked at 60° C for 3 hours, or an equivalent temperature/time treatment.

**Community comments:**

**This article should be deleted and addressed in another chapter (see comment in article 2.3.3.1.).**

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- text deleted

## CHAPTER 2.3.13.

**BOVINE SPONGIFORM ENCEPHALOPATHY**

## Article 2.3.13.1.

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

1. When authorising import or transit of the following *commodities* and any products made from these *commodities* and containing no other tissues from cattle, *Veterinary Authorities* should not require any BSE related conditions, regardless of the BSE risk status of the cattle population of the *exporting country, zone or compartment*:
  - a) *milk* and *milk products*;
  - b) semen and *in vivo* derived cattle embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society;
  - c) hides and skins;
  - d) gelatine and collagen prepared exclusively from hides and skins;
  - e) protein-free tallow (maximum level of insoluble impurities of 0.15% in weight) and derivatives made from this tallow;

**Comments of the Community:**

**The Community would like to remind the Code Commission of its previous opinion on this point and to restate its position.**

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

- f) dicalcium phosphate (with no trace of protein or fat);
- g) deboned skeletal muscle meat (excluding mechanically separated meat) from cattle 30 months of age or less, which were not subjected to a stunning process prior to *slaughter*, with a device injecting compressed air or gas into the cranial cavity or to a pithing process, and which passed ante-mortem and post-mortem inspections and which has been prepared in a manner to avoid contamination with tissues listed in Article 2.3.13.14.;

- h) blood and blood by-products, from cattle which were not subjected to a stunning process, prior to *slaughter*, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process.
2. When authorising import or transit of other *commodities* listed in this Chapter, *Veterinary Authorities* should require the conditions prescribed in this Chapter relevant to the BSE risk status of the cattle population of the *exporting country, zone or compartment*.

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

#### Article 2.3.13.2.

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

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

a) Release assessment

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

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

**Comment of the Community:**

**The assessment of the birth cohorts of the BSE cases if any should be taken into account: this will allow assessing the correct implementation of the feed ban provisions.**

- ii) production of *meat-and-bone meal* or *greaves* from the indigenous ruminant population;
- iii) imported *meat-and-bone meal* or *greaves*;
- iv) imported cattle, sheep and goats;
- v) imported animal feed and feed ingredients;
- vi) imported products of ruminant origin for human consumption, which may have contained tissues listed in Article 2.3.13.14. and may have been fed to cattle;
- vii) imported products of ruminant origin intended for *in vivo* use in cattle.

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

b) Exposure assessment

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

- i) recycling and amplification of the BSE agent through consumption by cattle of *meat-and-bone meal* or *greaves* of ruminant origin, or other feed or feed ingredients contaminated with these;
  - ii) the use of ruminant carcasses (including from fallen stock), by-products and *slaughterhouse* waste, the parameters of the rendering processes and the methods of animal feed manufacture;
  - iii) the feeding or not of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants, including measures to prevent cross-contamination of animal feed;
  - iv) the level of surveillance for BSE conducted on the cattle population up to that time and the results of that surveillance;
2. on-going awareness programme for veterinarians, farmers, and workers involved in transportation, marketing and *slaughter* of cattle to encourage reporting of all *cases* showing clinical signs consistent with BSE in target sub-populations as defined in Appendix 3.8.4.;
  3. the compulsory notification and investigation of all cattle showing clinical signs consistent with BSE;
  4. the examination carried out in accordance with the *Terrestrial Manual* in an ~~approved~~ laboratory of brain or other tissues collected within the framework of the aforementioned surveillance and monitoring system.

#### **Comment of the Community:**

**The Community can not approve the deletion of the word "approved": even if the definition of laboratory implies official approval, it should be clearly brought to the attention of the Member countries. Therefore it is much more preferable to retain the former wording.**

When the *risk assessment* demonstrates negligible risk, the country should conduct Type B surveillance in accordance with Appendix 3.8.4.

When the *risk assessment* fails to demonstrate negligible risk, the country should conduct Type A surveillance in accordance with Appendix 3.8.4.

#### Article 2.3.13.3.

#### **Negligible BSE risk**

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

1. a *risk assessment*, as described in point 1 of Article 2.3.13.2., has been conducted in order to identify the historical and existing risk factors, and the country has demonstrated that appropriate specific measures have been taken for the relevant period of time defined below to manage each identified risk;
2. the country has demonstrated that Type B surveillance in accordance with Appendix 3.8.4. is in place and the relevant points target, in accordance with Table 1, has been met;
3. EITHER:
  - a) there has been no *case* of BSE or, if there has been a *case*, every *case* of BSE has been demonstrated to have been imported and has been completely destroyed, and

- i) the criteria in points 2 to 4 of Article 2.3.13.2. have been complied with for at least 7 years; and
- ii) it has been demonstrated through an appropriate level of control and audit that for at least 8 years neither *meat-and-bone meal* nor *greaves* derived from ruminants has been fed to ruminants;

**Comment of the Community:**

**The Community would like to remind the Code Commission of its previous opinion on this point and to restate its position:**

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

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

**This comment also applies to Article 2.3.13.3., point 3a) ii), Article 2.3.13.4, point 3a)(ii) and 3b), Article 2.3.13.7, point 2), Article 2.3.13.8, point 3, Article 2.3.13.9, point 1) en 3b) and Article 10, point 3).**

OR

- b) if there has been an indigenous *case*, every indigenous *case* was born more than 11 years ago; and
  - i) the criteria in points 2 to 4 of Article 2.3.13.2. have been complied with for at least 7 years; and
  - ii) it has been demonstrated through an appropriate level of control and audit that for at least 8 years neither *meat-and-bone meal* nor *greaves* derived from ruminants has been fed to ruminants; and
  - iii) all BSE *cases*, as well as:
    - 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.

The country or *zone* will be included in the list of negligible risk only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information above be re-submitted annually and changes in the epidemiological situation or other significant events should be reported promptly to the OIE.

**Comment of the Community:**

**The submission of the whole dossier seems disproportionate without any added value. In addition, the option of declared status of a compartment should be included. The Community proposes only to communicate updates.**

**The Community proposes to modify as follows:**

**“ The country, zone or compartment will only be included in the negligible risk list after OIE has accepted the submitted evidence. Retention on the list requires that the country, zone or compartment submits updated evidence annually and promptly reports any decline in the epidemiological situation or significant events.”**

**This comment also applies to the proposed modification at the end of Article 2.3.13.4.”**

Article 2.3.13.4.

**Controlled BSE risk**

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

1. a *risk assessment*, as described in point 1 of Article 2.3.13.2., has been conducted in order to identify the historical and existing risk factors and the country has demonstrated that appropriate measures are being taken to manage all identified risks, but these measures have not been taken for the relevant period of time;
2. the country has demonstrated that Type A surveillance in accordance with Appendix 3.8.4. has been carried out and the relevant points target, in accordance with Table 1, has been met; Type B surveillance may replace Type A surveillance once the relevant points target is met;
3. EITHER:
  - a) there has been no *case* of BSE or, if there has been a *case*, every *case* of BSE has been demonstrated to have been imported and has been completely destroyed, the criteria in points 2 to 4 of Article 2.3.13.2. are complied with and it can be demonstrated through an appropriate level of control and audit that neither *meat-and-bone meal* nor *greaves* derived from ruminants has been fed to ruminants, but at least one of the following two conditions applies:
    - i) the criteria in points 2 to 4 of Article 2.3.13.2. have not been complied with for 7 years;
    - ii) it cannot be demonstrated that controls over the feeding of *meat-and-bone meal* or *greaves* derived from ruminants to ruminants have been in place for 8 years;

OR

- b) there has been an indigenous *case* of BSE, the criteria in points 2 to 4 of Article 2.3.13.2. are complied with, and it can be demonstrated through an appropriate level of control and audit that neither *meat-and-bone meal* nor *greaves* derived from ruminants has been fed to ruminants, ~~but at least one of the following two conditions applies:~~

**Comment of the Community:**

**The Community proposes a slight rewording as follows:**

**“ b) there has been an indigenous case of BSE, the criteria in points 2 to 4 of Article 2.3.13.2. are being complied with, and it can be demonstrated through an appropriate level of control and audit that neither meat-and-bone meal nor greaves derived from mammals is being fed to ruminants.”**

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



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

AND

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

- 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.

### Comment of the Community:

**The Community welcome that the previous comments was taken on board and can support the proposed modification.**

The country or *zone* will be included in the list of controlled risk only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information above be re-submitted annually and changes in the epidemiological situation or other significant events should be reported promptly to the OIE.

Article 2.3.13.5.

### Undetermined BSE risk

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

Article 2.3.13.6.

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

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

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

Article 2.3.13.7.

When importing from a country, *zone* or *compartment* posing a negligible BSE risk, but where there has been an indigenous *case*, *Veterinary Authorities* should require:

for cattle selected for export

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

1. are identified by a permanent identification system in such a way as to demonstrate that they are not exposed cattle as described in point 3.b)iii) of Article 2.3.13.3.;
2. 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.

**Comment of the Community:**

**The possibility of cases born just after the implementation of the feed ban should also be considered and should not always, based on the situation and an assessment, constitute a reason to question the negligible risk status.**

**The Community proposes the following:**

**“2. were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from mammals had been effectively enforced or after the date of birth of the last indigenous case if that indigenous case was born after the date of the feed ban .”**

**This comment also applies to Article 2.3.13.8, point 3..**

## Article 2.3.13.8.

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

for cattle

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

1. the country, *zone* or *compartment* complies with the conditions referred to in Article 2.3.13.4.;
2. cattle selected for export are identified by a permanent identification system in such a way as to demonstrate that they are not exposed cattle as described in point 3.b)iii) of Article 2.3.13.4.;
3. cattle selected for export were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants was effectively enforced.

## Article 2.3.13.9.

When importing from a country, *zone* or *compartment* with an undetermined BSE risk, *Veterinary Authorities* 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 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
  - b) 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 in such a way as to demonstrate that they are not exposed cattle as demonstrated in point 2 above;
- b) were born at least 2 years after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants was effectively enforced.

#### Article 2.3.13.10.

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

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

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

1. the country, *zone* or *compartment* complies with the conditions in Article 2.3.13.3.;
2. the cattle from which the *fresh meat* and *meat products* were derived passed ante-mortem and post-mortem inspections;
3. in countries with negligible BSE risk where there have been indigenous *cases*, the cattle from which the *fresh meat* and *meat products* were derived 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.

#### Article 2.3.13.11.

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

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

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

1. the country, *zone* or *compartment* complies with the conditions referred to in Article 2.3.13.4.;
2. the cattle from which the *fresh meat* and *meat products* were derived passed ante-mortem and post-mortem inspections;
3. cattle from which the *fresh meat* and *meat products* destined for export were derived were not subjected to a stunning process, prior to *slaughter*, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process;
4. the *fresh meat* and *meat products* were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:
  - a) the tissues listed in points 1 and 2 of Article 2.3.13.14.;
  - b) mechanically separated meat from the skull and vertebral column from cattle over 30 months of age.

### **Comment of the European Community:**

**The Community would like to remind the Code Commission of its previous opinion on this point and to restate its 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 2.3.13.11 point 4 b) with:**

**‘4) b) mechanically separated meat from all bones from cattle of all ages,’**

**This comment also applies to Article 2.3.13.12, point 2c).**

#### Article 2.3.13.12.

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

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

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

1. the cattle from which the *fresh meat* and *meat products* originate:
  - a) have not been fed *meat-and-bone meal* or *greaves* derived from ruminants;
  - b) passed ante-mortem and post-mortem inspections;
  - c) were not subjected to a stunning process, prior to *slaughter*, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process;
2. the *fresh meat* and *meat products* were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:
  - a) the tissues listed in points 1 and 3 of Article 2.3.13.14.;
  - b) nervous and lymphatic tissues exposed during the deboning process;
  - c) mechanically separated meat from the skull and vertebral column from cattle over 12 months of age.

#### Article 2.3.13.13.

1. Ruminant-derived *meat-and-bone meal* or *greaves*, or any *commodities* containing such products, which originate from a country, *zone* or *compartment* defined in Article 2.3.13.3., but where there has been an indigenous *case* of BSE, should not be traded if such products were derived from cattle born before the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants had been effectively enforced.
2. Ruminant-derived *meat-and-bone meal* or *greaves*, or any *commodities* containing such products, which originate from a country, *zone* or *compartment* defined in Articles 2.3.13.4. and 2.3.13.5. should not be traded between countries.

#### Article 2.3.13.14.

1. From cattle of any age originating from a country, *zone* or *compartment* defined in Articles 2.3.13.4. and 2.3.13.5., the following *commodities*, and any *commodity* contaminated by them, should not be

traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: tonsils and distal ileum. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these *commodities* (unless covered by other Articles in this Chapter) should also not be traded.

### Comments of the Community

**In its opinion of 29 June 2001 on adipose tissue associated with the digestive tract of cattle, sheep and goats, the Scientific Steering Committee pointed out that potential infectivity could be found in the mesenteric nerves and the mesenteric lymph nodes situated near the arteria mesenterica in bovine animals.**

**Furthermore, the Community would welcome any updated scientific basis to define only the distal ileum as specified risk material instead of the whole intestine.**

- From cattle that were at the time of *slaughter* over 30 months of age originating from a country, *zone* or *compartment* defined in Article 2.3.13.4., the following *commodities*, and any *commodity* contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, skull and vertebral column. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these *commodities* (unless covered by other Articles in this Chapter) should also not be traded.

### Comment of the Community:

**On 19 April 2007 the EFSA adopted an opinion which took into account the latest results of the pathogenesis studies as well as the epidemiological data available from the monitoring programme in the European Union since 2001.**

**Based on this opinion, the Community amended the age for the removal of the vertebral column as SRM from 24 to 30 months. No modifications were proposed for the age limit for the removal of brains, eyes, spinal cord and skull as SRM. We would urge for an age limit of 12 months for both controlled and undetermined risk as regards the brains, eyes, spinal cord and skull.**

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

#### Article 2.3.13.15.

*Veterinary Authorities* of *importing countries* should require:

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

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

- the *commodities* came from a country, *zone* or *compartment* posing a negligible BSE risk;

OR

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

- a) skulls from cattle over ~~30~~ 12 months of age at the time of *slaughter* have been excluded ;
- b) the bones have been subjected to a process which includes all of the following steps:
  - i) degreasing,
  - ii) acid demineralisation,
  - iii) acid or alkaline treatment,
  - iv) filtration,
  - v) sterilisation at  $\geq 138^{\circ}\text{C}$  for a minimum of 4 seconds,
 or to an equivalent or better process in terms of infectivity reduction (such as high pressure heating);

OR

- ~~3. they originate from a country, zone or compartment posing an undetermined BSE risk and are derived from cattle which have passed ante mortem and post mortem inspections; and that~~
  - ~~a) skulls and vertebrae (except tail vertebrae) from cattle over 12 months of age at the time of slaughter have been excluded;~~
  - ~~b) the bones have been subjected to a process which includes all of the following steps:
 
    - ~~i) degreasing,~~
    - ~~ii) acid demineralisation,~~
    - ~~iii) acid or alkaline treatment,~~
    - ~~iv) filtration,~~
    - ~~v) sterilisation at  $\geq 138^{\circ}\text{C}$  for a minimum of 4 seconds,~~
 or to an equivalent or better process in terms of infectivity reduction (such as high pressure heating);~~

**Comment of the Community:**

**The Community supports the reduction of the age limit for the removal of the skull as SRM from bovine animals originating from controlled BSE risk countries for the production of gelatine from 30 to 12 months.**

**On the other hand, the use of vertebral column from bovine animals of all ages from a country where the initial risk has not been quantified (i.e. undetermined risk country) and therefore cannot be assessed, to be used for the production of gelatine for food, poses a problem of principle for which the Community thinks more discussions should take place. The Community thus proposes that the words "(under study)" be added after the word "undetermined".**

Article 2.3.13.16.

*Veterinary Authorities of importing countries* should require:

for tallow and dicalcium phosphate (other than as defined in Article 2.3.13.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

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

1. the ~~commodities~~ tallow came from a country, *zone* or *compartment* posing a negligible BSE risk; or
2. ~~they~~ it originate from a country, *zone* or *compartment* posing a controlled BSE risk, ~~are~~ is derived from cattle which ~~have~~ has passed ante-mortem and post-mortem inspections, and have not been prepared using the tissues listed in points 1 and 2 of Article 2.3.13.14.

#### **Comment of the Community:**

**The Community would like to remind the Code Commission of its previous opinion on this point and to restate its position.**

**Based on the outcome of the Quantitative risk assessment and the subsequent update of the European Food Safety Authority (EFSA) of the scientific opinions on tallow, tallow can be considered safe if no SRM is used for the production of tallow and if the animals of which the raw material has been derived have passed ante- and post mortem inspection.**

**The Community propose to impose the same rules for tallow coming from undetermined risk countries. The Community proposes to include a new point 3.**

**"3. it originate from a country, zone or compartment posing an undetermined BSE risk, is derived from cattle which has passed ante-mortem and post-mortem inspections, and have not been prepared using the tissues listed in points 1 and 3 of Article 2.3.13.14."**

#### Article 2.3.13.16. bis

Veterinary Authorities of importing countries should require:

for dicalcium phosphate (other than as defined in Article 2.3.13.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

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

1. the dicalcium phosphate came from a country, *zone* or *compartment* posing a negligible BSE risk; or
2. it originates from a country, *zone* or *compartment* posing a controlled or undetermined BSE risk and is a by-product of bone gelatine produced according to Article 2.3.13.15.

#### **Comment of the Community:**

**On 16 March 2006 the EFSA adopted an opinion on the "Quantitative assessment of the residual BSE risk posed by di-calcium phosphate (DCP) and tri-calcium phosphate (TCP) from bovine bones used as an animal feed additive or as fertiliser".**

**The opinion defines that when the scenario is considered including the vertebral column from bovine animals originating from countries with a adequate surveillance system, this scenario would result in an adult dairy cow population of 20 million to on average 38 infected cattle per year.**

**Based on the scientific evidence, the Community oppose to the proposed amendment.**

**The Community proposes the following amendment replacing point 2:**

**"2. it originate from a country, zone or compartment posing a controlled BSE risk, is derived from cattle which has passed ante-mortem and post-mortem inspections, and have not been prepared using the tissues listed in points 1 and 2 of Article 2.3.13.14.**

**3. it originate from a country, zone or compartment posing an undetermined BSE risk, is derived from cattle which has passed ante-mortem and post-mortem inspections, and have not been prepared using the tissues listed in points 1 and 3 of Article 2.3.13.14"**

Article 2.3.13.17.

*Veterinary Authorities of importing countries* should require:

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

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

1. the *commodities* originate from a country, *zone* or *compartment* posing a negligible BSE risk; or
2. they are derived from tallow meeting the conditions referred to in Article 2.3.13.16.; or
3. they have been produced by hydrolysis, saponification or transesterification using high temperature and pressure.

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## APPENDIX 3.8.4.

**GUIDELINES ON SURVEILLANCE FOR BOVINE SPONGIFORM ENCEPHALOPATHY**

## Article 3.8.4.1.

**Introduction**

1. Depending on the risk category of a country, *zone* or *compartment* with regard to bovine spongiform encephalopathy (BSE), surveillance for BSE may have one or more goals:
  - a) detecting BSE, to a pre-determined design prevalence, in a country, *zone* or *compartment*;
  - b) monitoring the evolution of BSE in a country, *zone* or *compartment*;
  - c) monitoring the effectiveness of a feed ban and/or other risk mitigation measures, in conjunction with auditing;
  - d) supporting a claimed BSE status;
  - e) gaining or regaining a higher BSE status.
2. When the BSE agent is present in a country or *zone*, the cattle population will comprise the following sectors, in order of decreasing size:
  - a) cattle not exposed to the infective agent;
  - b) cattle exposed but not infected;
  - c) infected cattle, which may lie within one of three stages in the progress of BSE:
    - i) the majority will die or be killed before reaching a stage at which BSE is detectable by current methods;
    - ii) some will progress to a stage at which BSE is detectable by testing before clinical signs appear;
    - iii) the smallest number will show clinical signs.
3. The BSE status of a country, *zone* or *compartment* cannot be determined only on the basis of a surveillance programme but should be determined in accordance with all the factors listed in Article 2.3.13.2. The surveillance programme should take into account the diagnostic limitations associated with the above sectors and the relative distributions of infected cattle among them.
4. With respect to the distribution and expression of the BSE agent within the sectors described above, the following four subpopulations of cattle have been identified for surveillance purposes:
  - a) cattle over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects);
  - b) cattle over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; cattle over 30 months of age sent for emergency *slaughter* or condemned at ante-mortem

inspection (casualty or emergency *slaughter* or downer cattle);

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

#### **Comment of the Community:**

**The Community would propose the following amendment to point b) and c) which better defines the subpopulations:**

**"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 for human consumption or showing abnormal clinical signs at ante-mortem inspection (casualty or emergency slaughter or downer cattle);**

**c) cattle over 30 months of age which are found dead on farm or during transport , or killed other than for human consumption (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, *%ome* or *compartment*. This approach is consistent with Appendix 3.8.1. on general guidelines for animal health surveillance.
6. When establishing a surveillance strategy, authorities need to take into account the inherent difficulties of obtaining samples on farm, and overcome them. These difficulties include higher cost, the necessity to educate and motivate owners, and counteracting potentially negative socio-economic implications.

#### Article 3.8.4.2.

#### **Description of cattle subpopulations**

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

Cattle affected by illnesses that are refractory to treatment, and displaying progressive behavioural changes such as excitability, persistent kicking when milked, changes in herd hierarchical status, hesitation at doors, gates and barriers, as well as those displaying progressive neurological signs without signs of infectious illness are candidates for examination. These behavioural changes, being very subtle, are best identified by those who handle animals on a daily basis. Since BSE causes no pathognomonic clinical signs, all countries with cattle populations will observe individual animals displaying clinical signs consistent with BSE. It should be recognised that cases may display only some of these signs, which may also vary in severity, and such animals should still be investigated as potential BSE affected animals. The rate at which such suspicious cases are likely to occur will differ among epidemiological situations and cannot therefore be predicted reliably.

This subpopulation is the one exhibiting the highest prevalence. The accurate recognition, reporting and classification of such animals will depend on the ongoing owner/veterinarian awareness programme. This and the quality of the investigation and laboratory examination systems (Article 2.3.13.2.), implemented by the *Veterinary Services*, are essential for the credibility of the surveillance system.

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

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

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

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

4. Cattle over 36 months of age at routine slaughter

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

#### Article 3.8.4.3.

#### **Implementation of surveillance**

In order to implement efficiently a surveillance strategy for BSE, a country must use documented records or reliable estimates of the age distribution of the adult cattle population and the number of cattle tested for BSE stratified by age and by subpopulation within the country, *zone* or *compartment*.

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

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

- a) the design prevalence for Type A or Type B surveillance;
- 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 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.

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

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

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

#### 1. Type A surveillance

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

#### 2. Type B surveillance

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

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

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

### Article 3.8.4.4.

#### 1. Selecting the points target

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

Table 1. Points targets for different adult cattle population sizes in a country, zone or compartment

| Points targets for country, zone or compartment       |                     |                     |
|---|---------------------|---------------------|
| Adult cattle population size<br>(24 months and older) | Type A surveillance | Type B surveillance |
| >1,000,000  | 300,000             | 150,000             |
| 800,000-1,000,000                                     | 240,000             | 120,000             |
| 600,000-800,000                                       | 180,000             | 90,000              |
| 400,000-600,000                                       | 120,000             | 60,000              |
| 200,000-400,000                                       | 60,000              | 30,000              |
| 100,000-200,000                                       | 30,000              | 15,000              |
| 50,000-100,000  | 15,000              | 7,500               |

**Comment of the Community:**

**Points targets should also be specified for Member countries with a small adult cattle population.**

**The Community propose to include an additional line for countries with a adult cattle population between 25,000 -50,000 (Type A: 7,500 points and type B surveillance: 3,750 points).**

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.

**Comment of the Community:**

**Where the guidance in Article 3.8.4.3., last sentence, is in line with the position to test all four subpopulations, above it says that at least three of the four sub-populations should be tested.**

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

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 <sup>1</sup>           | Fallen stock <sup>2</sup> | Casualty slaughter <sup>3</sup> | Clinical suspect <sup>4</sup> |
| Age ≥1 year and ≤2years                  |                           |                                 |                               |
| 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                           |
| 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                            |

**Comment of the Community:**

The situation for animals with an exact age of 2, 4, 7 or 9 should be clarified.

The Community propose the following amendment:

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

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

- 
1. See point 4) of Article 3.8.4.2.
  2. See point 3) of Article 3.8.4.2.
  3. See point 2) of Article 3.8.4.2.
  4. See point 1) of Article 3.8.4.2.

## CHAPTER 2.5.5.

### EQUINE INFLUENZA

#### **Community comments:**

**The answer given by the Code Commission to the Community question regarding the scientific justification or vaccine manufacturers indication for the change from 14 to 21 days in article 6 point 3, is not satisfactory: if it has been changed without justification nor rationale in any of the TAHSC Reports, it is not to the OIE Members to bring new elements to put it back to the former value (which was the value indicated so far by the vaccine manufacturers). Any modification of the Code should be justified.**

**The Community thus can support the changes but reiterates its request for data justifying the change from 14 to 21 days in this article, and adds two comments below.**

#### Article 2.5.5.1.

For the purposes of the *Terrestrial Code*, equine influenza (EI) is defined as an *infection* of domestic horses, donkeys and mules.

For the purposes of *international trade*, this Chapter deals not only with the occurrence of clinical signs caused by equine influenza virus (EIV), but also with the presence of *infection* with EIV in the absence of clinical signs.

For the purposes of this chapter, isolation is defined as ‘the separation of horses from horses of a different equine influenza health status, utilising appropriate biosecurity measures, with the purpose of preventing the transmission of *infection*’.

For the purposes of the *Terrestrial Code*, the *infective period* for equine influenza is 21 days.

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

#### Article 2.5.5.2.

The EI status of a country, a *zone* or a *compartment* can be determined on the basis of the following criteria:

1. the outcome of a *risk assessment* identifying all potential factors for EI occurrence and their historic perspective;
2. whether EI is notifiable in the whole country, an on-going EI awareness programme is in place, and all notified suspect occurrences of EI are subjected to field and, where applicable, laboratory investigations;
3. appropriate surveillance is in place to demonstrate the presence of *infection* in the absence of clinical signs in horses.

#### Article 2.5.5.3.

#### **Equine influenza free country, zone or compartment**



A country or *zone* or *compartment* may be considered free from EI provided the *disease* is notifiable in the whole country and it shows evidence of an effective surveillance programme, planned and implemented according to the general principles in Appendix 3.8.1. The surveillance may need to be adapted to parts of the country, *zone* or *compartment* depending on historical or geographical factors, industry structure, population data, movements of equids into the country, *zone* or *compartment*, wild equid populations or proximity to recent *outbreaks*.

A country, *zone* or *compartment* seeking freedom from EI, in which vaccination is practised, should also demonstrate that EIV has not been circulating in the domestic horse population during the past 12 months, through surveillance, in accordance with Appendix 3.8.1, ~~at a level sufficient to provide at least a 95% level of confidence of detecting infection if it is present at a prevalence rate exceeding 1%.~~ In a country in which vaccination is not practised, surveillance could be conducted using serological testing. In countries where vaccination is practised, the surveillance should include methods of virus detection.

If an *outbreak* of clinical equine influenza occurs in a previously free country, *zone* or *compartment*, free status can be regained 12 months after the last clinical case, providing that surveillance for evidence of *infection* has been carried out during that 12-month period ~~at a level in accordance with Appendix 3.8.1. sufficient to provide at least a 95% level of confidence of detecting infection if it is present at a prevalence rate exceeding 1%.~~

Article 2.5.5.4.  
(under study)

Regardless of the EI status of the *exporting country*, *zone* or *compartment*, the *Veterinary Authority* of a country, *zone* or *compartment* should authorise without restriction on account of EI the importation into their *territory* of the following *commodities*:

1. semen;
2. *in vivo* derived equine embryos collected, processed and stored in conformity with the provisions of Appendix 3.3.1.

Article 2.5.5.5

When importing horses for immediate *slaughter*, the *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the horses showed no clinical sign of EI on the day of shipment.

**Community comments:**

**It must be clear that the animals are not going elsewhere in the country before the slaughterhouse. Thus the Community proposes that the word “direct” is included before “immediate”.**

Article 2.5.5.6.

When importing horses for unrestricted movement, *Veterinary Authorities* should require:

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

1. came from an EI free country, *zone* or *compartment* in which they had been resident for at least 21 days; in the case of a vaccinated horse, information on its vaccination status should be included in the veterinary certificate;

OR

2. came from a country, *zone* or *compartment* not known to be free from EI, were subjected to pre-export isolation for 21 days and showed no clinical sign of EI during isolation nor on the day of shipment; and
3. were vaccinated according to the manufacturer's instructions between 21 and 90 days before shipment either with a primary course or a booster.

**Community comments:**

**For competing or breeding animals traveling internationally, virtual elimination of virus excretion for a workable period of time is desirable. This can only be achieved with high potency vaccines containing up to date strains. The Community thus proposes to add the words "with a high potency vaccine according to the OIE Manual of Standards, containing the relevant strains," after the words "were vaccinated according to the manufacturer's instructions".**

**Furthermore, the Community proposes that an additional point is added as follows:**

**"OR**

**4) were subjected to an antigen test with negative result".**

Article 2.5.5.7.

When importing horses which will be kept in isolation (see Article 2.5.5.1.), *Veterinary Authorities* should require:

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

1. came from an EI free country, *zone* or *compartment* in which they had been resident for at least 21 days; in the case of a vaccinated horse, information on its vaccination status should be included in the veterinary certificate;

OR

2. showed no clinical sign of EI in any premises in which the horses had been resident for the 21 days prior to shipment nor on the day of shipment; and
3. were vaccinated according to the manufacturer's instructions.

Article 2.5.5.8.

When importing *fresh meat* of horses, mules or donkeys, *Veterinary Authorities* should require:

the presentation of an *international veterinary certificate* attesting that the *fresh meat* came from horses, mules or donkeys which had been subjected to ante-mortem and post-mortem inspections as described in Appendix 3.10.1.

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 — text deleted



## CHAPTER 2.5.7.

**EQUINE RHINOPNEUMONITIS**  
(~~Equine herpes virus type 1 infection~~)**Community comments:****The Community can approve the proposed change.**

## Article 2.5.7.1.

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

## Article 2.5.7.2.

*Veterinary Authorities of importing countries* should require:

for equines

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

1. showed no clinical sign of equine herpes virus type 1 infection, on the day of shipment and during the 21 days prior to shipment;
2. were kept for the 21 days prior to shipment in an *establishment* where no *case* of equine herpes virus type 1 infection was reported during that period.

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— text deleted



## CHAPTER 2.5.10.

**EQUINE VIRAL ARTERITIS****Community comments:**

**The Community could approve the proposed changes, and did not oppose to the adoption of this chapter in May 2007, but reiterates its former comments (February 2007) that the only risk regarding this disease is the "semen positive" stallion and this should be taken into account throughout the chapter, which should not address other animals than uncastrated males. The risk represented by acutely infected animals shedding airborne virus is minimal to negligible: it can be addressed with the clinical signs only. The Community thus proposes the changes below to the OiE.**

## Article 2.5.10.1.

The *infective period* for equine viral arteritis (EVA) shall be 28 days for all categories of equine except sexually mature stallion where the *infective period* may be for the life of the animal. Because the *infective period* may be extended in the case of virus shedding in semen, the status of seropositive stallions should be checked to ensure that they do not shed virus in their semen.

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

## Article 2.5.10.2.

*Veterinary Authorities of importing countries* should require:

for uncastrated male equines imported on a temporary basis for breeding or on a permanent basis

**Community comments:**

**The words "imported on a temporary basis for breeding or on a permanent basis" should be deleted.**

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

1. showed no clinical sign of EVA on the day of shipment and during the 28 days prior to shipment;
2. were isolated and subjected, to a test for EVA, as prescribed in the *Terrestrial Manual*, carried out either:
  - a) on a single blood sample collected during the 28 days prior to shipment with negative result, or
  - b) on blood samples taken on two occasions at least 14 days apart within 28 days prior to shipment, which demonstrated stable or declining antibody titres; or

**Community comments:**

**The point b) above should be deleted. It does not give enough security and the point 5 below deals with seropositive animals.**

3. were isolated and subjected between 6 and 9 months of age to a test for EVA, as prescribed in the *Terrestrial Manual*, carried out on two blood samples collected at least 14 days apart with stable or decreasing titre, immediately vaccinated for EVA and regularly revaccinated according to the manufacturer's instructions; or
4. were isolated and subjected to a test for EVA, as prescribed in the *Terrestrial Manual*, on a blood sample with negative results, immediately vaccinated for EVA, kept for 21 days following vaccination separated from other equidae and regularly revaccinated according to the manufacturer's instructions; or
5. have been subjected to a test for EVA, as prescribed in the *Terrestrial Manual*, carried out on a blood sample with positive results and then: either
  - a) were subsequently test mated to two mares within 12 months prior to shipment which were subjected to two tests for EVA as prescribed in the *Terrestrial Manual* with negative results on blood samples collected at the time of test mating and again 28 days after the mating; or
  - b) were subjected to a test for equine arteritis virus as prescribed in the *Terrestrial Manual* with negative results, carried out on semen collected during the 28 days prior to shipment.

Article 2.5.10.3.

*Veterinary Authorities of importing countries* should require:

for uncastrated male equines imported on a temporary basis other than for breeding, and for equines other than uncastrated males

**Community comments:**

**The words "for uncastrated male equines imported on a temporary basis other than for breeding, and " should be deleted.**

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

1. showed no clinical sign of EVA on the day of shipment and were kept in an *establishment* where no animals have shown any signs of EVA for the 28 days prior to shipment;

**Community comments:**

**The point 2) and 3) below should be deleted. The only risk with other than uncastrated males would be acutely infected animals shedding airborne virus, and**

**1. they would also show signs of the disease**

**2. the infective period is 28 days maximum.**

2. were isolated and subjected to a test for EVA, as prescribed in the *Terrestrial Manual*, carried out either:
  - a) on a single blood sample collected during the 28 days prior to shipment with negative results, or
  - b) on blood samples collected on two occasions at least 14 days apart within 28 days prior to shipment, which demonstrated stable or declining antibody titres;

OR

3. were isolated and subjected, between 6 and 9 months of age, to a diagnostic test for EVA, as prescribed in the *Terrestrial Manual*, carried out on two blood samples collected at least 14 days apart, with negative results or stable or declining titre, and immediately vaccinated for EVA and regularly revaccinated.

Article 2.5.10.4.

*Veterinary Authorities of importing countries* should require:

for semen

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

1. were kept for the 28 days prior to semen collection in an *establishment* where no equine has shown any clinical sign of EVA during that period;
2. showed no clinical sign of EVA on the day of semen collection;
3. were subjected between 6 and 9 months of age to a test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with stable or decreasing titre, immediately vaccinated for EVA and regularly revaccinated according to the manufacturer's instructions; or
4. were subjected to a test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with negative results, immediately vaccinated for EVA, kept for 21 days following vaccination separated from other equidae and regularly revaccinated according to the manufacturer's instructions; or
5. were subjected to a test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with negative results within 14 days prior to semen collection, and had been separated from other equidae from the time of the taking of the blood sample to the time of semen collection; or

**Community comments:**

**This point 5 is not sufficient: the stallion should be isolated for 10-14 days prior to blood sampling and between the date of blood sampling until semen collection is completed, otherwise it would be possible to miss a recent incubating infection when basing decisions on a single pre-collection blood sample.**

**Thus the Community proposes to add the words "for 14 days prior to blood sampling and" after the words "from other equidae", and to replace the words "to the time of" by the words "until the end of".**

6. have been subjected to a test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with positive results and then: either
  - a) were subsequently test mated to two mares within 12 months prior to semen collection, which were subjected to two tests for EVA as prescribed in the *Terrestrial Manual* with negative results on blood samples collected at the time of test mating and again 28 days after the test mating, or
  - b) were subjected to a test for equine arteritis virus as prescribed in the *Terrestrial Manual* with negative results, carried out on semen collected within one year prior to collection of the semen to be exported.





## CHAPTER 2.5.14.

**AFRICAN HORSE SICKNESS****Community comments:**

**The Community supports the proposed changes, but cannot accept the chapter unless the only but essential comment below is taken into account.**

**General comment: The definition of the disease is in the Guidelines on surveillance. If this is confirmed to be the right procedure, it should be the same for other diseases for which such Guidelines have been elaborated.**

## Article 2.5.14.1.

For the purposes of the *Terrestrial Code*, the *infective period* for African horse sickness virus (AHSV) shall be 40 days for domestic horses. Although critical information is lacking for some species, this Chapter applies to all equidae.

All countries or *zones* neighbouring, or considered to be at risk from, a country or *zone* not having free status should determine their AHSV status from an ongoing surveillance programme. Throughout the Chapter surveillance is in all cases understood as being conducted as described in Appendix 3.8.X.

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

## Article 2.5.14.2.

**AHSV free country or zone**

1. A country or *zone* may be considered free from AHSV when African horse sickness (AHS) is notifiable in the whole country, systematic vaccination is prohibited, importation of equidae, their semen, and oocytes or embryos, ~~and pathological material and biological products from these species~~ are carried out in accordance with this chapter, and either:
  - a) historical freedom as described in Appendix 3.8.1. has demonstrated no evidence of AHSV in the country or *zone*; or
  - b) the country or *zone* has not reported any case of AHS for at least 2 years and is not adjacent to a country or *zone* not having a free status; or
  - c) a surveillance programme has demonstrated no evidence of AHSV in the country or *zone* for at least 12 months; or
  - d) the country or *zone* has not reported any case of AHS and a surveillance programme has demonstrated no evidence of *Culicoides* likely to be competent AHSV vectors in the country or *zone*.

**Community comments:**

**The Community reiterates its former comment about a minimum period of time that should be included in point d): 40 days at least for the cases and 2 years at least for the**

**vectors. This is even more important as the climate change may very rapidly affect the geographical distribution and the competency of potential AHS vectors throughout the world.**

2. An AHSV free country or *zone* will not lose its free status through the importation of vaccinated or seropositive equidae, their semen, oocytes or embryos from infected countries or *infected zones*, provided these imports are carried out in accordance with this chapter.

Article 2.5.14.3.

**AHSV seasonally free zone**

1. An AHSV seasonally free *zone* is a part of an infected country or an *infected zone* for which for part of a year, ongoing surveillance and monitoring demonstrate no evidence of AHSV transmission and of the presence of adult *Culicoides* likely to be competent AHSV vectors.
2. For the application of Articles 2.5.14.6., 2.5.14.8. and 2.5.14.9., the seasonally free period is:
  - a) taken to commence the day following the last evidence of AHSV transmission and of the cessation of activity of adult *Culicoides* likely to be competent AHSV vectors as demonstrated by an ongoing surveillance programme, and
  - b) taken to conclude either:
    - i) at least 28 days before the earliest date that historical data show AHSV activity has recommenced; or
    - ii) immediately when current climatic data or data from a surveillance and monitoring programme indicate an earlier resurgence of activity of adult *Culicoides* likely to be competent AHSV vectors.
3. An AHSV seasonally free *zone* will not lose its free status through the importation of vaccinated or seropositive equidae, their semen, oocytes or embryos from infected countries or *infected zones*, provided these imports are carried out in accordance with this chapter.

Article 2.5.14.4.

**AHSV infected country or zone**

An AHSV infected country or *infected zone* is ~~a clearly defined area where~~ one in which the conditions of Article 2.5.14.2. or Article 2.5.14.3. do not apply.

Article 2.5.14.5.

When importing from AHSV free countries that are neither neighbouring nor considered to be at risk from an AHSV infected country or *infected zone*, ~~Veterinary Administrations~~ Authorities should require:

for equidae

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

1. showed no clinical sign of AHS on the day of shipment;
2. have not been vaccinated against AHS within the last 40 days;
3. were kept in an AHSV free country since birth or for at least 40 days prior to shipment;

4. either:
- a) did not transit through an infected country or *infected zone*; or
  - b) were protected from attack by *Culicoides* ~~likely to be competent AHSV vectors~~ at all times when transiting through an infected country or *infected zone*.

Article 2.5.14.6.

When importing from AHSV free countries or free *zones* or from AHSV seasonally free *zones* (during the seasonally free period) that are neighbouring or are considered to be at risk from an AHSV infected country or *infected zone*, ~~Veterinary Administrations~~ Authorities should require:

for equidae

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

1. showed no clinical signs of AHS on the day of shipment;
2. have not been vaccinated against AHS within the last 40 days;
3. were kept in an AHSV free country, free *zone* or seasonally free *zone* during the seasonally free period since birth or for at least 40 days prior to shipment; or
4. in a country or *zone* considered to be at risk, were held in quarantine for at least 40 days prior to shipment and protected at all times from attack by *Culicoides* ~~likely to be competent AHSV vectors~~; and
  - a) a serological test according to the *Terrestrial Manual* to detect antibodies to the AHSV group, was carried out with a negative result on a blood sample collected at least 28 days after introduction into the *quarantine station*; or
  - b) serological tests according to the *Terrestrial Manual* to detect ~~serotype specific~~ antibodies against ~~to the AHSV serotypes known to occur within the region~~ were carried out with no significant increase in antibody titre on blood samples collected on two occasions, with an interval of not less than 21 days, the first sample being collected at least 7 days after introduction into the *quarantine station*; or
  - c) agent identification tests according to the *Terrestrial Manual* were carried out with negative results on blood samples collected on two occasions with an interval of not less than 14 days between collection, the first sample being collected at least 7 days after introduction into the *quarantine station*;
5. were protected from attack by *Culicoides* ~~likely to be competent AHSV vectors~~ at all times during transportation (including to and at the *place of shipment*).

Article 2.5.14.7.

When importing from an AHSV infected country or an AHSV *infected zone*, ~~Veterinary Administrations~~ Authorities should require:

for equidae

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

1. showed no clinical sign of AHS on the day of shipment;
2. have not been vaccinated against AHS within the last 40 days;
3. were held continuously during the quarantine period of at least 40 days, in a vector-proof *quarantine station* and protected at all times from attack by *Culicoides* ~~likely to be competent AHSV vectors~~; and
  - a) a serological test according to the *Terrestrial Manual* to detect antibodies to the AHSV group, was carried out with a negative result on a blood sample collected at least 28 days after introduction into the *quarantine station*; or
  - b) serological tests according to the *Terrestrial Manual* to detect ~~serotype-specific~~ antibodies against ~~to the AHSV serotypes known to occur within the region~~ were carried out with no significant increase in antibody titre on blood samples collected on two occasions, with an interval of not less than 21 days, the first sample being collected at least 7 days after introduction into the *quarantine station*; or
  - c) agent identification tests according to the *Terrestrial Manual* were carried out with negative results on blood samples collected on two occasions with an interval of not less than 14 days between collection, the first sample being collected at least 7 days after introduction into the *quarantine station*;
4. were protected from attack by *Culicoides* ~~likely to be competent AHSV vectors~~ at all times during transportation (including during transportation to and at the place of shipment).

Article 2.5.14.8.

*Veterinary Administrations Authorities* of importing countries should require:

for equid semen

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

1. showed no clinical sign of AHS on the day of collection of the semen and for the following 40 days;
2. had not been vaccinated against AHS within 40 days prior to the day of collection;
3. were either:
  - a) kept in an AHSV free country or free ~~zone~~ or from an AHSV seasonally free zone (during the seasonally free period) for at least 40 days before commencement of, and during collection of the semen, or
  - b) kept in an AHSV free vector-proof *artificial insemination centre* throughout the collection period, and subjected to either:
    - i) a serological test according to the *Terrestrial Manual* to detect antibody to the AHSV group, carried out with a negative result on a blood sample collected at least 28 days and not more than 90 days after the last collection of semen; or
    - ii) agent identification tests according to the *Terrestrial Manual* carried out with negative results on blood samples collected at commencement and conclusion of, and at least every 7 days, during semen collection for this consignment.

Article 2.5.14.9.

*Veterinary Administrations Authorities* of importing countries should require:

for *in vivo* derived equid embryos/oocytes

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

1. the donor animals:
  - a) showed no clinical sign of AHS on the day of collection of the ~~semen~~ embryos/oocytes and for the following 40 days;
  - b) had not been vaccinated against AHS within 40 days prior to the day of collection;
  - c) were either:
    - i) kept in an AHSV free country or free *zone* or from an AHSV seasonally free zone (during the seasonally free period) for at least 40 days before commencement of, and during collection of the embryos/oocytes, or
    - ii) kept in an AHSV free vector-proof *collection centre* throughout the collection period, and subjected to either:
      - a serological test according to the *Terrestrial Manual* to detect antibody to the AHSV group carried out with a negative result on a blood sample collected at least 28 days and not more than 90 days after the last collection of ~~semen~~ embryos/oocytes; or
      - agent identification tests according to the *Terrestrial Manual* carried out with negative results on blood samples collected at commencement and conclusion of, and at least every 7 days during ~~semen~~ embryos/oocytes collection for this consignment;
2. the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.1;
3. semen used to fertilize the oocytes, complies at least with the requirements in Article 2.5.14.8.

Article 2.5.14.10.

**Protecting animals from *Culicoides* attack**

When transporting equines through AHSV infected countries or AHSV *infected zones*, *Veterinary Administrations Authorities* should require strategies to protect animals from attack by *Culicoides* ~~likely to be competent AHSV vectors~~ during transport, taking into account the local ecology of the vector.

Potential risk management strategies include a combination of:

1. treating animals with chemical repellents prior to and during transportation, in ~~insecticide treated and sanitized vehicles~~ treated with appropriate residual contact insecticide;
2. *loading*, transporting and *unloading* animals at times of low vector activity (i.e. bright sunshine and low temperature);
3. ensuring *vehicles* do not stop en route during dawn or dusk, or overnight, unless the animals are held behind insect proof netting;
4. darkening the interior of the *vehicle*, for example by covering the roof and/or sides of *vehicles* with shade cloth;
5. monitoring for vectors at common stopping and offloading points to gain information on seasonal variations;
6. using historical, ongoing and/or AHS modelling information to identify low risk ports and transport routes.

— text deleted

## APPENDIX 3.8.X.

## GUIDELINES ON SURVEILLANCE FOR AFRICAN HORSE SICKNESS

**Community comments:**

**The Community can approve the proposed changes however would like the comment below taken into account.**

## Article 3.8.X.1.

**Introduction**

This Appendix defines the principles and provides a guide on the surveillance for African horse sickness (AHS), complementary to Appendix 3.8.1., applicable to countries seeking to demonstrate recognition for a declared African horse sickness virus (AHSV) status. This may be for the entire country or zone. ~~Guidelines~~ Guidance for countries seeking free status following an outbreak and for the maintenance of AHS status is also provided.

AHS is a vector-borne *infection* transmitted by a limited number of species of *Culicoides* insects. Unlike the related bluetongue virus, AHSV is so far geographically restricted to sub Saharan Africa with periodic excursions into North Africa, southwest Europe, the Middle East and adjacent regions of Asia. An important component of AHSV epidemiology is vectorial capacity which provides a measure of *disease risk* that incorporates vector competence, abundance, seasonal incidence, biting rates, survival rates and the extrinsic incubation period. However, methods and tools for measuring some of these vector factors remain to be developed, particularly in a field context.

~~In addition to the general conditions described in~~ According to Chapter 2.5.14. of the *Terrestrial Code*, a Member ~~declaring~~ demonstrating freedom from AHSV *infection* for the entire country, or a *zone* 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. This requires the support of a laboratory able to undertake identification of AHSV *infection* through the virus detection and antibody tests described in the *Terrestrial Manual*.

Susceptible wild equid populations should be included in the surveillance programme ~~when these animals are intended for trade~~.

**Case definition**

For the purposes of surveillance, a *case* refers to an equid infected with AHSV.

The purpose of surveillance is to determine if a country or *zone* is free from AHSV or if a *zone* is seasonally free from AHSV. Surveillance deals not only with the occurrence of clinical signs caused by AHSV, but also with evidence of *infection* with AHSV in the absence of clinical signs.

The following defines the occurrence of AHSV *infection*:



1. AHSV has been isolated and identified as such from an equid or a product derived from that equid, or
2. viral antigen or viral RNA specific to one or more of the serotypes of AHSV has been identified in samples from one or more equids showing clinical signs consistent with AHS, or epidemiologically linked to a confirmed or suspected *case*, or giving cause for suspicion of previous association or contact with AHSV, or
3. serological evidence of active *infection* with AHSV by detection of seroconversion with production of antibodies to structural or nonstructural proteins of AHSV that are not a consequence of vaccination have been identified in one or more equids that either show clinical signs consistent with AHS, or epidemiologically linked to a confirmed or suspected *case*, or give cause for suspicion of previous association or contact with AHSV.

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

#### Article 3.8.X.2.

#### General conditions and methods

1. A surveillance system should be under the responsibility of the *Veterinary Administration Authority*. In particular the following should be in place:
  - a) a formal and ongoing system for detecting and investigating *outbreaks of disease*;
  - b) a procedure for the rapid collection and transport of samples from suspect cases of AHS to a laboratory for AHS diagnosis as described in the *Terrestrial Manual*;
  - c) a system for recording, managing and analysing diagnostic, epidemiologic and surveillance data.
2. The AHS surveillance programme should:
  - a) in a country/*zone*, free or seasonally free, include an early warning system for reporting suspicious cases. Persons who have regular contact with equids, as well as diagnosticians, should report promptly any suspicion of AHS to the *Veterinary Authority*. 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 AHS. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. All suspected cases of AHS should be investigated immediately and samples should be taken and submitted to an ~~approved~~ *laboratory*. This requires that sampling kits and other equipment are available for those responsible for surveillance;
  - b) conduct random or targeted serological and virological surveillance appropriate to the *infection* status of the country or *zone* in accordance with Appendix 3.8.1.

#### Article 3.8.X.3.

#### Surveillance strategies

The target population for surveillance aimed at identification of *disease* and/or *infection* should cover susceptible ~~domestic~~ equids within the country or *zone*. Active and passive surveillance for AHSV *infection* should be ongoing. Surveillance should be composed of random or targeted approaches using virological, serological and clinical methods appropriate for the *infection* status of the country or *zone*.

A country should justify the surveillance strategy chosen as appropriate to detect the presence of AHSV *infection* in accordance with Appendix 3.8.1. and the prevailing epidemiological situation. It may, for example, be appropriate to target clinical surveillance at particular species likely to exhibit clinical signs (e.g. horses). Similarly, virological and serological testing may be targeted to species that rarely show

clinical signs (e.g. donkeys).

In vaccinated populations serological and virological surveillance is necessary to detect the AHSV types circulating to ensure that all circulating types are included in the vaccination programme.

If a Member wishes to declare freedom from AHSV *infection* in a specific *zone*, the design of the surveillance strategy would need to be aimed at the population within the *zone*.

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

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

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

The principles for surveillance for *disease/infection* are technically well defined. Surveillance programmes to prove the absence of AHSV *infection/circulation*, need to be carefully designed to avoid producing results that are either insufficiently reliable to be accepted by 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 AHS in equids particularly during a newly introduced *infection*. In horses, clinical signs may include pyrexia, oedema, hyperaemia of mucosal membranes and dyspnoea.

AHS suspects detected by clinical surveillance should always be confirmed by laboratory testing.

#### 2. Serological surveillance

Serological surveillance of equid populations is useful to confirm absence of AHSV transmission in a country or *zone*. The species tested should reflect the local epidemiology of AHSV *infection*, and the equine species available. Management variables that may reduce the likelihood of *infection*, such as the use of insecticides and animal housing, should be taken into account when selecting equids to be included in the surveillance system.

#### **Community comments:**

**The Community reiterates its comment on the word "useful", which should be replaced by "an important tool".**

Samples should be examined for antibodies against AHSV using tests prescribed in the *Terrestrial Manual*. Positive AHSV antibody tests results can have four possible causes:

- a) natural *infection* with AHSV;
- b) vaccination against AHSV;
- c) maternal antibodies;
- d) positive results due to the lack of specificity of the test.

It may be possible to use sera collected for other purposes for AHSV surveillance. However, the principles of survey design described in these guidelines and the requirements for a statistically valid survey for the presence of AHSV *infection* should not be compromised.

The results of random or targeted serological surveys are important in providing reliable evidence that no AHSV *infection* is present in a country or *zone*. It is, therefore, essential that the survey is thoroughly documented. It is critical to interpret the results in light of the movement history of the animals being sampled.

Serological surveillance in a *free zone* should target those areas that are at highest risk of AHSV transmission, based on the results of previous surveillance and other information. This will usually be towards the boundaries of the *free zone*. In view of the epidemiology of AHSV, either random or targeted sampling is suitable to select herds and/or animals for testing.

Serological surveillance in a free country or *zone* should be carried out over an appropriate distance from the border with an infected country or *infected zone*, based upon geography, climate, history of *infection* and other relevant factors. The surveillance should be carried out over a distance of at least 100 kilometres from the border with that country or *zone*, but a lesser distance could be acceptable if there are relevant ecological or geographical features likely to interrupt the transmission of AHSV. An AHSV free country or *zone* may be protected from an adjacent infected country or *infected zone* by a *buffer zone*.

Serological surveillance in *infected zones* will identify changes in the boundary of the *zone*, and can also be used to identify the AHSV types circulating. In view of the epidemiology of AHSV *infection*, either random or targeted sampling is suitable.

### 3. Virological surveillance

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

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

- a) to identify virus circulation in at risk populations;
- b) to confirm clinically suspect cases;
- c) to follow up positive serological results;
- d) to better characterize the genotype of circulating virus in a country or *zone*.

### 4. Sentinel animals

Sentinel animals are a form of targeted surveillance with a prospective study design. They comprise groups of unexposed equids managed at fixed locations and sampled regularly to detect new AHSV *infections*.

The primary purpose of a sentinel equid programme is to detect AHSV *infections* occurring at a

particular place, for instance sentinel groups may be located on the boundaries of *infected zones* to detect changes in distribution of AHSV. In addition, sentinel equid programmes allow the timing and dynamics of *infections* to be observed.

A sentinel equid programme should use animals of known source and history of exposure, control management variables such as use of insecticides and animal housing (depending on the epidemiology of AHSV in the area under consideration), and be flexible in its design in terms of sampling frequency and choice of tests.

Care is necessary in choosing the sites for the sentinel groups. The aim is to maximise the chance of detecting AHSV activity at the geographical location for which the sentinel site acts as a sampling point. The effect of secondary factors that may influence events at each location, such as climate, may also be analysed. To avoid confounding factors sentinel groups should comprise animals selected to be of similar age and susceptibility to AHSV *infection*. The only feature distinguishing groups of sentinels should be their geographical location. Sera from sentinel animal programmes should be stored methodically in a serum bank to allow retrospective studies to be conducted in the event of new serotypes being isolated.

The frequency of sampling should reflect the equid species used and the reason for choosing the sampling site. In endemic areas virus isolation will allow monitoring of the serotypes and genotypes of AHSV circulating during each time period. The borders between infected and non infected areas can be defined by serological detection of *infection*. Monthly sampling intervals are frequently used. Sentinels in declared free zones add to confidence that AHSV *infections* are not occurring unobserved. Here sampling prior to and after the possible period of transmission is sufficient.

Definitive information on AHSV circulating in a country or *zone* is provided by isolation and identification of the viruses. If virus isolation is required sentinels should be sampled at sufficiently frequent intervals to ensure that some samples are collected during the period of viraemia.

#### 5. Vector surveillance

AHSV is transmitted between equine hosts by species of *Culicoides* which vary across the world. It is therefore important to be able to identify potential vector species accurately although many such species are closely related and difficult to differentiate with certainty.

The main purpose of vector surveillance is to define high, medium and low-risk areas and local details of seasonality by determining the various species present in an area, their respective seasonal occurrence, and abundance. Vector surveillance has particular relevance to potential areas of spread. Long term surveillance can also be used to assess vector abatement measures.

The most effective way of gathering this information should take account of the biology and behavioural characteristics of the local vector species of *Culicoides* and may include the use of Onderstepoort-type light traps or similar, operated from dusk to dawn in locations adjacent to equids.

Vector surveillance should be based on scientific sampling techniques. The choice of the number and types of traps to be used in vector surveillance and the frequency of their use should take into account the size and ecological characteristics of the area to be surveyed.

The operation of vector surveillance sites at the same locations as sentinel animals is advisable.

The use of a vector surveillance system to detect the presence of circulating virus is not recommended as a routine procedure as the typically low vector *infection* rates mean that such detections can be rare. Other surveillance strategies are preferred to detect virus circulation.

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## CHAPTER 2.6.6.

### AFRICAN SWINE FEVER

#### Community comments:

**The Community can approve the proposed changes, but requests the TAHSC to take into account its comment in article 7.**

**Furthermore, it should be defined what is meant by "adjacent country".**

**Guidelines should be developed for the surveillance of African Swine Fever, and of its vectors.**

#### Article 2.6.6.1.

The pig is the only natural host for African swine fever (ASF) virus. The definition of pig includes all varieties of *Sus scrofa*, both domestic and wild, warthogs (*Phacochoerus spp.*), bushpigs (*Potamochoerus spp.*) and giant forest hog (*Hydrochoerus meinertzhageni*). For the purposes of this chapter, a distinction is made between domestic pigs (permanently captive and farmed free-range pigs) and wild pigs (including feral pigs and wild boar) as well as between *Sus scrofa* and African pig species.

All varieties of *Sus scrofa* are susceptible to the pathogenic effects of ASF virus, while the African wild pigs are not and act as reservoirs of the *infection*. Ticks of the genus *Ornithodoros* are natural hosts of the virus and act as biological vectors of the *infection*.

For the purpose of the *Code* the *incubation period* in *Sus scrofa* is 15 days.

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

#### Article 2.6.6.2.

The ASF status of a country, *zone* or *compartment* can only be determined after considering the following criteria in domestic and wild pigs, as applicable:

1. ASF should be notifiable in the whole country, and all clinical signs suggestive of ASF should be subjected to appropriate field and/or laboratory investigations;
2. an on-going awareness programme should be in place to encourage reporting of all *cases* suggestive of ASF;
3. the *Veterinary Administration Authority* should have current knowledge of, and authority over, all domestic pigs in the country, *zone* or *compartment*;
4. the *Veterinary Administration Authority* should have current knowledge about the population and habitat of wild pigs in the country or *zone*.

#### Article 2.6.6.3.

#### ASF free country, zone or compartment

1. ASF free status

## a) Historically free status

A country or *zone* may be considered free from the *disease* without formally applying a specific surveillance programme, if the provisions of Article 3.8.1.6. are complied with.

## b) Free status as a result of an eradication programme

A *country* or *zone* which does not meet the conditions of point a) above or a *compartment* may be considered free from ASF when:

- i) there has been no outbreak of ASF during the past 3 years. This period can be reduced to 12 months, when there is no evidence of tick involvement in the epidemiology of the *infection*;
- ii) no evidence of ASFV infection has been found during the past 12 months;
- iii) surveillance ~~in accordance with appendix 3.8.8.~~ has been in place in domestic pigs for the past 12 months;
- iii) ~~no evidence of ASFV infection has been found during the past 12 months~~

AND

in the case of a country or *zone*, surveillance ~~in accordance with Appendix 3.8.8.~~ has been in place to determine the ASF status of the wild pig population and:

- iv) there has been no clinical evidence, nor virological evidence of ASF in wild pigs during the past 12 months;
- v) no seropositive wild pigs have been detected in the age class 6-12 months during the past 12 months;
- vi) imported wild pigs comply with the relevant requirements in Article 2.6.6.97

Article 2.6.6.4.

### Recovery of free status

Should an ASF *outbreak* occur in a free country, *zone* or *compartment*, the free status ~~of the country, *zone* or *compartment*~~ may be restored, where surveillance ~~in accordance with Appendix 3.8.8.~~ has been carried out with negative results, either:

1. 3 months after the last *case* where a *stamping-out policy* is practised and there is no evidence of tick involvement in the epidemiology of the *infection*;

OR

2. In the case where ticks are suspected to be involved in the epidemiology of the *infection*, 3 months after the last *case* where a *stamping-out policy*, followed by acaricide treatment and the use of sentinel pigs, is practised;

OR

3. where a *stamping-out policy* is not practised the provisions of point b) of Article 2.6.6.3 should be followed;

AND

4. in the case of a country or *zones*, based on surveillance ~~in accordance with Appendix 3.8.8.~~, ASF *infection* is not known to occur in any wild pig population in the country or *zone*.

Article 2.6.6.5.

When importing from countries, *zones* or *compartments* free of ASF, ~~Veterinary Administrations~~ Authorities should require:

for domestic pigs

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

1. showed no clinical sign of ASF on the day of shipment;
2. were kept in a country, *zone* or *compartment* free of ASF since birth or for at least the past 40 days.

Article 2.6.6.6.

When importing from ASF infected countries or ~~*zones* with ASF infection in domestic pigs,~~ ~~Veterinary Administrations~~ Authorities should require:

for domestic pigs

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

1. ~~were kept since birth or for the past 40 days in a ASF free *compartment*~~ showed no clinical sign of ASF on the day of shipment;
2. ~~showed no clinical sign of ASF on the day of shipment~~ were kept since birth or for the past 40 days in a ASF free *compartment*;

Article 2.6.6.7.

When importing from countries or *zones* free of ASF, ~~Veterinary Administrations~~ Authorities should require:

for wild pigs

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

1. showed no clinical sign of ASF on the day of shipment;
2. have been captured in a country or *zone* free from ASF.

**Community comments:**

**The risk represented by wild pigs, reservoir for this disease vector-transmitted, is important and if the animals come from a zone "adjacent" to an infected zone, there should be an additional condition (see article 2.6.6.13 for the meat of wild pigs).**

**A point 3 should be added:**

3. **if the *zone* where the animals have been captured is adjacent to a *zone* with infection in wild pigs, 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 2.6.6.8.

When importing from countries, *zones* or *compartments* free of ASF, *Veterinary Administrations Authorities* should require:

for semen of domestic pigs

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

1. the donor animals:
  - a) were kept in a country, *zone* or *compartment* free of ASF since birth or for at least 40 days prior to collection in accordance with 2.6.6.6;
  - b) showed no clinical sign of ASF on the day of collection of the semen;
2. the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.2.

## Article 2.6.6.9.

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

for semen of domestic pigs

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

1. the donor animals:
  - a) were kept in a *compartment* free of ASF ~~and~~ since birth or for at least 40 days prior to collection;
  - b) showed no clinical sign of ASF on the day of collection of the semen and for the following 40 days;
2. the semen was collected ~~in accordance with 2.6.6.8,~~ processed and stored in conformity with the provisions of Appendix 3.2.2.

## Article 2.6.6.10.

When importing from countries, *zones* or *compartments* free of ASF, *Veterinary Administrations Authorities* should require:

for *in vivo* derived embryos of pigs

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

1. the donor females:
  - a) were kept in a country, *zone* or *compartment* free of ASF in domestic pigs since birth or for at least 40 days ~~in accordance with 2.6.6.6.~~ on the days of collection of the embryos;
  - b) showed no clinical sign of ASF 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 2.6.6.11.

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

for in vivo derived embryos of pigs

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

1. the donor females:
  - a) were kept in a *compartment* free of ASF ~~and~~ since birth or for at least 40 days prior to collection;
  - b) showed no clinical sign of ASF on the day of collection of the embryos and for the following 40 days;
2. the embryos were collected ~~in accordance with 2.6.6.10,~~ processed and stored in conformity with the provisions of Appendix 3.3.1.

#### Article 2.6.6.12.

When importing from countries, *zones* or *compartments* free of ASF, Veterinary Administrations Authorities 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, *zone* or *compartment* free of ASF since birth or for at least the past 40 days, or which have been imported in accordance with Article 2.6.6.5 or Article 2.6.6.6;
2. have been slaughtered in an approved *abattoir*, have been subjected to ante-mortem and post-mortem inspections in accordance with Appendix 3.10.1. and have been found free of any sign suggestive of ASF.

#### Article 2.6.6.13.

When importing from countries or *zones* free of ASF, Veterinary Administrations Authorities 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:
  - ~~1.a)~~ have been killed in a country or *zone* free of ASF;
  - ~~2.b)~~ have been subjected to a post-mortem inspection in accordance with Appendix 3.10.1. in an approved examination centre, and have been found free of any sign suggestive of ASF;

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 killed, and has been subjected to a virological test and a serological test for ASF, with negative results.

#### Article 2.6.6.14.

Veterinary Administrations Authorities 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 2.6.6.12. or 2.6.6.13., as relevant;
  - b) in a processing establishment:
    - i) approved by the *Veterinary Administration Authority* for export purposes;
    - ii) processing only meat meeting the conditions laid down in Articles 2.6.6.12. or 2.6.6.13., as relevant;

OR

2. have been processed in an establishment approved by the *Veterinary Administration Authority* for export purposes so as to ensure the destruction of the ASF virus and that the necessary precautions were taken after processing to avoid contact of the product with any source of ASF virus.

**Article 2.6.6.15.**

*Veterinary Administrations Authorities* 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 2.6.6.12. or 2.6.6.13., as relevant;
  - b) in a processing establishment:
    - i) approved by the *Veterinary Administration Authority* for export purposes;
    - ii) 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 Authority* for export purposes so as to ensure the destruction of the ASF virus and that the necessary precautions were taken after processing to avoid contact of the product with any source of ASF virus.

**Article 2.6.6.15.bis**

*Veterinary Authorities* 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, *zone* or *compartment* free of ASF; or
2. have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the ASF virus and that the necessary precautions were taken after processing to avoid contact of the product with any source of ASF virus.

Article 2.6.6.16.

*Veterinary Administrations Authorities* 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, *zone* or *compartment* free of ASF; or
2. have been processed in an establishment approved by the *Veterinary Administration Authority* for export purposes so as to ensure the destruction of the ASF virus and that the necessary precautions were taken after processing to avoid contact of the product with any source of ASF virus.

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## CHAPTER 2.6.7.

**CLASSICAL SWINE FEVER****Community comments:**

**The Community still cannot support this new draft, as none of its previous comments were taken into account. The answer that was given to justify such a change, to a chapter that has been used until now without problems by member countries, is not satisfactory as it is not proven by field situation. CSF is not an airborne disease and field situation rather proves that when specific measures are implemented on the domestic pig population, it can very well keep a free status even if some cases appear in the wild. So there is no reason to apply to CSF the same methodology as for FMD or ASF, and it should be much similar to that applied to AI. In any case, there is no urgency, so the Community asks the draft to be sent back to the ad hoc group for further consideration.**

**In the draft below, some more specific comments are inserted. The Community reiterates its former comment regarding the delay of 3 months in a free zone before export of fresh meat: this is not any more to be required as the delay is included in the recovery of the free status in the proposed draft.**

**The Community thus cannot support the changes unless its general and specific comments are taken into account.**

## Article 2.6.7.1.

The pig is the only natural host for classical swine fever (CSF) virus. The definition of pig includes all varieties of *Sus scrofa*, both domestic ~~breeds~~ and wild ~~boar~~. For the purposes of this chapter, a distinction is made between domestic pigs (permanently captive and ~~owned~~ farmed free-range pigs) and wild pigs (including feral pigs).

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

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

## Article 2.6.7.2.

The CSF status of a country, *zone* or *compartment* can only be determined after considering the following criteria in domestic and wild pigs, as applicable:

- ~~1-~~ ~~a risk assessment has been conducted, identifying all potential factors for CSF occurrence and their historic perspective;~~
21. CSF should be notifiable in the whole country, and all clinical signs suggestive of CSF should be subjected to appropriate field and ~~or~~ laboratory investigations;

32. an on-going awareness programme should be in place to encourage reporting of all *cases* suggestive of CSF;
43. the *Veterinary Administration Authority* should have current knowledge of, and authority over, all domestic pigs in the country, *zone* or *compartment*;
54. the *Veterinary Administration Authority* should have current knowledge about the population and habitat of wild pigs in the country or *zone*.

#### Article 2.6.7.3.

### CSF free country, zone or compartment

#### 1. CSF free status in the absence of an outbreak

##### a) Historically free status

A country, ~~or zone or compartment~~ may be considered free from the *disease* after ~~conducting a risk assessment as referred to in Article 2.6.7.2.~~ but without formally applying a specific surveillance programme, if the provisions of Article 3.8.1.6. are complied with.

##### b) Free status as a result of a specific surveillance programme

A country, ~~zone or compartment~~ which does not meet the conditions of point 1 above may be considered free from CSF when a *risk assessment* as referred to in Article 2.6.7.2. has been conducted, surveillance in accordance with Appendix 3.8.8. has been in place for at least 12 months, and when no *outbreak* has been observed for at least 12 months.

#### 2. CSF free status following an outbreak b) Free status as a result of an eradication programme

A country, ~~or zone or compartment~~ which does not meet the conditions of point a) ~~or b)~~ above or a compartment may be considered free from CSF when: if surveillance in accordance with Appendix 3.8.8. has been in place and after a *risk assessment* as referred to in Article 2.6.7.2. has been conducted, and

- a) ~~where a stamping out policy without vaccination is practised and no outbreak has been observed in domestic pigs for at least 6 months;~~

OR

- b) ~~where a stamping out policy with vaccination is practised, and either:~~

- i) ~~vaccinated pigs are slaughtered, and no outbreak has been observed in domestic pigs for at least 6 months after the last vaccinated pig was slaughtered; or~~
- ii) ~~where there are validated means of distinguishing between vaccinated and infected pigs, no outbreak has been observed in domestic pigs for at least 6 months;~~

OR

- c) ~~where a vaccination strategy is practised without a stamping out policy:~~

- i) ~~vaccination has been banned in all domestic pigs in the country, zone or compartment for at least 12 months, unless there are validated means of distinguishing between vaccinated and infected pigs;~~

- ii) ~~if vaccination has been practised within the past 5 years, surveillance in accordance with Appendix 3.8.8. has been in place for at least 6 months to demonstrate the absence of infection within the population of domestic pigs 6 months to one year old; and~~
- iii) ~~no outbreak has been observed in domestic pigs for at least 12 months;~~

~~AND~~

~~in all cases, based on surveillance in accordance with Appendix 3.8.8., CSF infection is not known to occur in any wild pig population in the country or zone.~~

- i) there has been no outbreak of CSF during the past 12 months;
- ii) no evidence of CSFV infection has been found during the past 12 months;
- iii) no vaccination against CSF has been carried out during the past 12 months;
- iv) surveillance in accordance with Appendix 3.8.8. has been in place in domestic pigs for the past 12 months;

AND

in the case of a country or zone, surveillance in accordance with Appendix 3.8.8. has been in place to determine the CSF status of the wild pig population, and:

- v) there has been no clinical evidence or virological evidence of CSF in wild pigs during the past 12 months;
- vi) no seropositive wild pigs have been detected in the age class 6–12 months during the past 12 months;
- vii) there has been no vaccination in wild pigs for the past 12 months;
- viii) imported wild pigs comply with the relevant requirements in Article 2.6.7.7.

~~Article 2.6.7.4.~~

#### **Country free of CSF in domestic pigs but with a wild pig population**

~~Requirements in points 2a to 2e of Article 2.6.7.3., as relevant, are complied with. As CSF infection may be present in the wild pig population, the following additional conditions are complied with:~~

- 1- ~~a programme for the management of CSF in wild pigs is in place, 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- ~~zoning or compartmentalisation is applied the domestic pig population must be separated from the infected wild pig population through biosecurity measures to prevent transmission of CSF from wild pigs to domestic pigs.~~

~~Article 2.6.7.54.~~

#### **Recovery of free status**

~~Should a CSF outbreak occur in a previously free country, zone or compartment, the free status of the country, zone or compartment may be restored not less than 30 days after completion of a stamping-out policy where surveillance in accordance with Appendix 3.8.8. has been carried out with negative results. either:~~



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

~~1. 3 months after the last case where a stamping-out policy without vaccination is practised;~~

~~OR~~

~~2. where a stamping-out policy with emergency vaccination is practised:~~

- ~~i) 3 months after the last case and the slaughter of all vaccinated animals, or~~
- ~~ii) 3 months after the last case without the slaughter of vaccinated animals where there are validated means, validated to OIE standards (Chapter I.1.3. of the Terrestrial Manual), of distinguishing between vaccinated and infected pigs;~~

~~OR~~

~~3. where a stamping-out policy is not practised, the provisions of point b) of Article 2.6.7.3 should be followed;~~

~~AND~~

~~in the case of a country or zones, based on surveillance in accordance with Appendix 3.8.8., CSFV infection is not known to occur in any wild pig population in the country or zone.~~

**Community comments:**

**This article is not coherent with the previous: if there was an outbreak in the wild animal population, the status is lost and cannot be regained with the above procedures. The last sentence should be replaced by the same as in the preceding article:**

**"in the case of an outbreak in the wild pig population of a country or zone, surveillance in accordance with Appendix 3.8.8 has been in place to determine the CSF status of the wild pig population, and:**

- v) there has been no clinical evidence or virological evidence of CSF in wild pigs during the past 12 months;**
- vi) no seropositive wild pigs have been detected in the age class 6–12 months during the past 12 months;**
- vii) there has been no vaccination in wild pigs for the past 12 months;**
- viii) imported wild pigs comply with the relevant requirements in Article 2.6.7.7."**

~~Article 2.6.7.6.~~

~~**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- ~~surveillance in accordance with Appendix 3.8.8. has been in place to determine the CSF status of the wild pig population in the country, and in the country or *zone*:~~
  - a) ~~there has been no clinical evidence, nor virological evidence of CSF in wild pigs during the past 12 months;~~
  - b) ~~no seropositive wild pigs have been detected in the age class 6-12 months during the past 12 months;~~
- 3- ~~there has been no vaccination in wild pigs for the past 12 months;~~
- 4- ~~the feeding of swill to wild pigs is forbidden, unless the swill has been treated to destroy any CSF virus that may be present, in conformity with one of the procedures referred to in Article 3.6.4.1.;~~
- 5- ~~imported wild pigs comply with the relevant requirements set forth in the present chapter.~~

Article 2.6.7.75.

When importing from countries, *zones* or *compartments* free of CSF, *Veterinary Administrations Authorities* 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, *zone* or *compartment* free of CSF 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, validated to OIE standards (Chapter I.1.3. of the Terrestrial Manual), of distinguishing between vaccinated and infected pigs.

Article 2.6.7.8.

~~When importing from countries free of CSF in domestic pigs but 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 a CSF free zone or compartment;~~
- 4- ~~showed no clinical sign of CSF on the day of shipment.~~

Article 2.6.7.96.

When importing from CSF infected countries or zones with CSF infection in domestic pigs, Veterinary Administrations Authorities 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~~ showed no clinical sign of CSF on the day of shipment;
2. were kept since birth or for the past 3 months in a CSF free *compartment*;
3. ~~showed no clinical sign of CSF on the day of shipment~~ have not been vaccinated against CSF nor are they the progeny of vaccinated sows, unless there are validated means, validated to OIE standards (Chapter I.1.3. of the Terrestrial Manual), of distinguishing between vaccinated and infected pigs.

### Community comments:

**A point 4 should be added: "were not fed with uncooked swill".**

#### Article 2.6.7.407.

When importing from countries or *zones* free of CSF, Veterinary Administrations Authorities 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;
3. have not been vaccinated against CSF, unless there are validated means, validated to OIE standards (Chapter I.1.3. of the Terrestrial Manual), 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 2.6.7.448.

When importing from countries, *zones* or *compartments* free of CSF, Veterinary Administrations Authorities should require:

for semen of domestic pigs

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

1. the donor animals:
  - a) were kept in a country, *zone* or *compartment* free of CSF since birth or for at least 3 months prior to collection;

- b) showed no clinical sign of CSF on the day of collection of the semen;
2. the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.2.

~~Article 2.6.7.12.~~

~~When importing from countries 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- ~~were kept in a country, zone or compartment free of CSF in domestic pigs since birth or for at least 3 months prior to collection;~~
  - b- ~~showed no clinical sign of CSF on the day of collection of the semen and for the following 40 days;~~
- 2- ~~the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.2.~~

Article 2.6.7.439.

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

for semen of domestic pigs

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

- 1. the donor animals:
  - a) were kept in a *compartment* free of CSF in domestic pigs since birth or for at least 3 months prior to collection;
  - b) showed no clinical sign of CSF on the day of collection of the semen and for the following 40 days;
  - c) have not been vaccinated against CSF and were subjected to a serological test performed at least 21 days after collection, with negative results;

or

d) have been vaccinated against CSF and were subjected to a serological test performed at least 21 days after collection and it has been conclusively demonstrated by means, validated to OIE standards (Chapter I.1.3. of the *Terrestrial Manual*), that any antibody is due to the vaccine;

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

**Community comments:**

**A point 3 should be added: "were not fed with uncooked swill".**

Article 2.6.7.4410.

When importing from countries, *zones* or *compartments* free of CSF, *Veterinary Administrations Authorities* 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 2.6.7.15.~~

~~When importing from countries 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 in a country, zone or compartment free of CSF in domestic pigs since birth or for at least 3 months prior to collection;~~
  - 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 2.6.7.4611.

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

for *in vivo* derived embryos of pigs

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

1. the donor females:
  - a) were kept in a *compartment* free of CSF in domestic pigs since birth or for at least 3 months prior to collection;
  - b) showed no clinical sign of CSF on the day of collection of the embryos and for the following 40 days;
  - c) have not been vaccinated against CSF and were subjected, with negative results, to a serological test performed at least 21 days after collection;

**or**

d) have been vaccinated against CSF and were subjected to a serological test performed at least 21 days after collection and it has been conclusively demonstrated by means, validated to OIE standards (Chapter I.1.3. of the *Terrestrial Manual*), that any antibody is due to the vaccine;

2. the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.1.

**Community comments:**

**A point 3 should be added: "were not fed with uncooked swill".**

Article 2.6.7.4712.

When importing from countries, *zones* or *compartments* free of CSF, *Veterinary Administrations Authorities* 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, *zone* or *compartment* free of CSF since birth or for at least the past 3 months, or which have been imported in accordance with Article 2.6.7.5 or Article 2.6.7.6;

**Community comments:**

**The Community reiterates its comment that the delay of 3 months is useless, as it is already taken into account in the status recovery. The words "since birth or for at least the past 3 months" should be deleted.**

2. have been slaughtered in an approved *abattoir*, have been subjected to ante-mortem and post-mortem inspections in accordance with Appendix 3.10.1. and have been found free of any sign suggestive of CSF.

Article 2.6.7.18.

~~When importing from countries or zones free of CSF in domestic pigs but 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, zone or compartment free of CSF in domestic 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 as described in the Codex Alimentarius Code of Hygienic Practice for Meat and have been found free of any sign suggestive of CSF.~~

Article 2.6.7.4913.

When importing from countries or *zones* free of CSF, *Veterinary Administrations Authorities* 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;
  - b) have been subjected to a post-mortem inspection ~~as described in the Codex Alimentarius Code of Hygienic Practice for Meat~~ in accordance with Appendix 3.10.1, 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~~ killed, and has been subjected to a virological test and a serological test for CSF, with negative results.

**Community comments:**

**A point 3 should be added: "were not fed with uncooked swill".**

**Community comments:**

**An article should be included here:**

**Article 2.6.7.14**

**When importing from countries or zones not complying with article 1. b) v to vii, *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 in which the domestic pig population is separated from the wild pig population through biosecurity measures to prevent transmission of CSF from wild pigs to domestic pigs, and complies with the relevant points of article 2.6.7.3 or 2.6.7.4;**
- 2. have been slaughtered in an *approved abattoir*, have been subjected to ante-mortem and post-mortem inspections as described in Appendix 3.10.1 and have been found free of any sign suggestive of CSF.**
- 3. were not fed with uncooked swill.**

Article 2.6.7.~~2014~~

*Veterinary* ~~*Administrations*~~ *Authorities* 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 2.6.7.4712, ~~2.6.7.18.~~ or 2.6.7.4913, as relevant;
  - b) in a processing establishment:
    - i) approved by the *Veterinary Administration Authority* for export purposes;
    - ii) processing only meat meeting the conditions laid down in Articles 2.6.7.4712, ~~2.6.7.18.~~ or 2.6.7.4913, as relevant;

OR

2. have been processed in an establishment approved by the *Veterinary Administration Authority* for export purposes 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. and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSF virus.

Article 2.6.7.2415.

*Veterinary Administrations Authorities* 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 2.6.7.4712, ~~2.6.7.18.~~ or 2.6.7.4913, as relevant;
  - b) in a processing establishment:
    - i) approved by the *Veterinary Administration Authority* for export purposes;
    - ii) 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 Authority* for export purposes 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. and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSF virus.

Article 2.6.7.2216.

*Veterinary Administrations Authorities* 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, *zone* or *compartment* free of CSF; or
2. have been processed in an establishment approved by the *Veterinary Administration Authority* for export purposes so as to ensure the destruction of the CSF virus and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSF virus.

## Article 2.6.7.2317.

*Veterinary Administrations Authorities* 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, *zone* or *compartment* free of CSF; or
2. have been processed in an establishment approved by the *Veterinary Administration Authority* for export purposes so as to ensure the destruction of the CSF virus and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSF virus.

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— text deleted

## APPENDIX 3.8.8.

## GUIDELINES ~~FOR THE ON~~ SURVEILLANCE ~~OF~~ ~~FOR~~ CLASSICAL SWINE FEVER

**Community comments:**

**The Community can support the changes. Continuous updating will be necessary for the article on free *compartments*, in relevance with the changes in the Guidelines for compartmentalisation.**

## Article 3.8.8.1.

**Introduction**

This Appendix defines the principles and provides a guide on the surveillance for classical swine fever (CSF), complementary to in accordance with Appendix 3.8.1., applicable to countries seeking to demonstrate recognition of freedom from CSF status. This may be for the entire country or a *zone* within the country. Guidance for countries seeking reestablishment of freedom free status from CSF for the whole country or a zone, following an *outbreak*, as well as guidelines and for demonstrating the maintenance of CSF free status are is also provided. This Appendix complements Chapter 2.6.7.

The impact and epidemiology of CSF differ widely in different regions of the world, and it is, therefore, 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 Members to provide a well-reasoned argument to prove that absence of classical swine fever virus (CSFV) *infection* is assured at an acceptable level of confidence.

Surveillance for CSF should be in the form of a continuing programme designed to either establish that a population is free from CSFV infection (either the whole country, or a zone within the country is free from CSFV infection infection or a compartment) or to detect the introduction of CSFV into a population already recognized as free. 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 purposes 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 3.8.8.2.

## General conditions and methods

1. A surveillance system in accordance with Appendix 3.8.1. should be under the responsibility of the *Veterinary Administration Authority*. 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 Authority*. 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 standstill orders, etc.).

### Article 3.8.8.3.

## Surveillance strategies

### 1. Introduction

There are two basic strategies that can be employed for CSF surveillance depending on the purpose of the country for seeking recognition of freedom from CSF. In countries historically free of CSF, surveillance programmes should be designed to detect the introduction of CSFV into domestic or wild swine. The optimal strategy to meet this objective is most often targeted surveillance.

The target population for covered by surveillance aimed at identifying detecting *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 or 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 wishes to apply for recognition by other Members 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.

## 2. Clinical and virological surveillance

Beyond their role in targeted surveillance, clinical and virological surveillance for CSF has 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.

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.

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. 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.

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. Otherwise close physical examination of susceptible animals is useful as a selection criteria for CSF surveillance, particularly in diagnostic laboratories or *slaughter* establishments or when applied to high risk populations such as swill feeding operations.

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. Individually or as part of recently mixed batches, such animals may, however, 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.

### 3. Serological surveillance

Serological surveillance aims at detecting 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 3.8.8.4.

#### Country or zone historically 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, **infected** 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 the general conditions and methods described 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 3.8.8.5

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

##### 1. Country or zone free of CSF

~~In addition to the general conditions described in Chapter 2.6.7., a Member 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 in and around the country or *zone* and will be planned and implemented according to the general conditions and methods described 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. Compartment free of CSF

~~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 is to demonstrate the absence of CSFV *infection* in the *compartment*. The provisions of Chapter 1.3.5. should be followed. The effective separation of the two subpopulations should be demonstrated. To this end, a *biosecurity programme* which plan that 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;~~
- e) ~~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;~~
- a) 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 wild caught animals and their products;~~
- i) ~~registry record of animal movements into and out of *establishments*;~~
- j) ~~information and training programmes for farmers, hunters, processors, veterinarians, etc.~~

3. The ~~biosecurity programme *plan*~~ implemented ~~would~~ also requires internal and external monitoring by the ~~Veterinary Authorities *Authority*~~. ~~These elements~~ This monitoring 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 *plan*~~;
- d) periodic monitoring and review.

4. Monitoring the CSF status of wild and domestic pig populations outside the *compartment* will be of value in assessing the degree of risk they pose to the CSF free ~~domestic population *compartment*~~. The design of a monitoring system ~~for wild pig~~ is dependent on several factors such as the size and distribution of the population, the organisation of the *Veterinary Services* and resources available. The occurrence of CSF in wild and domestic pigs may vary considerably among countries. Surveillance design should be epidemiologically based, and the Member ~~must~~ should 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 organisations, 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 3.8.8.6.

### Recovery of free status

#### 1. Countries or zones seeking re-establishment of freedom from CSF following an outbreak

In addition to the general conditions described in Chapter 2.6.7., a country seeking reestablishment of country or *zone* freedom from CSF should show evidence of an active surveillance programme ~~for CSF as well as~~ to demonstrate absence of CSFV *infection*.



Populations under this surveillance programme should include, ~~but not be limited to:~~

- a) *establishments* in the ~~area~~ proximity 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 seeking reestablishment of country or *zone* freedom from CSF with vaccination or without vaccination should report the results of an active and a passive surveillance programme in which the pig population undergoes regular clinical, pathological, virological, and/or serological examination, planned and implemented according to the general conditions and methods described in these guidelines. The surveillance should be based on a statistically representative sample of the populations at risk.

## 2. Country or zone free of Surveillance for 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;
- e) ~~determination of the practicability of establishing a *zone*.~~
- c) determination of the practicability of establishing a *zone*.

~~The design of a monitoring system for wild pigs is dependent on several factors such as the organisation 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.~~

The design of a monitoring system for wild pigs is dependent on several factors such as the organisation 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 a target population.

Estimates of wild pig populations 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~~ include:

- a) areas with past history of CSF;
- b) sub-regions with high wild pig density;
- c) border regions with CSF affected countries or *zones*;
- d) ~~areas of contact~~ interface between wild and domestic pig sub-populations;
- e) picnic and camping areas;
- f) ~~around~~ farms with free-ranging pigs;
- g) garbage dumps;
- h) ~~special~~ other risk areas determined by ~~local~~ the *Veterinary Authorities*;
- g) ~~garbage dumps~~.

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CHAPTER 2.7.12.  
**AVIAN INFLUENZA**

**Community comments:**

**The Community can support the changes but would like the comments below to be taken on board.**

Article 2.7.12.1.

1. For the purposes of *international trade*, avian influenza in its notifiable form (NAI) is defined as an *infection* of poultry caused by any influenza A virus of the H5 or H7 subtypes or by any AI virus with an intravenous pathogenicity index (IVPI) greater than 1.2 (or as an alternative at least 75% mortality) as described below. NAI viruses can be divided into highly pathogenic notifiable avian influenza (HPNAI) and low pathogenicity notifiable avian influenza (LPNAI):
  - a) HPNAI viruses have an IVPI in 6-week-old chickens greater than 1.2 or, as an alternative, cause at least 75% mortality in 4-to 8-week-old chickens infected intravenously. H5 and H7 viruses which do not have an IVPI of greater than 1.2 or cause less than 75% mortality in an intravenous lethality test should be sequenced to determine whether multiple basic amino acids are present at the cleavage site of the haemagglutinin molecule (HA0); if the amino acid motif is similar to that observed for other HPNAI isolates, the isolate being tested should be considered as HPNAI;
  - b) LPNAI are all influenza A viruses of H5 and H7 subtype that are not HPNAI viruses.
2. Poultry is defined as ‘all domesticated birds, including backyard poultry, used for the production of meat or eggs for consumption, for the production of other commercial products, for restocking supplies of game, or for breeding these categories of birds, as well as fighting cocks used for any purpose’.
 

Birds that are kept in captivity for any reason other than those reasons referred to in the preceding paragraph, including those that are kept for shows, races, exhibitions, competitions, breeding or selling these categories of birds as well as pet birds, are not considered to be poultry.
3. For the purposes of *international trade*, this chapter deals not only with the occurrence of clinical signs caused by NAI virus, but also with the presence of *infection* with NAI virus in the absence of clinical signs.
4. For the purposes of *international trade*, a country should not impose immediate trade bans in response to a notification of *infection* with HPAI and LPAI virus in birds other than poultry according to Article 2.1.1.3. of the *Terrestrial Code*.
5. Antibodies to H5 or H7 subtype of NAI virus, which have been detected in poultry and are not a consequence of vaccination, have to be further investigated. 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*.
6. The following defines the occurrence of *infection* with NAI virus:

- a) HPNAI virus has been isolated and identified as such or viral RNA specific for HPNAI has been detected in poultry or a product derived from poultry; or
- b) LPNAI virus has been isolated and identified as such or viral RNA specific for LPNAI has been detected in poultry or a product derived from poultry.

For the purposes of the *Terrestrial Code*, 'NAI free establishment' means an *establishment* in which the poultry have shown no evidence of NAI *infection*, based on surveillance in accordance with Appendix 3.8.9.

For the purposes of the *Terrestrial Code*, the *incubation period* for NAI shall be 21 days.

Standards for diagnostic tests, including pathogenicity testing, are described in the *Terrestrial Manual*. Any vaccine used should comply with the standards described in the *Terrestrial Manual*.

#### Article 2.7.12.2.

The NAI status of a country, a *zone* or a *compartment* can be determined on the basis of the following criteria:

- ~~1. the outcome of a *risk assessment* identifying all potential factors for NAI occurrence and their historic perspective;~~
21. 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;
32. appropriate surveillance is in place to demonstrate the presence of *infection* in the absence of clinical signs in poultry, and the risk posed by birds other than poultry; this may be achieved through an NAI surveillance programme in accordance with Appendix 3.8.9.
3. consideration of all epidemiological factors for NAI occurrence and their historical perspective.

#### Article 2.7.12.3.

##### **NAI free country, zone or compartment**

A country, *zone* or *compartment* may be considered free from NAI when it has been shown that neither HPNAI nor LPNAI infection has been present in the country, *zone* or *compartment* for the past 12 months, based on surveillance in accordance with Appendix 3.8.9. The surveillance may need to be adapted to parts of the country or existing *zones* or *compartments* depending on historical or geographical factors, industry structure, population data, or proximity to recent outbreaks.

If infection has occurred in a previously free country, zone or compartment, NAI free status can be regained:

1. In the case of HPNAI infections, 3 months after a *stamping-out policy* (including *disinfection* of all affected *establishments*) is applied, providing that surveillance in accordance with Appendix 3.8.9. has been carried out during that three-month period.
2. In the case of LPNAI infections, poultry may be kept for slaughter for human consumption subject to conditions specified in Article 2.7.12.18. or 2.7.12.19. or a *stamping-out policy* may be applied; in either case, 3 months after the *disinfection* of all affected *establishments*, providing that surveillance in accordance with Appendix 3.8.9. has been carried out during that three-month period.

#### Article 2.7.12.4.

##### **HPNAI free country, zone or compartment**

A country, *zone* or *compartment* may be considered free from HPNAI when it has been shown that HPNAI infection has not been present in the country, *zone* or *compartment* for the past 12 months, although its LPNAI status may be unknown, or when, based on surveillance in accordance with Appendix 3.8.9., it does not meet the criteria for freedom from NAI but any NAI virus detected has not been identified as

HPNAI virus. The surveillance may need to be adapted to parts of the country or existing *zones* or *compartments* depending on historical or geographical factors, industry structure, population data, or proximity to recent *outbreaks*.

If infection has occurred in a previously free country, *zone* or *compartment*, HPNAI free status can be regained 3 months after a *stamping-out policy* (including *disinfection* of all affected *establishments*) is applied, providing that surveillance in accordance with Appendix 3.8.9. has been carried out during that three-month period.

Article 2.7.12.5.

When importing from an NAI free country, zone or compartment, *Veterinary Authorities* should require:

for live poultry (other than day-old poultry)

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

1. the poultry showed no clinical sign of NAI on the day of shipment;
2. the poultry were kept in an NAI free country, zone or compartment since they were hatched or for at least the past 21 days;
3. the required surveillance, in accordance with Appendix 3.8.9., has been carried out on the *establishment* within at least the past 21 days;
4. if vaccinated, the poultry have been vaccinated in accordance with Appendix 3.8.9., and the relevant information is attached.

**Community comments:**

**The Community would like to replace the word "relevant" by the actual details required, e.g. "date of vaccination, type of vaccine and batch number". This would also be coherent with the chapter on ND.**

Article 2.7.12.6.

Regardless of the NAI status of the country, *zone* or *compartment* of origin, *Veterinary Authorities* should require:

for live birds other than poultry

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

1. the birds showed no clinical sign of infection with a virus which would be considered NAI in poultry on the day of shipment;
2. the birds were kept in isolation approved by the *Veterinary Services* since they were hatched or for at least the 21 days prior to shipment and showed no clinical sign of *infection* with a virus which would be considered NAI in poultry during the isolation period;
3. the birds were subjected to a diagnostic test 7 to 14 days prior to shipment to demonstrate freedom from *infection* with a virus which would be considered NAI in poultry;
4. the birds are transported in new containers.

**Community comments:**

**In point 4 it is rather restrictive just allowing for use of new containers: this is not the same as for ND and the Commission proposes to add "or properly cleaned and disinfected containers".**

If the birds have been vaccinated, the relevant information should be attached to the certificate.

**Community comments:**

**The Community would like to replace the word "relevant" by the actual details required, e.g. "date of vaccination, type of vaccine and batch number". This would also be coherent with the chapter on ND.**

Article 2.7.12.7.

When importing from an NAI free country, zone or compartment, *Veterinary Authorities* 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, zone or compartment since they were hatched;
2. the poultry were derived from parent flocks which had been kept in an NAI free country, zone or compartment for at least 21 days prior to and at the time of the collection of the eggs;
3. if the poultry or the parent flocks were vaccinated, vaccination was carried out in accordance with Appendix 3.8.9., and the relevant information is attached.

**Community comments:**

**The Community would like to replace the word "relevant" by the actual details required, e.g. "date of vaccination, type of vaccine and batch number". This would also be coherent with the chapter on ND.**

Article 2.7.12.8.

When importing from an HPNAI free country, zone or compartment, *Veterinary Authorities* 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, zone or compartment since they were hatched;
2. the poultry were derived from parent flocks which had been kept in an NAI free *establishment* for at least 21 days prior to and at the time of the collection of the eggs;
3. the poultry are transported in new containers;
4. if the poultry or the parent flocks were vaccinated, vaccination was carried out in accordance with Appendix 3.8.9., and the relevant information is attached.

**Community comments:**

**The Community would like to replace the word "relevant" by the actual details required, e.g. "date of vaccination, type of vaccine and batch number". This would also be coherent with the chapter on ND.**

Article 2.7.12.9.

When importing from an NAI free country, zone or compartment, *Veterinary Authorities* should require:

for hatching eggs

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

1. the eggs came from an NAI free country, zone or compartment;
2. the eggs were derived from parent flocks which had been kept in an NAI free country, zone or compartment for at least 21 days prior to and at the time of the collection of the eggs;
3. if the parent flocks were vaccinated, vaccination was carried out in accordance with Appendix 3.8.9., and the relevant information is attached.

**Community comments:**

**The Community would like to replace the word "relevant" by the actual details required, e.g. "date of vaccination, type of vaccine and batch number". This would also be coherent with the chapter on ND.**

Article 2.7.12.10.

When importing from an HPNAI free country, zone or compartment, *Veterinary Authorities* should require:

for hatching eggs

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

1. the eggs came from an HPNAI free country, zone or compartment;
2. the eggs were derived from parent flocks which had been kept in an NAI free *establishment* for at least 21 days prior to and at the time of the collection of the eggs;
3. the eggs have had their surfaces sanitised (in accordance with Article 3.4.1.7) and are transported in new packing material;
4. if the parent flocks were vaccinated, vaccination was carried out in accordance with Appendix 3.8.9., and the relevant information is attached.

**Community comments:**

**The Community would like to replace the word "relevant" by the actual details required, e.g. "date of vaccination, type of vaccine and batch number". This would also be coherent with the chapter on ND.**

Article 2.7.12.11.

When importing from an NAI free country, zone or compartment, *Veterinary Authorities* should require:



for eggs for human consumption

the presentation of an *international veterinary certificate* attesting that the eggs come from an NAI free country, zone or compartment.

## Article 2.7.12.12.

When importing from an HPNAI free country, zone or compartment, *Veterinary Authorities* should require:

for eggs for human consumption

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

1. come from an HPNAI free country, zone or compartment;
2. have had their surfaces sanitised (in accordance with Article 3.4.1.7.) and are transported in new packing material.

## Article 2.7.12.13.

When importing from an NAI free country, zone or compartment, *Veterinary Authorities* should require:

for egg products

the presentation of an *international veterinary certificate* attesting that the egg products come from, and were processed in, an NAI free country, zone or compartment.

## Article 2.7.12.14.

Regardless of the NAI status of the country, ~~zone or compartment of origin~~ When importing from countries, zones or compartments not considered free from NAI, *Veterinary Authorities* should require:

for egg products

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

1. the egg products are derived from eggs which meet the requirements of Articles 2.7.12.9., 2.7.12.10., 2.7.12.11. or 2.7.12.12.; or
2. the egg products were processed to ensure the destruction of NAI virus in accordance with Appendix 3.6.5.;
3. the necessary precautions were taken after processing to avoid contact of the *commodity* with any source of NAI virus.

## Article 2.7.12.15.

When importing from an NAI free country, zone or compartment, *Veterinary Authorities* should require:

for poultry semen

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

1. showed no clinical sign of NAI on the day of semen collection;
2. were kept in an NAI free country, zone or compartment for at least the 21 days prior to and at the time of semen collection.

## Article 2.7.12.16.

When importing from an HPNAI free country, zone or compartment, *Veterinary Authorities* should require:  
for poultry semen

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

1. showed no clinical sign of HPNAI on the day of semen collection;
2. were kept in an HPNAI free country, zone or compartment for at least the 21 days prior to and at the time of semen collection.

Article 2.7.12.17.

Regardless of the NAI status of the country, *zone* or *compartment* of origin, *Veterinary Authorities* should require:

for semen of birds other than poultry

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

1. were kept in isolation approved by the *Veterinary Services* for at least the 21 days prior to semen collection;
2. showed no clinical sign of infection with a virus which would be considered NAI in poultry during the isolation period;
3. were tested between 7 and 14 days prior to semen collection and shown to be free of NAI infection.

Article 2.7.12.18.

When importing from an NAI free country, zone or compartment, *Veterinary Authorities* should require:

for fresh meat of poultry

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

1. which have been kept in an NAI free country, zone or compartment since they were hatched or for at least the past 21 days;
2. which have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for NAI with favourable results.

Article 2.7.12.19.

When importing from an HPNAI free country, *zone* or *compartment*, *Veterinary Authorities* should require:

for fresh meat of poultry

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

1. which have been kept in an HPNAI free country, *zone* or *compartment* since they were hatched or for at least the past 21 days;

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

Article 2.7.12.20.

Regardless of the NAI status of the country, *zone* or *compartment* of origin, *Veterinary Authorities* should require:

for meat products of poultry

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

1. the *commodity* is derived from *fresh meat* which meets the requirements of Articles 2.7.12.18. or 2.7.12.19.; or
2. the *commodity* has been processed to ensure the destruction of avian influenza virus in accordance with Appendix 3.6.5.;
3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Article 2.7.12.21.

Regardless of the NAI status of the country, *zone* or *compartment* of origin, *Veterinary Authorities* 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 poultry which have been kept in an NAI free country, zone or compartment since they were hatched or for at least the past 21 days; or
2. these *commodities* have been processed to ensure the destruction of avian influenza virus (under study);
3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Article 2.7.12.22.

Regardless of the NAI status of the country, *zone* or *compartment* of origin, *Veterinary Authorities* should require:

for feathers and down (from poultry)

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

1. these *commodities* come from poultry which have been kept in an NAI free country, zone or compartment since they were hatched or for at least the past 21 days; or
2. these *commodities* have been processed to ensure the destruction of avian influenza virus (under study);
3. the necessary precautions were taken to avoid contact of the *commodity* with any source of avian influenza virus.

Article 2.7.12.23.

Regardless of the NAI status of the country, *zone* or *compartment*, *Veterinary Authorities* 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 avian influenza virus (under study);
2. the necessary precautions were taken after processing to avoid contact of the *commodity* with any source of NAI virus.

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## APPENDIX 3.6.5.

**GUIDELINES FOR ON THE INACTIVATION OF THE AVIAN INFLUENZA VIRUS****Community comments:****The Community can support the changes.**

## Article 3.6.5.1.

**Eggs and egg products**

The following times for industry standard temperatures are suitable for the inactivation of highly pathogenic notifiable avian influenza (HPNAI) virus present in eggs and egg products:

|                  | Temperature (°C) | Time        |
|------------------|------------------|-------------|
| Whole egg        | 60               | 188 seconds |
| Whole egg blends | 60               | 188 seconds |
| Whole egg blends | 61.1             | 94 seconds  |
| Liquid egg white | 55.6             | 870 seconds |
| Liquid egg white | 56.7             | 232 seconds |
| 10% salted yolk  | 62.2             | 138 seconds |
| Dried egg white  | 67               | 0.83 days   |
| Dried egg white  | 54.4             | 21.38 days  |

The listed temperatures are indicative of a range that achieves a 7-log kill. Where scientifically documented, variances from these times and temperatures may also be suitable when they achieve the inactivation of the virus.

## Article 3.6.5.2.

**Meat**

A procedure which produces a core temperature of 70°C for 3,5 seconds is suitable for the inactivation of HPNAI virus present in meat.

|              | Temperature (°C) | Time         |
|--------------|------------------|--------------|
| Poultry meat | 60.0             | 507 seconds  |
|              | 65.0             | 42 seconds   |
|              | 70.0             | 3.5 seconds  |
|              | 73.9             | 0.51 seconds |

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## APPENDIX 3.8.9.

**GUIDELINES FOR ON THE SURVEILLANCE OF FOR AVIAN INFLUENZA****Community comments:**

**The Community can support the changes, but asks the TAHSV to take into account its former comment on article 3, and its general comment about "approved" laboratories.**

## Article 3.8.9.1.

**Introduction**

This Appendix defines the principles and provides a guide on the surveillance for notifiable avian influenza (NAI) complementary to ~~in accordance with~~ Appendix 3.8.1., applicable to countries seeking to demonstrate ~~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 is also provided. ~~This Appendix complements Chapter 2.7.12.~~

The presence of avian influenza viruses in wild birds creates a particular problem. In essence, no country can declare itself free from avian influenza (AI) in wild birds. However, the definition of NAI in Chapter 2.7.12. refers to the *infection* in poultry only, and this Appendix was developed under this definition.

The impact and epidemiology of NAI differ widely in different regions of the world and therefore it is impossible to provide specific guidelines for all situations. It is axiomatic that the surveillance strategies employed for demonstrating freedom from NAI at an acceptable level of confidence will need to be adapted to the local situation. Variables such as the frequency of contacts of poultry with wild birds, different biosecurity levels and production systems and the commingling of different susceptible species including domestic waterfowl require specific surveillance strategies to address each specific situation. It is incumbent upon the country to provide scientific data that explains the epidemiology of NAI in the region concerned and also demonstrates how all the risk factors are managed. There is therefore considerable latitude available to Members to provide a well reasoned argument to prove that absence of NAI virus (NAIV) *infection* is assured at an acceptable level of confidence.

Surveillance for NAI should be in the form of a continuing programme designed to establish that the country, *zone* or *compartment*, for which application is made, is free from NAIV *infection*.

## Article 3.8.9.2.

**General conditions and methods**

1. A surveillance system in accordance with Appendix 3.8.1. should be under the responsibility of the *Veterinary Authority*. In particular:
  - a) a formal and ongoing system for detecting and investigating *outbreaks of disease* or NAI *infection* 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 Services*. They should be supported directly or indirectly (e.g. through private veterinarians or *veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. All suspected cases of NAI should be investigated immediately. As suspicion cannot be resolved by epidemiological and clinical investigation alone, 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 NAIIV.

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 NAIIV. 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 NAIIV *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 standstill orders, etc.).

#### Article 3.8.9.3.

### Surveillance strategies

#### 1. Introduction

The target population for surveillance aimed at identification of *disease* and *infection* should cover all the susceptible poultry species within the country, *zone* or *compartment*. Active and passive surveillance for NAI should be ongoing. The frequency of active surveillance should be at least every 6 months. Surveillance should be composed of random and targeted approaches using virological, serological and clinical methods.

The strategy employed may be based on randomised sampling requiring surveillance consistent with demonstrating the absence of NAIIV *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 NAIIV *infection* in accordance with Appendix 3.8.1. and the prevailing epidemiological situation, including cases of HPNAI detected in any birds. 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).

**Community comments:**

**In order to be coherent with Chapter 2.7.12 Article 1 paragraph 4, and with Chapter 2.1.1 article 3 point 6, in the above paragraph, "HPNAI" should be replaced by "HPAI", as there is a cross reference with a contradiction: HPNAI refers to Chapter 2.7.12 Article 1 point 1 which deals with poultry only, whereas this paragraph includes all species of birds.**

If a Member wishes to declare freedom from NAIIV *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 NAIIV *infection/circulation* needs to be carefully followed to avoid producing results that are either insufficiently reliable, or excessively costly and logistically complicated. The design of any surveillance programme, therefore, requires inputs from professionals competent and experienced in this field.

## 2. Clinical surveillance

Clinical surveillance aims at the detection of clinical signs of NAI at the flock level. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, surveillance based on clinical inspection should not be underrated. Monitoring of production parameters, such as increased mortality, reduced feed and water consumption, presence of clinical signs of a respiratory disease or a drop in egg production, is important for the early detection of NAIIV 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 NAIIV and to enable the molecular, antigenic and other biological characteristics of the virus to be determined. It is essential that NAIIV isolates are sent regularly to the regional Reference Laboratory for genetic and antigenic characterization.

### 3. Virological surveillance

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

- a) to monitor at risk populations;
- b) to confirm clinically suspect cases;
- c) to follow up positive serological results;
- d) to test 'normal' daily mortality, to ensure early detection of infection in the face of vaccination or in establishments epidemiologically linked to an outbreak.

### 4. Serological surveillance

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

- a) natural infection with NAIIV;
- 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) false 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 NAIIV 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 NAIIV infection is present in a country, zone or compartment. It is therefore essential that the survey be thoroughly documented.

### 5. Virological and serological surveillance in vaccinated populations

The surveillance strategy is dependent on the type of vaccine used. The protection against AI is haemagglutinin subtype specific. Therefore, two broad vaccination strategies exist: 1) inactivated whole AI viruses, and 2) haemagglutinin expression-based vaccines.

In the case of vaccinated populations, the surveillance strategy should be based on virological and/or serological methods and clinical surveillance. It may be appropriate to use sentinel birds for this purpose. These birds should be unvaccinated, AI virus antibody free birds and clearly and permanently identified. The interpretation of serological results in the presence of vaccination is described in Article [3.8.9.7](#).

#### Article 3.8.9.4.

### Documentation of NAI or HPNAI free status

#### 1. Countries declaring freedom from NAI or HPNAI for the country, zone or compartment

In addition to the general conditions described in the [Terrestrial Code](#), a Member declaring freedom from NAI or highly pathogenic notifiable avian influenza (HPNAI) for the entire country, or a [zone](#) or a [compartment](#) should provide evidence for the existence of an effective surveillance programme. The strategy and design of the surveillance programme will depend on the prevailing epidemiological circumstances and should be planned and implemented according to general conditions and methods described in this Appendix, to demonstrate absence of NAIV or HPNAIV infection, during the preceding 12 months in susceptible poultry populations (vaccinated and non-vaccinated). This requires the support of a laboratory able to undertake identification of NAIV or HPNAIV infection through virus detection and antibody tests described in the [Terrestrial Manual](#). This surveillance may be targeted to poultry population at specific risks linked to the types of production, possible direct or indirect contact with wild birds, multi-age flocks, local trade patterns including live bird markets, use of possibly contaminated surface water, and the presence of more than one species on the holding and poor biosecurity measures in place.

#### 2. Additional requirements for countries, zones or compartments that practise vaccination

Vaccination to prevent the transmission of HPNAI virus may be part of a disease control programme. The level of flock immunity required to prevent transmission will depend on the flock size, composition (e.g. species) and density of the susceptible poultry population. It is therefore impossible to be prescriptive. The vaccine must also comply with the provisions stipulated for NAI vaccines in the [Terrestrial Manual](#). Based on the epidemiology of NAI in the country, [zone](#) or [compartment](#), it may be that a decision is reached to vaccinate only certain species or other poultry subpopulations.

In all vaccinated flocks there is a need to perform virological and serological tests to ensure the absence of virus circulation. The use of sentinel poultry may provide further confidence of the absence of virus circulation. The tests have to be repeated at least every 6 months or at shorter intervals according to the risk in the country, [zone](#) or [compartment](#).

Evidence to show the effectiveness of the vaccination programme should also be provided.

#### Article 3.8.9.5.

### Countries, zones or compartments declaring that they have regained freedom from NAI or HPNAI following an outbreak

In addition to the general conditions described in Chapter [2.7.12](#), a country declaring that it has regained country, [zone](#) or [compartment](#) freedom from NAI or HPNAI virus infection should show evidence of an active surveillance programme depending on the epidemiological circumstances of the [outbreak](#) to demonstrate the absence of the infection. This will require surveillance incorporating virus detection and antibody tests described in the [Terrestrial Manual](#). The use of sentinel birds may facilitate the interpretation of surveillance results.

A Member declaring freedom of country, [zone](#) or [compartment](#) after an [outbreak](#) of NAI or HPNAI (with or without vaccination) should report the results of an active surveillance programme in which the NAI or HPNAI susceptible poultry population undergoes regular clinical examination and active surveillance

planned and implemented according to the general conditions and methods described in these guidelines. The surveillance should at least give the confidence that can be given by a randomized representative sample of the populations at risk.

#### Article 3.8.9.6.

#### **NAI free establishments within HPNAI free compartments**

The declaration of NAI free establishments requires the demonstration of absence of NAIIV 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 3.8.9.7.

#### **The use and interpretation of serological and virus detection tests**

Poultry infected with NAI virus produce antibodies to haemagglutinin (HA), neuraminidase (NA), nonstructural proteins (NSPs), nucleoprotein/matrix (NP/M) and the polymerase complex proteins. Detection of antibodies against the polymerase complex proteins will not be covered in this Appendix. Tests for NP/M antibodies include direct and blocking ELISA, and agar gel immunodiffusion (AGID) tests. Tests for antibodies against NA include the neuraminidase inhibition (NI), indirect fluorescent antibody and direct ELISA tests. For the HA, antibodies are detected in haemagglutination inhibition (HI) and neutralization (SN) tests. The HI test is reliable in avian species but not in mammals. The SN test can be used to detect subtype specific antibodies to the haemagglutinin and is the preferred test for mammals and some avian species. The AGID test is reliable for detection of NP/M antibodies in chickens and turkeys, but not in other avian species. As an alternative, blocking ELISA tests have been developed to detect NP/M antibodies in all avian species.

#### **Community comments:**

**In order to update this article with the latest data and available techniques, the words "and blocking" should be inserted in the fourth sentence between "and direct" and "ELISA", and the word "ELISA" in the fifth sentence before "and neutralisation".**

The HI and NI tests can be used to subtype AI viruses into 16 haemagglutinin and 9 neuraminidase subtypes. Such information is helpful for epidemiological investigations and in categorization of AI viruses.

Poultry can be vaccinated with a variety of AI vaccines including inactivated whole AI virus vaccines, and haemagglutinin expression-based vaccines. Antibodies to the haemagglutinin confer subtype specific protection. Various strategies can be used to differentiate vaccinated from infected birds including serosurveillance in unvaccinated sentinel birds or specific serological tests in the vaccinated birds.

AI virus infection of unvaccinated birds including sentinels is detected by antibodies to the NP/M, subtype specific HA or NA proteins, or NSP. Poultry vaccinated with inactivated whole AI vaccines containing an influenza virus of the same H sub-type but with a different neuraminidase may be tested for field exposure by applying serological tests directed to the detection of antibodies to the NA of the field virus. For example, birds vaccinated with H7N3 in the face of a H7N1 epidemic may be differentiated from infected birds (DIVA) by detection of subtype specific NA antibodies of the N1 protein of the field virus. Alternatively, in the absence of DIVA, inactivated vaccines may induce low titres of antibodies to NSP and the titre in infected birds would be markedly higher. Encouraging results have been obtained experimentally with this system, but it has not yet been validated in the field. In poultry vaccinated with haemagglutinin expression-based vaccines, antibodies are detected to the specific HA, but not any of the other AI viral proteins. Infection is evident by antibodies to the NP/M or NSP, or the specific NA protein of the field virus. 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 NAIIV 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 NAIIV by either virus isolation or detection of virus specific genomic material or proteins.
- b) Haemagglutinin expression-based vaccines contain the HA protein or gene homologous to the HA of the field virus. Sentinel birds as described above can be used to detect AI infection. In vaccinated or sentinel birds, the presence of antibodies against NP/M, NSP or field virus NA is indicative of infection. Sampling should be initiated to exclude the presence of NAIIV 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

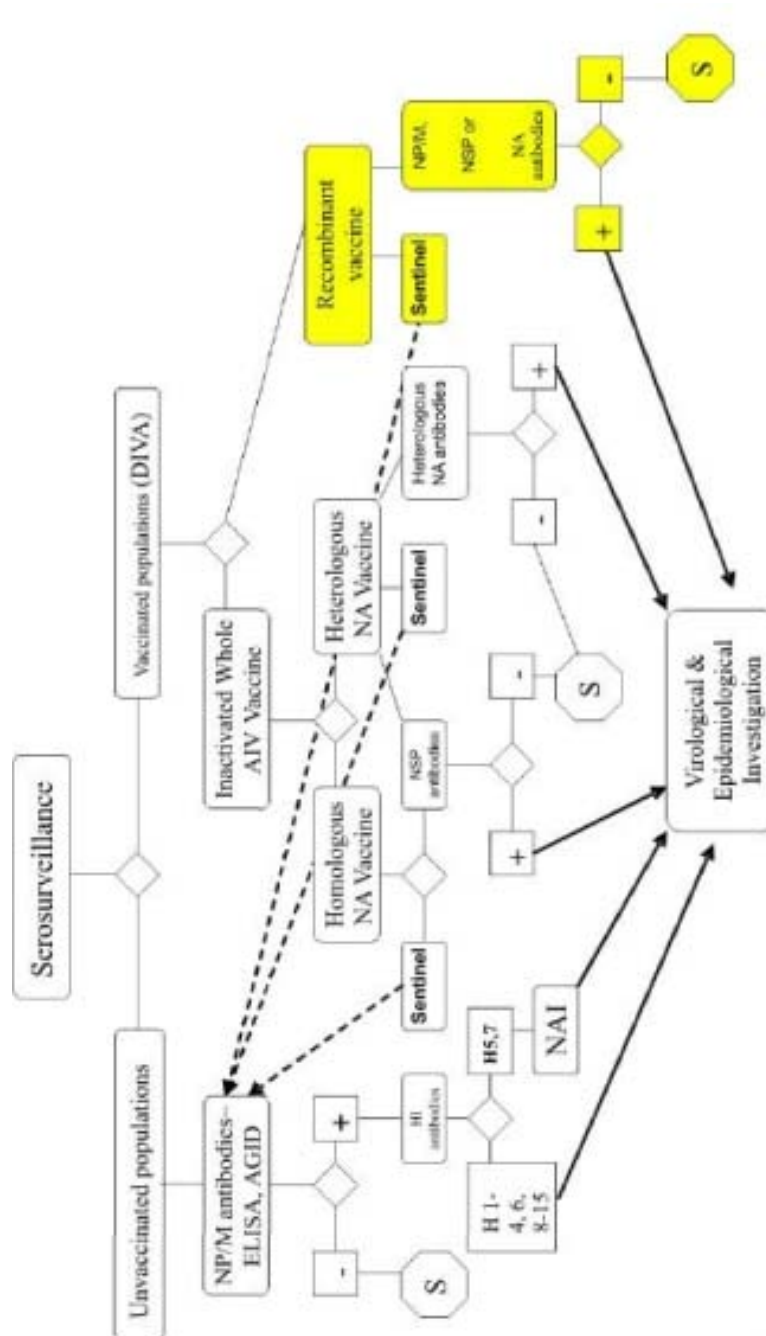
detection of influenza A specific proteins or nucleic acids (Figure 2). Virus isolation is the gold standard for detecting infection by AI virus and the method is described in the Terrestrial Manual. All AI virus isolates should be tested to determine HA and NA subtypes, and *in vivo* tested in chickens 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.

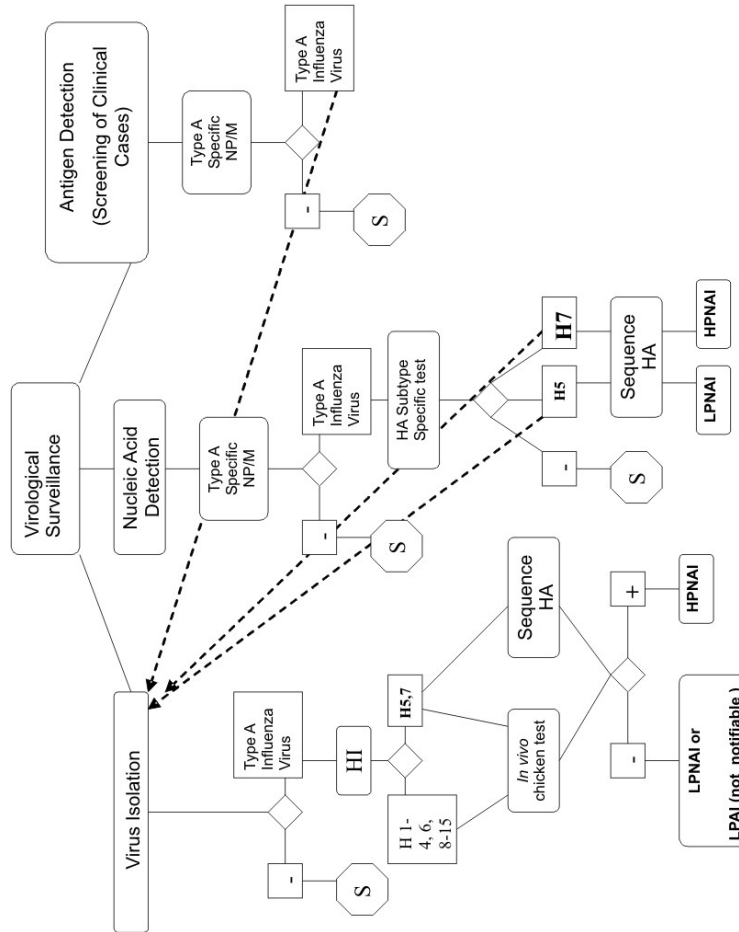
Fig. 1. Schematic representation of laboratory tests for determining evidence of NAI infection through or following serological surveys





Annex XVIII (contd)

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



The above diagram indicates the tests which are recommended for use in the investigation of poultry flocks.

|       |  |
|-------|--|
| Key:  |  |
| AGID  | Agar gel immunodiffusion                         |
| DIVA  | Differentiating infected from vaccinated animals |
| ELISA | Enzyme-linked immunosorbant assay                |
| HA    | Haemagglutinin                                   |
| HI    | Haemagglutination inhibition                     |
| NA    | Neuraminidase                                    |
| NP/M  | Nucleoprotein and matrix protein                 |
| NSP   | Nonstructural protein                            |
| S     | No evidence of NAI                               |

----- text deleted

## CHAPTER 2.7.13.

## NEWCASTLE DISEASE

**Community comments:**

**The Community welcomes and supports the changes but reiterates one of his comments on article 1:**

**Indeed, the use of the terms "virulent Newcastle Disease Virus" (vNDV) implies that there are other "Newcastle Disease Virus" (NDV) less virulent that do not cause Newcastle Disease... and this may cause a great confusion. Even if the laboratories are used to a complex terminology, the Community suggests that the TAHSC uses for the Code a clear and as simple as possible terminology and that the word "virulent" (and letter "v" where appropriate throughout the chapter) be deleted.**

## Article 2.7.13.1

1. ~~For the purposes of the *international trade*, An outbreak of Newcastle Disease (ND) for the purpose of the *Terrestrial Code* is defined in the *Terrestrial Manual* is defined~~ as an *infection of birds-poultry* caused by a virus of avian paramyxovirus serotype 1 (APMV-1), termed virulent Newcastle disease virus (vNDV), that meets one of the following criteria for *virulence*:
  - a) The virus has an intracerebral pathogenicity index (ICPI) in day-old chicks (*Gallus gallus*) of 0.7 or greater; or
  - b) Multiple basic amino acids have been demonstrated in the virus (either directly or by deduction) at the C-terminus of the F2 protein and phenylalanine at residue 117, which is the N-terminus of the F1 protein. The term 'multiple basic amino acids' refers to at least three arginine or lysine residues between residues 113 and 116. Failure to demonstrate the characteristic pattern of amino acid residues as described above would require characterisation of the isolated virus by an ICPI test.<sup>7</sup>

In this definition, amino acid residues are numbered from the N-terminus of the amino acid sequence deduced from the nucleotide sequence of the F0 gene, 113–116 corresponds to residues –4 to –1 from the cleavage site.<sup>7</sup>

~~Viruses classified as APMV 1 are synonymous with Newcastle disease virus (NDV). Those viruses that meet the criteria of virulence to be the cause of ND are termed virulent Newcastle disease virus (vNDV). All other APMV 1s that do not meet the criteria for vNDV are termed low virulent NDV (lvNDV).~~

2. Poultry is defined as 'all domesticated birds, including backyard poultry, used for the production of meat or eggs for consumption, for the production of other commercial products, for restocking supplies of game, or for breeding these categories of birds, as well as fighting cocks used for any purpose'. ~~All backyard and game fowl regardless of use will be defined as poultry.~~

Birds that are kept in captivity for any reason other than those ~~defined as poultry~~ reasons referred to in the preceding paragraph, including those that are kept for shows, races, exhibitions, competitions,

~~or sale breeding or selling these categories of birds as well as pet birds,~~ are not considered to be poultry.

3. This chapter ~~only~~ deals with vNDV ~~infection of birds-poultry as defined in 2.7.13.1.1,~~ in the presence or absence of clinical signs. For the purposes of *international trade*, a country should ~~interpret an~~ not impose immediate trade bans in response to reports occurrence of *infection* with vNDV in birds other than poultry ~~according to the Terrestrial Code and should not impose immediate trade bans, although such infections should be notified.~~
4. ~~The following defines~~ †The occurrence of *infection* with vNDV is defined as the isolation and identification of:
  - a) ~~vNDV has been isolated and identified as such or~~ the detection of viral RNA specific for vNDV has been detected.
  - b) ~~5.~~ For the purposes of the *Terrestrial Code*, the *incubation period* for ND shall be 21 days.
  - c) ~~6.~~ Standards for diagnostic tests, including pathogenicity testing, are described in the *Terrestrial Manual*. When the use of ND vaccines is appropriate those vaccines should comply with the standards described in the *Terrestrial Manual*

#### Article 2.7.13.2.

The ND status of a country, a *zone* or a *compartment* can ~~only~~ be determined ~~and certified~~ on the basis of the following criteria:

1. ND is notifiable in the whole country, an on-going ND awareness programme is in place, and all notified suspect occurrences of ND are subjected to field and, where applicable, laboratory investigations;
2. appropriate surveillance is in place to demonstrate the presence of vNDV *infection* in the absence of clinical signs in poultry, this may be achieved through an ND surveillance programme in accordance with Appendix 3.8.x.;
3. consideration of all epidemiological factors for ND occurrence and their historical perspective.

#### Article 2.7.13.3.

##### ND free country, zone or compartment

A country, *zone* or *compartment* may be considered free from ND when it has been shown that vNDV *infection* has not been present in the country, *zone* or *compartment* for the past 12 months, based on surveillance in accordance with Appendix x.x.x. ~~The surveillance may need to be adapted to parts of the country or existing zones or compartments depending on historical or geographical factors, industry structure, population data, or proximity to recent outbreaks.~~

If *infection* has occurred in a previously free country, *zone* or *compartment*, ND free status can be regained three months after a *stamping-out policy* (including *disinfection* of all affected *establishments*) is applied, providing that surveillance in accordance with Appendix x.x.x. has been carried out during that three-month period.

#### Article 2.7.13.4.

When importing from an ND free country, *zone* or *compartment* as defined in Article 2.7.13.3, *Veterinary Administrations Authorities* 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 suggestive of ND on the day of shipment;
2. the poultry were kept in an ND free country, *zone* or *compartment* since they were hatched or for at least the past 21 days;
3. the poultry have not been vaccinated against ND or if the birds were vaccinated against ND the nature of the vaccine used and the date of vaccination shall be attached to the certificate;
4. the ~~birds~~ poultry are transported in new or appropriately sanitized containers.

Article 2.7.13.5.

Regardless of the ND status of the country, *zone* or *compartment* of origin, ~~Veterinary Administrations~~ Authorities should require:

for live birds other than poultry

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

1. the birds showed no clinical sign suggestive of ND on the day of shipment;
2. the birds were kept in isolation approved by the *Veterinary Services* since they were hatched or for at least the 21 days prior to shipment and showed no clinical sign of *infection with a virus which would be considered ND in poultry* during the isolation period;

**Community comments:**

**The Community proposes that the words suppressed are replaced by “with NDV”. Even if ND is only applicable to poultry, the definition of NDV is applicable to any birds.**

3. the birds were subjected to a diagnostic test 7 to 14 days prior to shipment to demonstrate freedom from *infection* with vNDV;
4. ~~the birds are transported in new or appropriately sanitized containers~~ the birds have not been vaccinated against ND or if the birds were vaccinated against ND the nature of the vaccine used and the date of vaccination shall also be attached to the certificate;
5. ~~the birds have not been vaccinated against ND or if the birds were vaccinated against ND the nature of the vaccine used and the date of vaccination shall also be attached to the certificate~~ the birds are transported in new or appropriately sanitized containers.

Article 2.7.13.6.

When importing from an ND free country, *zone* or *compartment* as defined in Article 2.7.13.3, ~~Veterinary Administrations~~ Authorities should require:

for day-old live poultry

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

1. the poultry were hatched and kept in an ND free country, *zone* or *compartment*;
2. the poultry were derived from parent flocks which had been kept in an ND free country, *zone* or *compartment* for at least 21 days prior to and at the time of the collection of the eggs;

3. the poultry have not been vaccinated against ND or if poultry or parent flocks were vaccinated against ND the nature of the vaccine used and the date of vaccination shall also be attached to the certificate;
4. the ~~birds~~ poultry are transported in new or appropriately sanitized containers.

~~Article 2.7.13.7.~~

Regardless of the ND status of the country, *zone* or *compartment*, ~~Veterinary Administrations~~ Authorities should require:

~~for day-old live birds other than poultry~~

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

- ~~1. the birds showed no clinical sign suggestive of ND on the day of shipment;~~
- ~~2. the birds were hatched and kept in isolation approved by the *Veterinary Services*;~~
- ~~3. the parent flock birds were subjected to a diagnostic test at the time of the collection of the eggs to demonstrate freedom from infection with vNDV;~~
- ~~4. the birds are transported in new or appropriately sanitized containers;~~
- ~~5. the birds have not been vaccinated against ND or if the birds or parent flocks were vaccinated against ND the nature of the vaccine used and the date of vaccination shall also be attached to the certificate.~~

Article 2.7.13.87.

When importing from an ND free country, *zone* or *compartment* as defined in Article 2.7.13.2, ~~Veterinary Administrations~~ Authorities should require:

for hatching eggs from poultry

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

1. the eggs came from an ND free country, *zone* or *compartment*;
2. the eggs were derived from parent flocks which had been kept in an ND free country, *zone* or *compartment* for at least 21 days prior to and at the time of the collection of the eggs;
3. the parent flocks have not been vaccinated against ND; or if parent flocks were vaccinated against ND the nature of the vaccine used and the date of vaccination shall also be attached to the certificate;
4. the eggs are transported in new or appropriately sanitized containers.

Article 2.7.13.98.

Regardless of the ND status of the country, *zone* or *compartment* origin, ~~Veterinary Administrations~~ Authorities should require:

for hatching eggs from birds other than poultry

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

1. the parent flock birds were subjected to a diagnostic test 7 days prior to and at the time of the collection of the eggs to demonstrate freedom from *infection* with vNDV;

2. the ~~birds~~ eggs are transported in new or appropriately sanitized containers;
3. the parent flocks have not been vaccinated against ND; or if parent flocks were vaccinated against ND the nature of the vaccine used and the date of vaccination shall also be attached to the certificate.

Article 2.7.13.409.

When importing from an ND free country, *zone* or *compartment* as defined in Article 2.7.13.3, *Veterinary Administrations Authorities* should require:

for poultry eggs for human consumption

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

1. the eggs were produced and packed in an ND free country, *zone* or *compartment*;
2. the eggs are transported in new or appropriately sanitized packing material.

Article 2.7.13.4410.

When importing from an ND free country, *zone* or *compartment* as defined in Article 2.7.13.2, *Veterinary Administrations Authorities* should require:

for poultry egg products

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

1. the egg products come from, and were processed in, an ND free country, *zone* or *compartment*;
2. the egg products are transported in new or appropriately sanitized containers.

Article 2.7.13.4211.

~~Regardless of the ND status of the country, *zone* or *compartment* of origin~~ When importing from countries, *zones* or *compartments* not considered free of ND, *Veterinary Administrations Authorities* should require:

for poultry egg products

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

1. the *commodity* is processed to ensure the destruction of vNDV(under study);
2. the necessary precautions were taken after processing to avoid contact of the *commodity* with any source of vNDV;
3. the egg products are transported in new or appropriately sanitized containers.

Article 2.7.13.4312.

When importing from an ND free country, *zone* or *compartment* as defined in Article 2.7.13.3, *Veterinary Administrations Authorities* should require:

for poultry semen

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

1. showed no clinical sign suggestive of ND on the day of semen collection;

2. were kept in an ND free country, *zone* or *compartment* for at least the 21 days prior to and at the time of semen collection.

Article 2.7.13.4413.

Regardless of the ND status of the country, *zone* or *compartment* of origin, *Veterinary Administrations Authorities* should require:

for semen of birds other than poultry

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

1. were kept in isolation approved by the *Veterinary Services* for at least the 21 days prior to and on the day of semen collection;
2. showed no clinical sign suggestive of infection with vNDV during the isolation period and on the day of semen collection;
3. the donor birds were subjected to a diagnostic test 7 to 14 days prior to semen collection to demonstrate freedom from *infection* with vNDV.

Article 2.7.13.4514.

When importing from an ND free country, *zone* or *compartment* as defined in Article 2.7.13.3, *Veterinary Administrations Authorities* should require:

for fresh meat of poultry

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

1. which have been kept and slaughtered in an ND free country, *zone* or *compartment* since they were hatched or for at least the past 21 days;
2. which have been slaughtered in an approved *abattoir* and have been subjected to ante-mortem and post-mortem inspections in accordance with Appendix 3.10.1. and have been found free of any sign suggestive of ND.

Article 2.7.13.4615.

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

for meat products of poultry

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

1. the *commodity* is derived from *fresh meat* which meets the requirements of Article 2.7.13.15 (*fresh meat*) and has been processed in an ND free country, *zone* or *compartment*;

**Community comments:**

**The reference to "Article 2.7.13.15" should be changed to "Article 2.7.13.14".**

2. the necessary precautions were taken to avoid contact of the *commodity* with any source of vNDV.

Article 2.7.13.16.

When importing from countries, zones or compartments not considered free of ND Regardless of the ND status of the country, ~~zone or compartment~~ of origin, ~~Veterinary Administrations~~ Authorities should require:

for meat products of poultry

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 and have been found free of any signs suggestive of ND;
- ~~2.~~ the *commodity* is derived from *fresh meat* which meet the requirements of Article 2.7.13.15 (fresh meat) and has been processed in an ND free country, zone or compartment; or the *commodity* has been processed to ensure the destruction of vNDV (under study);
- ~~3.~~ the necessary precautions were taken to avoid contact of the *commodity* with any source of vNDV.

Article 2.7.13.17.

When importing from ND free countries, zones or compartments, ~~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. the commodities come from poultry which have been kept and processed in an ND free country, zone or compartment since they were hatched or for at least the past 21 days;
2. the necessary precautions were taken to avoid contact of the commodity with any source of vNDV.

Article 2.7.13.17.bis

When importing from countries, zones or compartments not considered free of ND Regardless of the ND status of the country, ~~zone or compartment~~ of origin, ~~Veterinary Administrations~~ Authorities 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 poultry which have been kept and processed in an ND free country, zone or compartment since they were hatched or for at least the past 21 days; or these commodities have been processed to ensure the destruction of vNDV (under study);~~
2. the necessary precautions were taken to avoid contact of the *commodity* with any source of vNDV.

Article 2.7.13.18.

Regardless of the ND status of the country, ~~zone or compartment~~ of origin, ~~Veterinary Administrations~~ Authorities should require:

for feathers and down

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

1. these *commodities* come from poultry which have been kept and processed in an ND free country, ~~zone or compartment~~ since they were hatched or for at least the past 21 days; or these *commodities* have been processed to ensure the destruction of vNDV (under study);



2. the necessary precautions were taken to avoid contact of the *commodity* with any source of vNDV.

Article 2.7.13.19.

Regardless of the ND status of the country, ~~zone~~ or *compartment*, ~~Veterinary Administrations~~ Authorities 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 vNDV (under study);
2. the necessary precautions were taken after processing to avoid contact of the *commodity* with any source of vNDV.

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— text deleted

## APPENDIX 3.8.X.

## GUIDELINES ON SURVEILLANCE FOR NEWCASTLE DISEASE

### Community comments:

**The Community can support the changes, but the same comment as in Chapter 2.7.13 is reiterated regarding the definition of the disease. The second paragraph of article 1 below is very unclear: how could "APMV-1 isolates synonymous with Newcastle disease virus" cause infections "which are not Newcastle disease"?**

**The paragraph should be much clearer as follows:**

**"Surveillance for ND is complicated by the known prevalence of avian paramyxovirus serotype 1 (APMV-1) *infections* in many bird species, both domestic and wild, and the widespread utilization of ND vaccines in domestic poultry. Consequently it is required that APMV-1 isolates be characterized to differentiate those *infections* of high virulence (NDV) that cause Newcastle disease (ND) as defined in Chapter 2.7.13 and are notifiable, from those of low virulence which are not ND."**

**Then in the whole Guidelines vNDV should be replaced by NDV and the TAHSC should review and clarify throughout the text whenever necessary between ND and NDV.**

**The Community makes the same comment about the "approved" laboratories.**

### Article 3.8.X.1.

#### Introduction

This Appendix defines the principles and provides a guide on the surveillance for Newcastle Disease (ND) ~~complementary to in accordance with Appendix 3.8.1., applicable to countries seeking to demonstrate recognition for a declared ND 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 ND status is also provided. ~~This Appendix complements Chapter 2.7.13.~~

Surveillance for ND is complicated by the known prevalence of avian paramyxovirus serotype 1 (APMV-1) *infections* in many bird species, both domestic and wild, and the widespread utilization of ND vaccines in domestic poultry. Consequently it is required that APMV-1 isolates synonymous with Newcastle disease ~~virus~~ virus (NDV) be characterized to differentiate those *infections* of virulent NDV (vNDV) that are notifiable ~~as defined in Chapter 2.7.13.~~ from those of low virulence (loNDV) which are not: Newcastle Disease (ND) is ~~described~~ defined in Chapter ~~x.x.x.x~~ 2.7.13 ~~as an infection of birds with APMV-1,~~ however this appendix is only concerned with vNDV infections of poultry).

The impact and epidemiology of ND differ widely in different regions of the world and therefore it is not possible to provide specific guidelines for all situations. Therefore surveillance strategies employed for demonstrating freedom from ND 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,—production systems and the commingling of different susceptible species require specific surveillance strategies to address each specific situation. It is incumbent upon the country to provide scientific data that explains the epidemiology of ND in the region concerned and also demonstrates how all the risk factors are managed. There is, therefore, considerable latitude available to Members to provide a well-reasoned argument to prove freedom from vNDV *infection*.

Surveillance for ND 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 vNDV *infection*.

#### Article 3.8.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 Authority*. In particular there should be in place:
  - a) a formal and ongoing system for detecting and investigating *outbreaks of disease* or vNDV *infection*;
  - b) a procedure for the rapid collection and transport of samples from suspect cases of ND to an ~~approved~~ laboratory for ND diagnosis as described in the *Terrestrial Manual*;
  - c) a system for recording, managing and analysing diagnostic and surveillance data.
2. The ND 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 ND 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 Authority*. All suspected cases of ND should be investigated immediately. As suspicion cannot be resolved by epidemiological and clinical investigation alone, samples should be taken and submitted to an ~~approved~~ laboratory. 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 ND diagnosis and control;
  - b) implement, when relevant, regular and frequent clinical virological and serological surveillance of high risk groups of poultry within the target population, (e.g. those adjacent to an ND infected ~~population~~ country, zone, compartment, places where birds and poultry of different origins are mixed, or other sources of vNDV).

An effective surveillance system may periodically identify suspicious cases that require follow-up and investigation to confirm or exclude that the cause of the condition is due to vNDV *infection*. 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 vNDV *infection* should provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of laboratory testing and the control measures to which the animals concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

#### Article 3.8.X.3.

##### Surveillance strategies

###### 1. Introduction

The principles involved in surveillance for *disease / infection* are technically well defined. Any surveillance programme requires inputs from professionals competent and experienced in this field and should be thoroughly documented. The design of surveillance programmes to prove the absence of vNDV *infection*/circulation needs to be carefully followed to avoid producing results that are either unreliable, or excessively costly and logistically complicated.

If a country wishes to declare freedom from vNDV *infection* in a country, *zone* or *compartment*, the sub-population used for surveillance *disease infection* should be representative of all poultry within the country, *zone* or *compartment*. Multiple surveillance methods should be used concurrently to accurately define the true ND status of poultry populations. Active and passive surveillance for ND should be ongoing with the frequency of active surveillance being at least every 6 months. Surveillance should be composed of random and/or targeted approaches, dependent on the local epidemiological situation and using clinical, virological and serological methods as described in the *Terrestrial Manual* (Chapter x.x.x.x). If alternative tests are used they must have been validated as fit-for-purpose in accordance with OIE standards. A country should justify the surveillance strategy chosen as adequate to detect the presence of vNDV *infection* in accordance with Appendix 3.8.1. and the prevailing epidemiological situation.

For random ~~surveillance surveys~~, the design of the sampling strategy will need to incorporate ~~be of an epidemiologically appropriate design to demonstrate the prevalence of vNDV infection~~. The sample size selected for testing should ~~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 survey design and frequency of sampling should be dependent on the historical and current local epidemiological situation. The ~~applicant~~ country must justify the choice of survey design and confidence level based on the objectives of surveillance and the epidemiological situation, in accordance with Appendix 3.8.1.

Targeted surveillance (e.g. based on the increased likelihood of *infection* in a population) may be an appropriate strategy.

It may, for example, be appropriate to target clinical surveillance at particular species likely to exhibit clear clinical signs (e.g. unvaccinated chickens). Similarly, virological and serological testing could target species that may not show clinical signs (Article 2.7.13.2) of ND and are not routinely vaccinated (e.g. ducks). Surveillance may also target poultry populations at specific risk, for example direct or indirect contact with wild birds, multi-age flocks, local trade patterns including live poultry markets, the presence of more than one species on the holding and poor biosecurity measures in place. In situations where wild birds have been shown to play a role in the local epidemiology of ND, surveillance of wild birds may be of value in alerting Veterinary Services to the possible exposure of free ranging poultry.

### Community comments

**The Community proposes to add the words “in particular” after “possible exposure.”**

**This is because this could involve other poultry or birds.**

The sensitivity and specificity of the diagnostic tests are key factors in the choice of survey design, which should anticipate the occurrence of false positive and false negative reactions. Ideally, the sensitivity and specificity of the tests used should be validated for the vaccination/*infection* history and for the different species in the target population. If the characteristics of the testing system are known, the rate at which these false reactions 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 results of active and passive surveillance are important in providing reliable evidence that no vNDV *infection* is present in a country, *zone* or *compartment*.

## 2. Clinical surveillance

Clinical surveillance aims to detect clinical signs suggestive of ND at the flock level and should not be underestimated as an early indication of *infection*. Monitoring of production parameters (e.g. a drop in feed or water consumption or egg production) is important for the early detection of vNDV *infection* in some populations, as there may be no, or mild clinical signs, particularly if they are vaccinated. Any sampling unit within which suspicious animals are detected should be considered as infected until evidence to the contrary is produced. Identification of infected flocks is vital to the identification of sources of vNDV.

A presumptive diagnosis of clinical ND in suspect infected populations should always be confirmed by virological testing in an ~~approved~~ *laboratory*. This will enable the molecular, antigenic and other biological characteristics of the virus to be determined.

It is desirable that NDV isolates are sent promptly to an OIE Reference Laboratory for archiving and further characterization if required.

### 3. Virological surveillance

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

- a) monitor at risk populations;
- b) confirm suspect clinical cases;
- c) follow up positive serological results in unvaccinated populations or sentinel birds;
- d) test 'normal' daily mortalities (if warranted by an increased risk e.g. *infection* in the face of vaccination or in *establishments* epidemiologically linked to an *outbreak*).

### 4. Serological surveillance

Where systematic vaccination is carried out, serological surveillance is of limited value. Serological surveillance cannot be used to discriminate between vNDV and other NDV strains ~~aims at the detection of antibodies against NDV but is not diagnostic of the presence of vNDV~~. Test procedures and interpretations of results are as described in Chapter x.x.x of the *Terrestrial Manual*. Positive NDV antibody test results can have ~~four~~ five possible causes:

- a) natural *infection* with NDV;
- b) vaccination against ND (~~whether intentional or not~~);
- c) exposure to vaccine virus;
- ed) 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;
- de) non-specific test reactions.

It may be possible to use serum collected for other survey purposes for ND surveillance. However, the principles of survey design described in these guidelines and the requirement for a statistically valid survey for the presence of NDV should not be compromised.

Discovery of seropositive, unvaccinated flocks must be investigated further by conducting a thorough epidemiological investigation. Since seropositive results are not necessarily indicative of ~~active~~ *infection*, virological ~~surveillance~~ methods should be used to confirm the presence of vNDV in such populations. Until validated strategies and tools to differentiate vaccinated animals from those infected with field ND viruses are available serological tools should not be used to identify NDV *infection* in vaccinated populations.

### 5. Use of sentinel poultry

There are various applications of the use of sentinel poultry as a surveillance tool ~~in susceptible populations to detect virus circulation by the presence of clinical disease or seroconversion.~~ They may be used to monitor vaccinated populations or species which are less susceptible to the development of clinical *disease* for the circulation of virus. Sentinel poultry should ideally be immunologically naïve and may be used in vaccinated flocks ~~subject to a risk assessment.~~ In case of the use of sentinel poultry, the structure and organisation of the poultry sector, the type of vaccine used and local epidemiological factors will determine the type of production systems where sentinels should be placed, the frequency of placement and monitoring of the sentinels.

Sentinel poultry must be in close contact with, but should be identified to be clearly differentiated from, the target population. Sentinel poultry must be observed regularly for evidence of clinical *disease* and any *disease* incidents investigated by prompt ~~virological~~ laboratory testing. The species to be used as sentinels should be proven to be highly susceptible to *infection* and ideally develop clear signs of clinical *disease*. Where the sentinel poultry do not necessarily develop overt clinical *disease* a programme of regular active testing by virological and serological tests should be used (the development of clinical *disease* may be dependent on the sentinel species used or use of live vaccine in the target population that may infect the sentinel poultry). The testing regime and the interpretation of the results will depend on the type of vaccine used in the target population.

#### Article 3.8.X.4.

### Documentation of ND free status

The requirements for a country, *zone* or *compartment* to declare freedom from ND are given in Article x.x.13.3.

A country declaring freedom of a country, *zone* or *compartment* (with or without vaccination) should report the results of a surveillance programme in which the ND susceptible poultry population undergoes regular surveillance planned and implemented according to the general conditions and methods described in these guidelines.

~~A country, *zone* or *compartment* may be considered free from ND when it has been shown that vNDV infection has not been present in the country, *zone* or *compartment* for the past 12 months, based on surveillance in accordance with Appendix x.x.x. The surveillance may need to be adapted to parts of the country or existing *zones* or *compartments* depending on historical or geographical factors, industry structure, population data, or proximity to recent outbreaks.~~

~~If infection has occurred in a previously free country, *zone* or *compartment*, ND free status can be regained three months after a *stamping-out policy* (including *disinfection* of all affected *establishments*) is applied, providing that surveillance in accordance with Appendix x.x.x. has been carried out during that three-month period.~~

#### 1. Countries declaring freedom from ND for the country, *zone* or *compartment*

In addition to the general conditions described in the *Terrestrial Code*, a Member declaring freedom from ND for the entire country, or a *zone* or a *compartment* should provide evidence for the existence of an effective surveillance programme. The surveillance programme should be planned and implemented according to general conditions and methods described in this Appendix to demonstrate absence of vNDV *infection* in poultry during the preceding 12 months. ~~This requires the support of an *approved laboratory* capable of identification of vNDV infection through virus detection and antibody tests described in the *Terrestrial Manual*.~~

#### 2. Additional requirements for countries, zones or compartments that practice vaccination

Vaccination against ND may be used ~~for risk management (to reduce the risk of introduction and subsequent transmission) or as part a component of a *disease prevention and 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 used must also comply with the provisions stipulated for ND vaccines in of the *Terrestrial Manual*.~~

In ~~all~~ vaccinated populations there is a need to perform surveillance (Article x.x.x) to ensure the absence of vNDV circulation. The use of sentinel poultry may provide further confidence of the absence of virus circulation. The surveillance must 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.

#### **Community comments:**

**The Community does not see the advantage of carrying out such surveillance when blanket vaccination is carried out. The use of sentinel poultry might even be counterproductive as they could be infected by wild birds without proving anything regarding the status of the vaccinated poultry.**

**Thus the Community suggests that the last sentence reads: "... zone or compartment, or evidence to show the effectiveness of the vaccination programme is regularly provided."**

Article 3.8.X.5.

#### **Countries, zones or compartments regaining freedom from ND following an outbreak**

~~In addition to the general conditions described in Chapter 2.7.13, a A country regaining country, *zone* or *compartment* freedom from ~~vNDV infection~~ should show evidence of an active surveillance programme depending on the epidemiological circumstances of the *outbreak* to demonstrate the absence of the *infection*. This will require surveillance incorporating virus detection and antibody tests described in the *Terrestrial Manual*. The use of sentinel poultry may facilitate the interpretation of surveillance results.~~

A country declaring freedom of a country, *zone* or *compartment* after an *outbreak* of ND (with or without vaccination) should report the results of ~~an active~~ a surveillance programme in which the ND 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 give at least the same confidence that can be achieved by testing a randomized representative sample of the populations at risk.~~

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— text deleted

CHAPTER 2.2.XX.  
WEST NILE FEVER

**Community comments:**

**The Community acknowledges the work of the TAHSC on this chapter but cannot support this draft.**

**It reiterates one strong comment: species or animals which are considered as dead end hosts (e.g. equidae) should not be restricted so much for trade in relation with WNF; only species or animals which may transmit the disease should (e.g. birds other than poultry, geese and ducks).**

**The whole Chapter should remain under study, and Guidelines for surveillance should be drafted and presented at the same time.**

**The ad hoc group should include more experts than at present, and the Community would be happy to help in this regard.**

**Other comments are indicated below.**

Article 2.2.XX.1.

When authorising import or transit of the following commodities and any products made from these, Veterinary Authorities should not require any WNV related conditions, regardless of the WNF risk status of the animal population of the exporting country or zone.

- a. hatching eggs;
- b. eggs for human consumption;
- c. egg products;
- d. poultry semen;
- e. fresh meat and meat products of poultry;
- f. products of poultry origin intended for use in animal feeding, or for agricultural or industrial use;
- g. feathers and down from poultry;
- h. semen of horses;
- i. fresh meat and meat products of horses.

Article 2.2.XX.2.

West Nile fever (WNF) is a zoonotic *disease* caused by certain strains of the mosquito-borne West Nile virus (WNV).



For the purpose of this Chapter the susceptible species are equidae, geese, ducks (under study) and chicken and turkey chicks less than 12 days old and birds other than poultry.

~~Although most avian species are susceptible to infection, the outcome of the infection is highly variable according to the species. Chickens and turkeys, are usually resistant to disease and do not develop viremia sufficient to infect mosquitoes, with the exception of chicks less than 12 days old.~~

~~Birds are responsible for virus dispersal, including reintroduction of WNV from endemic areas into regions that may subsequently experience sporadic outbreaks.~~

WNV is maintained in a mosquito–bird–mosquito transmission cycle, whereas humans and equidae are considered dead-end hosts. Most human *infections* occur by natural transmission from mosquitoes.

~~Many animal species are known to be susceptible to WNV infection and outbreaks of a fatal neurological disease have been reported in humans, equidae, geese and wild birds.~~

In relation to domestic animal trade, geese and ducks ~~might represent~~ pose a risk for the spread of the WNV ~~the WNF~~ as some species have been documented to develop a viraemia sufficient to infect mosquitoes.

~~WNV has been reported to date in a wide geographical range that includes portions of Europe, Asia, Africa, Australia and the Americas. Although competent vectors and susceptible bird species are nearly ubiquitous, WNV circulation in sylvatic cycles may spill over occasionally in domestic population.~~

Surveillance for WNF will be carried out according to Appendix 3.8.X.

The following criteria defines the occurrence of WNF ~~ease~~:

1. WNV has been isolated ~~and identified as such~~ from an animal, ~~including human~~; or
2. viral antigen or viral RNA specific to WNV has been identified in samples from one or more animals ~~including human~~ that showing clinical signs consistent with WNF, or that is epidemiologically linked to a confirmed or suspected outbreak of WNF; or
3. antibodies to WNV that are not a consequence of vaccination, have been identified in an animal, ~~including human~~ showing clinical signs consistent with WNF, or that is epidemiologically linked to a confirmed or suspected outbreak of WNF.

For the purposes of the Terrestrial Code, the *incubation period* for WNF shall be ~~3~~-15 days.

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

~~Article 2.2.XX.2.~~

**WNF infected country, ~~or zone or compartment~~**

~~A WNF infected country, or zone or compartment is a country, zone or compartment clearly defined where one in which a case of WNF has been reported during the past 2 years~~

Article 2.2.XX.3.

**WNF free country, ~~or zone or compartment~~**

1. A country; ~~or zone or compartment~~ may be considered free from WNF when WNF is notifiable in the whole country and either:
  - a) no clinical occurrence of indigenous WNF cases have been recorded for the past 2 years; or

- b) a surveillance programme in accordance with Appendix 3.8.X. has demonstrated no evidence of WNV in the country or zone or compartment during the past 2 years; or
- c) a surveillance programme has demonstrated no evidence of ~~Culex~~ mosquitoes likely to be competent WNV vectors in the country; or zone or compartment.

**Community reiterates its comment:**

**Points a) and b) have by no means the same value or extent. In point a) the sentence could be replaced by the notion of "historically free" as defined in Appendix 3.8.1. The surveillance programme of WNV should in any case include surveillance of potential vectors. And the surveillance of the vectors should follow standardized procedures. Recent discussions regarding that topic, knowing that vector distribution and competency are of the utmost difficulty to establish, tend to show that the sole surveillance on vectors is not sufficient to assess a disease status.**

- 2. A WNF free country; or zone or compartment will not lose its free status through the importation from WNF infected countries, or zones or compartment of:
  - a) seropositive animals;
  - b) semen, embryo or ova;
  - c) animals vaccinated in accordance with the Terrestrial Manual at least 30 days prior to dispatch, and ~~that the animals~~ are identified in the accompanying certification as having been vaccinated; or
  - d) animals not vaccinated if a surveillance programme in accordance with Appendix 3.8.X. has been in place in the source population for a period of 30 days immediately prior to dispatch, and no evidence of WNV transmission has been detected.

**Community reiterates its comment:**

**A seropositive wild bird or geese could well be bearing viruses and be infective. Therefore, the words ", in accordance with the present chapter," should be added after the words "infected countries or zones".**

Article 2.2.XX.4.

**WNF seasonally free country or zone**

- 1. A WNF seasonally free country or ~~zone~~ is ~~a country or a zone for one in~~ which for part of a year, surveillance demonstrates no evidence either of WNV transmission or presence of adult ~~Culex~~ mosquitoes likely to be competent WNV vectors.
- 2. For the application of Articles 2.2.XX.6., the seasonally free period is taken to commence 21 days following the last evidence of WNV transmission (as demonstrated by the surveillance programme), or the cessation of activity of ~~adult Culex~~ mosquitoes likely to be competent WNV vectors.
- 3. For the application of Articles 2.2.XX.6., the seasonally free period is taken to conclude either:
  - a) at least 21 days before the earliest date that historical data show WNV transmission cycle has recommenced; or

- b) immediately if current climatic data or data from a surveillance programme indicate an earlier resurgence of activity of ~~adult *Culex* mosquitoes~~ mosquitoes likely to be competent WNV vectors.

**Community comment:**

**The surveillance programme of WNV should in any case include surveillance of potential vectors. And the surveillance of the vectors should follow standardized procedures. Recent discussions regarding that topic, knowing that vector distribution and competency are of the utmost difficulty to establish, tend to show that the sole surveillance on vectors is not sufficient to assess a disease status.**

4. A WNF seasonally free country or ~~zone~~ will not lose its free status through the importation of ~~animals or semen or embryo and ova~~ from infected countries or ~~zones~~ of:-
- a) seropositive animals;
  - b) semen, embryo or ova;
  - c) animals vaccinated in accordance with the *Terrestrial Manual* at least 30 days prior to dispatch, and are identified in the accompanying certification as having been vaccinated; or
  - d) animals not vaccinated if a surveillance programme in accordance with Appendix 3.8.X. has been in place in the source population for a period of 30 days immediately prior to dispatch, and no evidence of WNV transmission has been detected.

**Community reiterates its comment:**

**A seropositive wild bird or geese could well be bearing viruses and be infective. Therefore, the words ", in accordance with the present chapter," should be added after the words "infected countries or zones".**

Article 2.2.XX.4bis.

WNF infected country, or zone or compartment

A WNF infected country, or zone or compartment is a country, zone or compartment clearly defined where one in which a case of WNF has been reported during the past 2 years

**Community comment:**

**With the new definition of *infected country or zone*, this article is useless and should be deleted.**

Article 2.2.XX.5.

When importing from WNF free countries, ~~or zones or compartment~~ Veterinary Administrations Authorities should require:

for susceptible species

**Community comment:**

**Species or animals which are susceptible but considered dead end hosts (e.g. equidae) should not be restricted in such a way for trade in relation with WNF, unlike species or animals which may transmit the disease (e.g. birds other than poultry, geese and ducks).**

**Furthermore, in terms of risk management, there are nearly no differences between the countries or zones, as soon as the animals are vaccinated. It seems that for the horses, freedom of status of the zone of origin or vaccination, and a general recommendation of vaccination when GOING TO (or through) an infected country or zone would be sufficient. The restrictions would then be applied to the risky species or animals.**

**As for the requirements, following the logic of article 4 (4), the animal could be serologically tested with positive results for IgG, like in article 7; there is no logic at all being more stringent with animals coming from a free zone than an infected zone. In fact those three articles could be reduced to one and only article dealing with risk species/animals (birds other than poultry, geese and ducks) and providing for each situation.**

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

1. the animals were kept in a WNF free country; ~~or zone or compartment~~ since birth or for at least 30 days prior to shipment; or
2. the animals were kept in a WNF free country; ~~or zone or compartment~~ for at least 7 days, were subjected, with negative results, to an agent identification test according to the Terrestrial Manual, ~~with negative results~~, carried out on a sample collected at least 3 days after the commencement of the residence period and remained in the WNF free country; ~~or zone or compartment~~ until shipment; or
3. the animals:
  - a) were vaccinated in accordance with the Terrestrial Manual 30 days before introduction into the free country; ~~or zone or compartment~~; and
  - b) were identified as having been vaccinated; and
  - c) were kept in a WNF free country or *zone* for at least 7 days; and
  - d) remained in the WNF free country or *zone* until shipment;

AND

4. if the animals were exported from a WNF 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 ~~WNV~~ mosquito ~~vectors~~ at all times when transiting through an infected *zone*; or
  - c) had been vaccinated in accordance with point 3 above.

Article 2.2.XX.6.

When importing from WNF seasonally free countries or zones, Veterinary Administrations Authorities should require:

for susceptible species

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

1. were kept during the seasonally free period in a WNF seasonally free country or *zone* for at least 30 days prior to shipment; or
2. were kept during the WNF seasonally free period in a WNF seasonally free country or *zone* for at least 7 days prior to shipment, and were subjected during the residence period in the country or *zone* to an agent identification test according to the Terrestrial Manual, with negative results, carried out ~~at~~ ~~carried~~ ~~out~~ on a sample collected at least 3 days after the commencement of the residence period and remained in the WNF seasonally free country; or *zone* until shipment; or
3. were kept during the seasonally free period in a WNF seasonally free country or *zone*, and were vaccinated in accordance with the Terrestrial Manual 30 days before introduction into the free country or *zone* against WNF, were identified as having been vaccinated and remained in the WNF seasonally free country or *zone* until shipment;

AND

4. if the animals were exported from a WNF-free country or *zone*, either:
  - a) did not transit through an infected country or *zone* during transportation to the place of shipment; or
  - b) were protected from attack from ~~WNV~~ mosquito ~~vectors~~ at all times when transiting through an infected country or *zone*; or
  - c) were vaccinated in accordance with point 3 above.

Article 2.2.XX.7.

When importing from WNF infected countries or zones, Veterinary Administrations Authorities should require:

for susceptible species

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

1. were protected from attack from ~~WNV~~ mosquito ~~vectors~~ for at least 30 days prior to shipment; or
2. were subjected to a serological test according to the Terrestrial Manual to detect WNV neutralizing antibodies with positive results; or
3. were protected from attack from ~~WNV~~ mosquito ~~vectors~~ for at least 15 days prior to shipment, and were subjected during that period to an agent identification test according to the Terrestrial Manual, with negative results, carried out on a sample collected at least 3 days after being introduced in the mosquito free *zone*; or
4. were vaccinated in accordance with the Terrestrial Manual at least 30 days before shipment, against WNV, and were identified in the accompanying certification as having been vaccinated; or
5. are not vaccinated and a surveillance programme in accordance with Appendix 3.8.X. has been in place in the source population for a period of 30 days immediately prior to shipment, and no evidence of WNV transmission has been detected;

AND

6. were protected from attack from ~~WNV~~ mosquito ~~vectors~~ during transportation to the place of shipment; ~~or~~
7. ~~were vaccinated 30 days before shipment or had antibodies against WNV.~~

Article 2.2.XX.8.

When importing wild birds Veterinary Administrations Authorities should require the presentation of an international veterinary certificate attesting that

1. showed no clinical sign of WNF on the day of shipment; and
2. the birds were kept in a quarantine station in a mosquito-free environment for 30 days prior to shipment, and were subjected, with negative results, to an agent identification test according to the Terrestrial Manual carried out on samples collected at least 3 days after the commencement of the residence period.

**Community comments:**

**The Community does not agree with the testing of each bird e.g. finches, and in any case is this necessary for all species? In addition why should this apply to a free country or zone? Finally there could be provision for quarantine after import.**

Article 2.2.XX.9.

**Protecting animals from WNV mosquito vectors**

When transporting animals through WNF infected countries or ~~zones~~, Veterinary Administrations Authorities should require strategies to protect animals from attack from WNV mosquito vectors during transport, taking into account the local ecology of the vectors.

Potential risk management strategies include:

1. treating animals with chemical repellents prior to and during transportation;
2. ensuring vehicles do not stop en route unless the animals are held behind insect proof netting;
3. surveillance for vectors at common stopping and offloading points to gain information on seasonal variations;
4. integrated pest management practices at holding, common stopping and offloading points;
5. using historical, ongoing and/or WNF modelling information to identify low risk ports and transport routes.— text deleted



## DRAFT GUIDELINES ON THE DESIGN AND IMPLEMENTATION OF IDENTIFICATION SYSTEMS TO ACHIEVE ANIMAL TRACEABILITY

### Community comments:

**The Community welcomes the work of the TAHSC on these draft Guidelines. Some comments should still be taken into account as they are important for the practical field application and usefulness of the guidelines.**

### INTRODUCTION AND OBJECTIVES

These guidelines are based on the general principles presented in Article 3.5.1.1. The Guidelines outline for Member Countries the basic elements that need to be taken into account in the design and implementation of an *animal identification system* to achieve *animal traceability*. Whatever *animal identification system* the country adopts, it should comply with relevant OIE standards. Each country should design a program in accordance with the scope and relevant performance criteria to ensure that the desired *animal traceability* outcomes can be achieved.

### DEFINITIONS

These following definitions apply for the purpose of this Appendix.

***Desired outcomes:*** describe the overall goals of a programme and are usually expressed in qualitative terms, e.g. 'to help ensure that animals and/or animal products are safe and suitable for use'. Safety and suitability for use could be defined in terms such as animal health, food safety, trade and husbandry aspects.

***Performance criteria:*** are specifications for performance of a programme and are usually expressed in quantitative terms, such as 'all animals can be traced to the *establishment* of birth within 48 hours of an enquiry'.

***Reporting:*** means advising the *Veterinary Administration Authority* in accordance with the procedures listed in the programme.

***Scope:*** specifies the targeted species, population and/or production/trade sector within a defined area (country, zone) or compartment that is the subject of the identification and traceability programme.

***Transhumance:*** periodic/seasonal movements of *animals* between different pastures or premises within or between countries.

### KEY ELEMENTS OF THE ANIMAL IDENTIFICATION SYSTEM

#### 1. Desired outcomes

Desired outcomes should be defined through consultation between the *Veterinary Administration Authority* and other parties, which should include (depending on scope) animal producers and food processors, private sector veterinarians, scientific research organisations and other government agencies. Desired outcomes may be defined in terms of any or all of the following:

- a) animal health (e.g. *disease* surveillance and notification; detection and control of *disease*;



vaccination programmes);

- b) public health (e.g. surveillance and control of zoonotic diseases and food safety);
- c) management of emergencies e.g. natural catastrophies or man-made events;
- d) trade (support for inspection and certification activities of *Veterinary Services*).
- e) animal husbandry aspects (e.g. animal performance, genetic data)

## 2. Scope

Scope should also be defined through consultation between the *Veterinary Administration Authority* and other parties, as discussed above. The scope of *animal identification systems* is often based on the definition of a species and sector, to take account of particular characteristics of the farming systems e.g. pigs in pork export production; cattle within a defined FMD-free zone. Different systems will be appropriate according to the production systems used in countries and the nature of their industries and trade.

## 3. Performance criteria

Performance criteria are also designed in consultation with other parties, as discussed above. The performance criteria depend on the desired outcomes and scope of the program. They are usually described in quantitative terms. For example, some countries consider it necessary to trace susceptible animals within 24-48 hours when dealing with highly contagious *diseases* such as FMD and avian influenza. For food safety, animal tracing to support investigation of incidents may also be urgent. For chronic animal *diseases*, such as bovine ~~para~~tuberculosis it may be considered appropriate that animals can be traced within 30 days.

## 4. Preliminary studies

In designing *animal identification systems* it is useful to conduct preliminary studies, which should take into account:

- a) Animal populations, species, distribution, herd management
- b) Farming and industry structures, production and location
- c) Animal health
- d) Public health
- e) Trade issues
- f) Animal husbandry

### **Community comments:**

**The Community believes that animal husbandry management is covered by a) and b) and suggests that it should be replaced by the words “Animal breeding.” to cover the herd book etc.**

- fg) Zoning and compartmentalisation
- gh) Animal movement patterns (including transhumance)
- hi) Information management and communication

- ij) Availability of resources (human and financial)
- jk) Social and cultural aspects
- kl) Stakeholder knowledge of the issues and expectations
- lm) Gaps between current enabling legislation and what is needed long term
- mn) International experience
- no) National experience
- op) Available technology options
- q) Existing identification system(s).
- r) Benefits from the identification scheme and to whom they accrue

Pilot projects may form part of the preliminary study to test the *animal identification system* and *animal traceability* and to gather information for the design and the implementation of the programme

Economic analysis may consider costs, benefits, funding mechanisms and sustainability.

#### 5. Design of the programme

##### a) General provisions

The programme should be designed in consultation with the stakeholders to facilitate the implementation of the *animal identification system* and *animal traceability*. It should take into account the scope, performance criteria and desired outcomes as well as the results of any preliminary study.

All the specified documentation should be standardised as to format, content and context.

To protect and enhance the integrity of the system, procedures should be incorporated into the design of the programme to prevent, detect and correct errors e.g. use of algorithms to prevent duplication of identification numbers in an electronic database.

##### b) Means of animal identification

The choice of a physical animal identifier should take into account elements such as the durability, human resources, species and age of the animals to be identified, required period of identification, *animal welfare*, cultural aspects, technology compatibility and relevant standards, farming practices, animal population, climatic conditions, resistance to tampering, trade considerations, cost, and retention and readability of the identification method.

The *Veterinary Administration Authority* is responsible for approving the materials and equipment chosen, to ensure that these means of animal identification comply with technical and field performance specifications, and for the supervision of their distribution. The *Veterinary Administration Authority* is also responsible for ensuring that identifiers are unique and are used in accordance with the requirements of the *animal identification system*.

|                           |
|---------------------------|
| <b>Community comment:</b> |
|---------------------------|

**In order to be clearer and applicable the paragraph should be slightly modified:**

**The word "materials" should be replaced by "identifiers" (as the Veterinary Authority cannot approve all the materials), and the words "their distribution" by "the distribution of the identifiers" (as the Veterinary Authority cannot supervise the distribution of all the equipments). The word "individual" should be inserted between "ensuring that" and "identifiers", as the same group identifier is applied to all the animals of the group. An alternative would be to replace "identifiers" by "identifying numbers or codes".**

The *Veterinary Administration Authority* should establish procedures for *animal identification* and *animal traceability* including:

- i) The time period within which an animal born on an *establishment* should be identified.
- ii) Animals imported into an *establishment*.

**Community comment:**

**For coherence with the rest, the word "Animals" should be replaced by the words "When animals are".**

iii) When an animal loses its identification or the identifier becomes unusable.

iv) Arrangements and rules for the destruction and/or reuse of identifiers.

Where group identification without a physical identifier is adequate, documentation should be created specifying at least the number of animals in the group, the species, the date of identification, the person legally responsible for the animals and/or establishment. This documentation constitutes a unique group identifier.

Where all animals in the group are physically identified with a group identifier, documentation should also specify the unique group identifier.

**Community comment:**

**These last two paragraphs are not clear.**

**At the end of the second should be added the words "number or code".**

- c) Registration

Procedures need to be incorporated into the design of the programme in order to ensure that relevant events and information are registered in a timely and accurate manner.

Depending on the scope, performance criteria and desired outcomes, records as described below should specify, at least, the species, the unique animal or group identifier, the date of the event, the identifier of the *establishment* where the event took place, and the code for the event itself.

- i) Establishments/owners

**Community comment:**

**The Community reiterates its comment: the word "owners" is too restrictive, as the owner is not always the person responsible for the animals. The word "keepers" should be used instead everywhere in the text, as well as "keepership" should replace "ownership" in point iv) under.**

*Establishments* where animals are kept should be identified and registered, including at least their physical location (such as geographical coordinates or street address), the type of *establishment* and the species kept. The register should include the name of the person legally responsible for the animals at the *establishment*.

The types of establishments that may need to be registered include holdings (farms), assembly centres (e.g. agriculture shows and fairs, sporting events, transit centres, breeding centres), *markets*, *abattoirs*, rendering plants, dead stock collection points, transhumance areas, centres for necropsy and diagnosis, research centres, zoos, *border posts*, *quarantine stations*.

In cases where the registration of establishments is not applicable e.g. some transhumance systems, the animal owner, the owner's place of residence and the species kept should be recorded.

## ii) Animals

*Animal identification* and species should be registered for each *establishment/owner*. Other relevant information about the animals at each establishment/owner may also be recorded e.g. date of birth, production category, sex, breed, *animal identification* of the parents.

## iii) Movements

The *registration* of animal movements is necessary to achieve *animal traceability*. When an animal is introduced into or leaves an *establishment*, these events constitute a movement.

Some countries classify birth, *slaughter* and *death* of the animal as movements.

The information registered should include the date of the movement, the *establishment* from which the animal or group of animals was dispatched, the number of animals moved, the destination *establishment*, and any in transit *establishment*.

When *establishments* are not registered as part of the *animal identification system*, ownership and location changes constitute a movement record. Movement recording may also include means of *transport* and the *vehicle* identifier.

Procedures should be in place to maintain *animal traceability* during *transport* and when animals arrive and leave an *establishment*.

## iv) Events other than movements

The following events may also be *registered*:

- birth, *slaughter* and *death* of the animal (when not classified as a movement)
- attachment of the unique identifier to an animal

- change of ownership regardless of change of *establishment*
- observation of an animal on an *establishment* (testing, health investigation, health certification, etc.)
- animal imported: a record of the *animal identification* from the *exporting country* should be kept and linked with the *animal identification* assigned in the *importing country*.
- animal exported: a record of the *animal identification* from the *exporting country* should be provided to the *Veterinary Administration Authority* in the *importing country*.
- animal identifier lost or replaced
- animal missing (lost, stolen, etc)
- animal identifier retired (at *slaughter*, following loss of the identifier or death of the animal on a farm, at diagnostic laboratories, etc)

**d) Documentation**

Documentation requirements should be clearly defined and standardised, according to the scope, performance criteria and desired outcomes and supported by the legal framework.

**e) Reporting**

Depending on the scope, performance criteria and desired outcomes, relevant information (such as *animal identification*, movement, events, changes in numbers of livestock, *establishments*) should be reported to the *Veterinary Administration Authority* by the person responsible for the animals.

**f) Information system**

An information system should be designed according to the scope, performance criteria and desired outcomes. This may be paper based or electronic. The system should provide for the collection, compilation, storage and retrieval of information on matters relevant to *registration*. The following considerations are important:

- Have the potential for linkage to traceability in the other parts of the food chain.
- Minimise duplication.
- Relevant components, including databases, should be compatible.
- Confidentiality of data.
- Appropriate safeguards to avoid loss of data, including backup system.

The *Veterinary Administration Authority* should have access to this information system as appropriate to meet the scope, performance criteria and desired outcomes.

**g) Laboratories**

The results of diagnostic tests should record the animal identifier or the group identifier and the *establishment* where the sample was collected.

**h) *Abattoirs*, rendering plants, dead stock collection points, markets, assembly centres**

*Abattoirs*, rendering plants, dead stock collection points, *markets* and assembly centres should document arrangements for the maintenance of *animal identification* and *animal traceability* in compliance with the legal framework.

These *establishments* are critical points for control of animal health and food safety.

*Animal identification* should be recorded on documents accompanying samples collected for analysis.

The components of the *animal identification system* operating within *abattoirs* should complement and be compatible with arrangements for tracking animal products throughout the food chain. At an *abattoir*, *animal identification* should be maintained during the processing of the animal's carcass until the carcass is deemed fit for human consumption.

The *animal identification* and the *establishment* from which the animal was dispatched should be registered by the *abattoir*, rendering plant and dead stock collection points.

*Abattoirs*, rendering plants and dead stock collection points should ensure that identifiers are collected and disposed of according to the procedures established and regulated within the legal framework. These procedures should minimize the risk of unauthorized reuse and, if appropriate, should establish arrangements and rules for the reuse of identifiers.

Reporting of movement by *abattoirs*, rendering plants and dead stock collection points should occur according to the scope, performance criteria and desired outcomes and the legal framework.

i) Penalties

Different levels and types of penalties should be defined in the programme and supported by the legal framework

ii) Commercial arrangements

An animal identification system requires producers, processors and others (depending on the design of the system) to purchase equipment. There are many possible commercial arrangements that will have a variety of implications for the uptake of the animal identification system.

k) Transition planning

Any transition from an existing animal identification system needs to be designed to ensure it is easy for users of the existing system to make the change and to insure that data integrity is maintained during the transition and integrated into the new animal identification system.

l) Use of incentives

Depending on the drivers for participation in the animal identification scheme, incentives may be useful to encourage early adoption of the system or to fill capability, capacity or technology gaps.

6. Legal framework

The *Veterinary Administration Authority*, with other relevant governmental agencies and in consultation with stakeholders, should establish a legal framework for the implementation and enforcement of *animal identification system* and *animal traceability* in the country. The structure of this framework will vary from country to country.

*Animal identification, animal traceability* and animal movement should be under the responsibility of the *Veterinary Administration Authority*.

This legal framework should address:

- i) desired outcomes and scope
- ii) obligations of the *Veterinary Administration Authority* and other parties
- iii) organisational arrangements, including the choice of technologies and methods used for the *animal identification system* and *animal traceability*
- iv) management of animal movement
- v) confidentiality of data
- vi) data access / accessibility
- vii) checking, verification, inspection and penalties
- viii) where relevant, funding mechanisms
- ix) where relevant, arrangements to support a pilot project.

## 7. Implementation

### a) Action plan

For implementing the *animal identification system*, an action plan should be prepared specifying the timetable and including the milestones and performance indicators, the human and financial resources, and checking, enforcement and verification arrangements.

The following activities should be addressed in the action plan:

#### i) Communication

The scope, performance criteria, desired outcomes, responsibilities, movement and registration requirements and sanctions need to be communicated to all parties. Communication strategies need to be targeted to the audience, taking into account elements such as the level of literacy (including technology literacy) and spoken languages.

#### ii) Training programmes

It is desirable to implement training programmes to assist the *Veterinary Services* and other parties.

#### iii) Technical support

Technical support should be provided to address practical problems.

### b) Checking and Verification

Checking activities should start at the beginning of the implementation to detect, prevent and correct errors and to provide feedback on programme design.

Verification should begin after a preliminary period as determined by the *Veterinary Administration Authority* in order to determine compliance with the legal framework and operational requirements.

c) Auditing

Auditing should be carried out under the authority of the *Veterinary Administration Authority* to detect any problems with the *animal identification system* and *animal traceability* and to identify *possible* improvements.

d) Review

The programme should be subject to periodic review, taking into account the results of *checking*, verification and auditing activities.

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— text deleted





## **GUIDELINES FOR THE CONTROL OF HAZARDS OF ANIMAL HEALTH AND PUBLIC HEALTH IMPORTANCE IN ANIMAL FEED**

### **Community comments:**

**The Community welcomes the TAHSC work in this field but believes that still more clarity is needed in particular for the definitions. It wishes to participate to this work and keeps its experts at OIE's disposition. Some comments have been inserted in the text below, but more comments could be provided to the members of the ad hoc group.**

**These Guidelines should also address the issue of feed homogeneity, which is an important part of feed safety. A too high concentration of one of the feed component because of bad homogeneity could lead to animal and/or public health hazards.**

## **PART 1**

### **INTRODUCTION**

Animal feed is a critical component of the food-chain that has a direct impact on animal health and welfare and also on food safety and public health.

Historically, the OIE primarily addressed animal feed as an important pathway for the entry and spread of contagious epidemic *diseases*, such as foot and mouth disease, swine vesicular disease and avian influenza. In recent years, the role of feed as a vector for *disease* agents, including zoonotic organisms, was a focus of standards development in regards to bovine spongiform encephalopathy. Animal feed and feed ingredients are widely traded internationally and trade disruptions have the potential to impact economies in both developed and developing countries. Since 2002 the OIE has expanded its zoonotic disease mandate to encompass animal production food safety, working in collaboration with the Codex Alimentarius Commission (CAC) and other international organisations. In 2006 the International Committee resolved that the OIE should develop guidance on foodborne zoonoses and animal feeding, complementing relevant CAC texts.

### **PURPOSE OBJECTIVE AND SCOPE**

The purpose objective of this OIE guideline is to provide guidance on animal feeding in relation to animal health and to complement the guidance provided by the Codex Code of Practice on Good Animal Feeding (CAC/RCP 54-2004) which deals primarily with food safety.

This guideline aims at ensuring the control of animal and public health hazards through adherence to recommended practices during the production (procurement, handling, storage, processing and distribution) and use of both commercial and on-farm produced animal feed and feed ingredients for food producing animals.

### **SCOPE**

This guideline applies to the production and use of all products destined for animal feed and feed ingredients at all levels whether produced commercially or on farm. It also includes grazing or free-range

feeding, forage crop production and water for drinking. Swill feeding is a particular aspect of on-farm practice that is specifically addressed because of its recognised role in *disease* transmission.

~~This~~ ~~These~~ ~~e~~ Guidelines deals with food or feed for terrestrial ~~food-producing~~ animals, ~~other than aquatic animals~~ (i.e. livestock and poultry).

**Community comment:**

**The word "food" should not be used for animals and should be deleted as it is confusing in the context of this chapter relating to animal feed.**

## DEFINITIONS

### *Hazard*

means a biological, chemical or physical agent in, or a condition of, ~~feed or a feed ingredient~~ an animal or animal product with the potential to cause an adverse effect ~~on animal or public health~~.

**Community comment:**

**The Community does not see why this definition should be limited to animal products as there can be potential hazards for animals in vegetal products.**

**The following wording is suggested: "of an animal, a feed, a feed ingredient or product, including of animal origin".**

### *Feed*

means any material (single or multiple), whether processed, semi-processed or raw, which is intended to be fed directly to food-producing animals.

**Community comment:**

**The Community does not see why the scope would be only food-producing animals. The words "food-producing" should be deleted.**

### *Feed additives*

means any intentionally added ingredient not normally consumed as feed by itself, whether or not it has nutritional value, which affects the characteristics of feed, ~~or~~ health of the animal and the characteristics of products. Microorganisms, enzymes, acidity regulators, trace elements, vitamins and other products fall within the scope of this definition depending on the purpose of use and method of administration. This excludes veterinary drugs.

**Community comment:**

**If the feed additive "affects the health of the animal", then it is a veterinary medicine or medicated feed. Thus the word "health" should not be inserted and the idea should be formulated otherwise e.g. "which affects the characteristics of feed or products and can have a physiological effect on the animals".**

**Furthermore, it is unclear what is meant by "products".**

### *Medicated feed*

means any feed which contains a veterinary drug administered to food producing animals, for therapeutic or prophylactic purposes or for modification of physiological functions.

**Community comment:**

**The following should be included in the definition: "Medicated feed is a veterinary medicinal product; it can only be delivered and administered to animals after a prescription by a veterinarian".**

***Feed ingredient***

means a component part or constituent of any combination or mixture making up a feed, whether or not it has a nutritional value in the animal's diet, including feed additives. Ingredients are of plant, or animal or aquatic origin, or other organic or inorganic substances.

***Undesirable substance***

means a ~~contaminant or other substance~~ material which is present in and/or on feed and feed ingredients and ~~which constitute a risk~~ whose presence is potentially harmful to animal or public health and/or is restricted under current regulations.

***Commercial feed***

means all materials that are sold and distributed as feed, or to be mixed with feed, for animals except: unmixed seed, whole, processed, or unprocessed; straw, stover, silage, cobs, husks, and hulls; or individual chemical compounds not mixed with other ingredients.

**Community comment:**

**The Community does not see the interest of this definition, which could be deleted.**

**~~*Cross contamination*~~**

means ~~contamination~~ the presence of a material or product ~~with another material or product containing a component that~~ in a feed or feed additive and whose presence in that feed or feed additive is potentially harmful for animal or public health or is restricted under the regulatory framework current regulations.

**Community comment:**

**The words "or biological, chemical or physical agent" should be added after the words "material or product".**

**Furthermore, a clear definition should be added for "cross contamination".**

## GENERAL PRINCIPLES

### Roles and responsibilities

The Competent Authority has the legal power to set and enforce regulatory animal feeding requirements, and has final responsibility for verifying that these requirements are met. The Competent Authority may establish regulatory requirements for relevant parties to provide it with information and assistance. Refer to Chapters 1.3.3. and 1.3.4. of the OIE *Terrestrial Code*.

Those involved in the production and use of animal feed and feed ingredients have the responsibility to ensure that these products meet regulatory requirements. All personnel involved in the manufacture, storage and handling of feed and feed ingredients should be adequately trained

and aware of their role and responsibility in preventing the spread of ~~animal health and public health~~ hazards. Appropriate contingency plans should be developed. Equipment should be maintained in good working order and in a sanitary condition.

**Community comment:**

**The words "occurrence and/or" should be added before the words "in preventing the". Furthermore, the word "Equipment" should be replaced by "Manufacturing equipment, storage and transport facilities". Requirements regarding cleaning and disinfection of transport vehicles should be more clearly addressed including restrictions for transport of hazardous chemicals before the transport of feed (to avoid undesirable cross-contamination).**

It is a particular responsibility of Veterinary Services to set and enforce the regulatory requirements pertaining to the use of veterinary drugs, animal *disease* control and the food safety aspects that relate to the management of live animals on farm.

**Community comment:**

**The words "feed and" should be added before the words "food safety".**

Those providing specialist services to producers and to the feed industry (e.g. private veterinarians and laboratories) may be required to meet specific regulatory requirements pertaining to the services they provide (e.g. *disease* reporting, quality standards, transparency).

**Regulatory safety standards**

All feed and feed ingredients should meet regulatory safety standards. In defining limits and tolerances for hazards, scientific evidence, including the sensitivity of analytical methods and on the characterisation of risks, should be taken into account.

**Community comment: The wording should be amended to read: "technical and/or scientific evidence".**

**Risk analysis (risk assessment, risk management and risk communication)**

Internationally accepted principles and practices on risk analysis (Section 1.3. of the OIE *Terrestrial Code*; and relevant Codex texts) should be used in developing and applying the regulatory framework.

Application of a generic framework should provide a systematic and consistent process for managing all biosecurity risks, while recognising the different risk assessment methodologies used in animal and public health.

**Good practices**

Where national guidelines exist, good agricultural practices and good manufacturing practices (including good hygienic practices) should be followed. Countries without such guidelines are encouraged to develop them.

Where appropriate, Hazard Analysis and Critical Control Point (HACCP) principles should be followed to control hazards that may occur in the manufacture of feed and feed additives.

**Community comment:**

**The words ", medicated feed" should be added before the words "and feed additives".**

#### **Geographic and environmental considerations**

Land and facilities used for production of animal feed and feed ingredients and water sources should not be located in close proximity to sources of hazards for animal health or food safety. Animal health considerations include factors such as *disease* status, location of quarantined premises and existence of *zones/compartments* of specified health status. Food safety considerations include factors such as industrial operations that generate pollutants and waste treatment plants.

#### **Zoning and compartmentalisation**

Feed is an important component of biosecurity and needs to be considered when defining a compartment or zone in accordance with Chapter 1.3.5. of the OIE *Terrestrial Code*.

#### **Sampling and analysis**

Sampling and analytical protocols should be based on scientifically recognized principles and procedures.

#### **Labelling**

Labelling on how the feed or feed ingredients should be handled, stored and used should be ~~clear and~~ informative as to ~~how the feed and feed ingredients should be handled, stored and used~~ unambiguous, legible and conspicuously placed on the package if sold in bagged form and on the waybill and other sales documents if sold in bulk, un-bagged form, and should comply with regulatory requirements.

#### **Community comment:**

**The words ", medicated feed" should be added before the words "or feed ingredients".**

See Codex Code of practice on good animal feeding (CAC/RCP 54-2004).

#### **Design and management of inspection programmes**

In meeting animal and public health objectives prescribed in national legislation or required by *importing countries*, Competent Authorities contribute through the direct performance of some tasks or through the auditing of animal and public health activities conducted by other agencies or the private sector.

#### **Community comment:**

**The words "performance of some tasks" are unclear and should be replaced by the words "physical inspection".**

Feed and feed ingredients business operators and other relevant parts of industry should practice self-regulation to secure compliance with required standards for procurement, handling, storage, processing, distribution and use. Operators have the primary responsibility for implementing systems for process control. ~~Where such systems are applied, the~~ Competent Authority should verify that they achieve all regulatory requirements.

#### **Assurance and certification**

*Competent Authorities* are responsible for providing assurances domestically and to trading partners that regulatory ~~requirements~~ safety standards have been met. For international trade in animal product based feeds, *Veterinary Services* are required to provide international veterinary certificates.

#### **Community comment**

**The following sentence should be added at the beginning of the paragraph: "Feed business operators are responsible for demonstrating the safety of the establishments under their control."**

#### **Hazards associated with animal feed**

##### Biological hazards

Biological hazards that may occur in feed and feed ingredients include agents such as bacteria, viruses, prions, fungi and parasites.

##### Chemical hazards

Chemical hazards that may occur in feed and feed ingredients include naturally occurring chemicals (such as mycotoxins and gossypol), industrial and environmental contaminants (such as dioxins and PCBs), residues of veterinary drugs and pesticides and also radionuclides.

#### **Community comment:**

**The words "toxic botanical impurities," should be added before the word "mycotoxins", and the word ", biocides" before the words "and pesticides".**

##### Physical hazards

Physical hazards that may occur in feed and feed ingredients include foreign objects (such as pieces of glass, metal, plastic or wood).

#### **Cross contamination**

It is important to avoid cross-contamination during the manufacture, storage, distribution (including transport) and use of feed and feed ingredients and relevant provisions should be included in the regulatory framework. Scientific evidence, including the sensitivity of analytical methods and on the characterisation of risks, should be drawn upon in developing this framework.

**Community comment: The wording should be amended to read: "technical and/or scientific evidence".**

Procedures, such as flushing, sequencing and physical clean-out, should be used to avoid cross-contamination between batches of feed or feed ingredients.

#### **Antimicrobial resistance**

Concerning the use of antimicrobials in animal feed refer to Section 3.9. of the OIE *Terrestrial Code*.

#### **Management of information**

The Competent Authority should establish clear requirements for the provision of information by the private sector as this relates to regulatory requirements.

Records should be maintained in a readily accessible form regarding the production, distribution and use of feed and feed ingredients. These records are required to facilitate the prompt trace-back of feed and feed ingredients to the immediate previous source, and trace-forward to the next subsequent recipients, to address identified animal health or public health concerns.

*Animal identification* and *animal traceability* are tools for addressing animal health (including zoonoses), and food safety risks arising from animal feed (see Section 3.5. of the OIE *Terrestrial Code*; Section 4.3. of CAC/RCP 54-2004).

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## APPENDIX 3.7.2.

## GUIDELINES FOR THE TRANSPORT OF ANIMALS BY SEA

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

## Article 3.7.2.1.

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

## Article 3.7.2.2

1. 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.

The desire of some animals to control their personal space should be taken into account in designing *loading* and *unloading* facilities, transport *vessels* and *containers*.

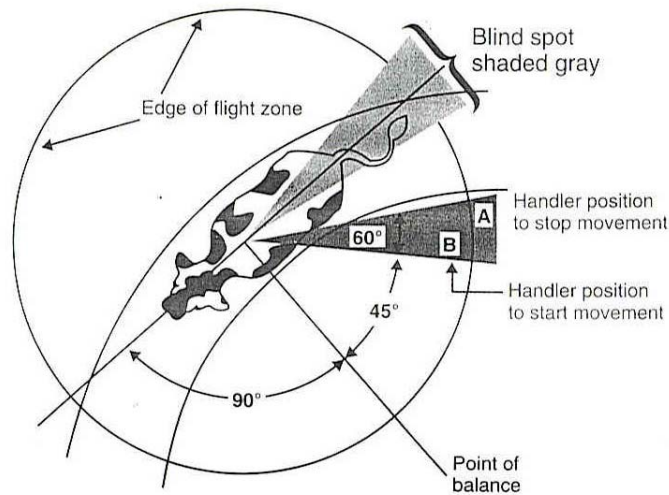
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|--|
| <p><b>Community comment:</b></p> <p><b>The following words should be added at the end of the paragraph:" and compromise the welfare of the animals".</b></p> |
|--|

Domestic animals will try to escape if any person 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

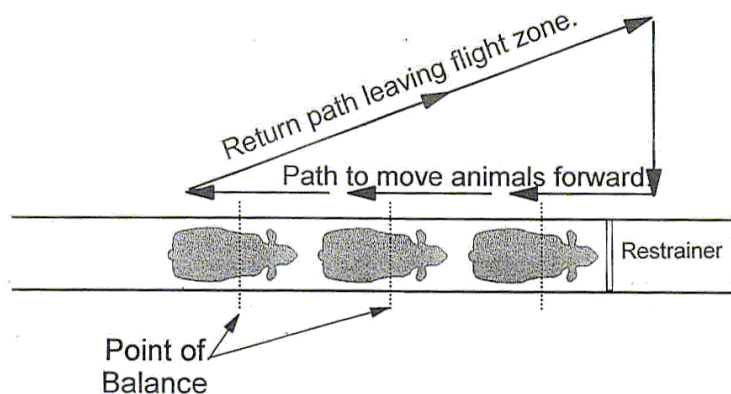


humans (i.e. tame) have a smaller flight zone, whereas those kept in free range or extensive systems may have flight zones which may vary from one metre to many metres. *Animal handlers* should avoid sudden penetration of the flight zone which may cause a panic reaction which could lead to aggression or attempted escape.

#### An example of a flight zone (cattle)



#### Animal handler movement pattern to move cattle forward



*Animal handlers* should use the point of balance at the 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 a wide-angle vision but only have a 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.

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 noises and by sudden noises, which

may cause them to panic. Sensitivity to such noises should also be taken into account when handling animals.

## 2. Distractions and their removal

Design of new *loading* and *unloading* facilities or modification of existing facilities should aim to minimise the potential for distractions that may cause approaching animals to stop, baulk or turn back. Below are examples of common distractions and methods for eliminating them:

- a) reflections on shiny metal or wet floors - move a lamp or change lighting;
- b) dark entrances - illuminate with indirect lighting which does not shine directly into the eyes of approaching animals;
- c) animals seeing moving people or equipment up ahead - install solid sides on chutes and races or install shields;
- d) dead ends-avoid if possible by curving the passage, or make an illusory passage;
- e) chains or other loose objects hanging in chutes or on fences - remove them;
- f) uneven floors or a sudden drop in floor levels – avoid uneven floor surfaces or install a solid false floor to provide an illusion of a solid and continuous walking surface;
- g) sounds of air hissing from pneumatic equipment - install silencers or use hydraulic equipment or vent high pressure to the external environment using flexible hosing;
- h) clanging and banging of metal objects - install rubber stops on gates and other devices to reduce metal to metal contact;
- i) air currents from fans or air curtains blowing into the face of animals - redirect or reposition equipment.

### Article 3.7.2.3.

#### **Responsibilities**

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

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

#### **Previous Community comment:**

**In the following paragraph the word "importers" and the related text should be deleted**

#### **Justification:**

**For the moment it is not clear what the definition and the responsibilities for importers are.**

## 1. General considerations

- a) Exporters, importers, owners of animals, business or buying/selling agents, shipping companies, masters of *vessels* and managers of facilities are jointly responsible for the general health of the animals and their fitness for the *journey*, and for their overall welfare during the *journey*, regardless of whether duties are subcontracted to other parties during transport.
- b) Exporters, shipping companies, business or buying/selling agents, and masters of *vessels* are jointly responsible for planning the *journey* to ensure the care of the animals, including:
  - i) choosing appropriate *vessels* and ensuring that *animal handlers* are available to care for the animals;

**Community comment:**

**On the following point (ii) between the word "adverse" and "weather", add the following wording " sea and ".**

**Justification:**

**In order to clarify the conditions during transport.**

- ii) developing and keeping up to date contingency plans to address emergencies (including adverse weather conditions) and minimise stress during transport;
  - iii) correct *loading* of the ship, provision of appropriate food, water, ventilation and protection from adverse weather, regular inspections during the *journey* and for appropriate responses to problems arising;
  - iv) disposal of carcasses according to international law.
  - c) To carry out the above mentioned responsibilities, the parties involved should be competent regarding transport regulations, equipment usage, and the humane handling and care of animals.
2. Specific considerations
- a) The responsibilities of the exporters include:
    - i) the organisation, carrying out and completion of the *journey*, regardless of whether duties are subcontracted to other parties during transport;
    - ii) ensuring that equipment and medication are provided as appropriate for the species and the *journey*;
    - iii) securing the presence of the appropriate number of *animal handlers* competent for the species being transported;
    - iv) ensuring compliance of the animals with any required veterinary certification, and their fitness to travel;
    - v) in case of animals for export, ensuring compliance with any requirements of the *importing and exporting countries*.
  - b) The responsibilities of the importers include:  
(under study)

- c) The responsibilities of the owners of the animals include the selection of animals that are fit to travel based on veterinary recommendations.
- d) The responsibilities of the business or buying/selling agent include:
  - i) selection of animals that are fit to travel based on veterinary recommendations;
  - ii) availability of suitable facilities for the assembly, *loading*, transport, *unloading* and holding of animals at the start and at the end of the *journey*, and for emergencies.
- e) The responsibilities of shipping companies include:
  - (under study)

**Community comment:**

**At the following point (f) add: "and to consider adverse weather and sea conditions which can be expected during the journey".**

- f) The responsibilities of masters of *vessels* include the provision of suitable premises for animals on the *vessel*.
- g) The responsibilities of managers of facilities during *loading* include:
  - i) providing suitable premises for *loading* the animals;
  - ii) providing an appropriate number of *animal handlers* to load the animals with minimum stress and the avoidance of injury;
  - iii) minimising the opportunities for *disease* transmission while the animals are in the facilities;
  - iv) providing appropriate facilities for emergencies;
  - v) providing facilities, *veterinarians* or *animal handlers* capable of *killing* animals humanely when required.
- h) The responsibilities of managers of facilities during *unloading* include:
  - i) 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;
  - ii) providing *animal handlers* to unload the animals with minimum stress and injury;
  - iii) minimising the opportunities for *disease* transmission while the animals are in the facilities;
  - iv) providing appropriate facilities for emergencies;
  - v) providing facilities, and *veterinarians* or *animal handlers* capable of *killing* animals humanely when required.
- i) The responsibilities of the *animal handlers* include humane handling and care of the animals, especially during *loading* and *unloading*.
- j) The responsibilities of the *Competent Authority* of the *exporting country* include:

- i) establishing minimum standards for animal welfare, including requirements for inspection of animals before and during their travel, and for certification and record keeping;
- ii) approving facilities, *containers, vehicles/vessels* for the holding and transport of animals;
- iii) setting competence standards for *animal handlers* and managers of facilities;
- v) implementation of the standards, including through accreditation of / interaction with other organisations and *Competent Authorities*;

**Previous Community comment:**

**Point vi) The part of the sentence "performance...medications" should be replaced by "of the animals at the point of loading"**

**Justification:**

**The new wording clarifies the responsibilities of the competent authorities which correspond to their practical and legal ability to verify animal welfare standards.**

- vi) monitor and evaluate health and welfare performance, including the use of any veterinary medications.
- k) The responsibilities of the *Competent Authority* of the *importing country* include:
  - i) establishing minimum standards for animal welfare, including requirements for inspection of animals after their travel, and for certification and record keeping;
  - ii) approve facilities, *containers, vehicles/vessels* for the holding and transport of animals;
  - iii) setting competence standards for *animal handlers* and managers of facilities;
  - iv) implementation of the standards, including through accreditation of / interaction with other organisations and *Competent Authorities*;
  - v) ensuring that the *exporting country* is aware of the required standards for the *vessel* transporting the animals;

**Previous Community comment:**

**Point vi) The part of the sentence "performance...medications" should be replaced by "of the animals at the point of unloading".**

**Justification:**

**The new wording clarifies the responsibilities of the competent authorities which correspond to their practical and legal ability to verify animal welfare standards.**

- vi) monitor and evaluate health and welfare performance, including the use of any veterinary medications.
- vii) give animal consignments priority to allow import procedures to be completed without unnecessary delay.

- m) The responsibilities of *veterinarians* or in the absence of a *veterinarian*, the *animal handlers* travelling on the *vessel* with the animals include:
  - i) humane handling and treatment of animals during the *journey*, including in emergencies, such as humane killing of the animals;
  - ii) possess ability to report and act independently;
  - iii) meet daily with the master of the *vessel* to obtain up-to-date information on animal health and welfare status.
- n) The receiving *Competent Authority* should report back to the sending *Competent Authority* on *significant* animal welfare problems which occurred during the *journey*.

#### Article 3.7.2.4.

### Competence

1. All people responsible for animals during *journeys*, should be competent to carry out the relevant responsibilities listed in Article 3.7.2.3. Competence in areas other than animal welfare would need to be addressed separately. Competence may be gained through formal training and/or practical experience.
2. The assessment of competence of *animal handlers* should at a minimum address knowledge, and ability to apply that knowledge, in the following areas:
  - a) planning a *journey*, including appropriate *space allowance*, feed, water and ventilation requirements;
  - b) responsibilities for the welfare of animals during the *journey*, including *loading* and *unloading*;
  - c) sources of advice and assistance;
  - d) animal behaviour, general signs of *disease*, and indicators of poor animal welfare such as stress, pain and fatigue, and their alleviation;
  - e) assessment of fitness to travel; if fitness to travel is in doubt, the animal should be examined by a *veterinarian*;
  - f) relevant authorities and applicable transport regulations, and associated documentation requirements;
  - g) general *disease* prevention procedures, including cleaning and *disinfection*;
  - h) appropriate methods of animal handling during transport and associated activities such as assembling, *loading*, and *unloading*;
  - i) methods of inspecting animals, managing situations frequently encountered during transport such as adverse weather conditions, and dealing with emergencies, including euthanasia;
  - j) species-specific aspects and age-specific aspects of animal handling and care, including feeding, watering and inspection; and
  - k) maintaining a *journey* log and other records.
5. Assessment of competence for exporters should at a minimum address knowledge, and ability to apply that knowledge, in the following areas:

- a) planning a *journey*, including appropriate *space allowances*, and feed, water and ventilation requirements;
- b) relevant authorities and applicable transport regulations, and associated documentation requirements;
- c) appropriate methods of animal handling during transport and associated activities such as cleaning and *disinfection*, assembling, *loading*, and *unloading*;
- d) species-specific aspects of animal handling and care, including appropriate equipment and medication;
- e) sources of advice and assistance;
- f) appropriate record keeping; and
- g) managing situations frequently encountered during transport, such as adverse weather conditions, and dealing with emergencies.

#### Article 3.7.2.5.

### Planning the journey

#### 1. General considerations

- a) Adequate planning is a key factor affecting the welfare of animals during a *journey*.
- b) Before the *journey* starts, plans should be made in relation to:
  - i) preparation of animals for the *journey*;
  - ii) type of transport *vessel* required;
  - iii) route, taking into account distance, expected weather and sea conditions;
  - iv) nature and duration of *journey*;
  - v) daily care and management of the animals, including the appropriate number of *animal handlers*, to help ensure the health and welfare of all the animals;
  - vi) avoiding the mixing of animals from different sources in a single pen group;
  - vii) provision of appropriate equipment and medication for the numbers and species carried; and
  - viii) emergency response procedures.

#### 2. Preparation of animals for the journey

- a) When animals are to be provided with a novel diet or unfamiliar methods of supplying of feed or water, they should be preconditioned.
- b) There should be planning for water and feed availability during the *journey*. Feed should be of appropriate quality and composition for the species, age, condition of the animals, etc.
- c) Extreme weather conditions are hazards for animals undergoing transport and require appropriate *vessel* design to minimise risks. Special precautions should be taken for animals that

have not been acclimatised or which are unsuited to either hot or cold conditions. In some extreme conditions of heat or cold, animals should not be transported at all.

- d) Animals more accustomed to contact with humans and with being handled are likely to be less fearful of being loaded and transported. Animals should be handled and loaded in a manner that reduces their fearfulness and improves their approachability.
- e) Behaviour-modifying (such as tranquillisers) 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.

### 3. Control of disease

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

- a) When possible and agreed by the *Veterinary Authority* of the *importing country*, animals should be vaccinated against *diseases* to which they are likely to be exposed at their destination.
- b) Medications used prophylactically or therapeutically should only be administered by a *veterinarian* or other person who has been instructed in their use by a *veterinarian*.
- c) Mixing of animals from different sources in a single consignment should be minimized.

### 4. Vessel and container design and maintenance

- a) *Vessels* used for the sea transport of animals should be designed, constructed and fitted as appropriate to the species, size and weight of the animals to be transported. Special attention should be paid to the avoidance of injury to animals through the use of secure smooth fittings free from sharp protrusions and the provision of non-slip flooring. The avoidance of injury to *animal handlers* while carrying out their responsibilities should be emphasised.
- b) *Vessels* should be properly illuminated to allow animals to be observed and inspected.
- c) *Vessels* should be designed to permit thorough cleaning and *disinfection*, and the management of faeces and urine.
- d) *Vessels* and their fittings should be maintained in good mechanical and structural condition.
- e) *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 effective when the *vessel* is stationary. An emergency power supply should be available to maintain ventilation in the case of primary machinery breakdown.
- f) 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.
- g) *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.
- h) *Loading* and stowage of feed and bedding should be carried out in such a way to ensure protection from fire hazards, the elements and sea water.
- i) 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.



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

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

- a) Road *vehicles* and *containers* should be equipped with a sufficient number of adequately designed, positioned and maintained securing points enabling them to be securely fastened to the *vessel*.
- b) Road *vehicles* and *containers* should be secured to the ship before the start of the sea *journey* to prevent them being displaced by the motion of the *vessel*.
- c) *Vessels* should have adequate ventilation to meet variations in climate and the thermo-regulatory needs of the animal species being transported, especially where the animals are transported in a secondary *vehicle/container* on enclosed decks.
- d) Due to the risk of limited airflow on certain decks of a *vessel*, a road *vehicle* or *container* may require a forced ventilation system of greater capacity than that provided by natural ventilation.

#### 6. Nature and duration of the journey

The maximum duration of a *journey* should be determined taking into account factors that determine the overall welfare of animals, such as:

- a) the ability of the animals to cope with the stress of transport (such as very young, old, lactating or pregnant animals);
- b) the previous transport experience of the animals;
- c) the likely onset of fatigue;
- d) the need for special attention;
- e) the need for feed and water;
- f) the increased susceptibility to injury and *disease*;
- g) *space allowance* and *vessel* design;
- h) weather conditions;
- i) vessel type used, method of propulsion and risks associated with particular sea conditions.

#### 7. Space allowance

- a) The number of animals which should be transported on a *vessel* and their allocation to different pens on the *vessel* should be determined before *loading*.
- b) The amount of space required, including headroom, depends on the species of animal and should allow the necessary thermoregulation. Each animal should be able to assume its natural position for transport (including during *loading* and *unloading*) without coming into contact with the roof or upper deck of the *vessel*. When animals lie down, there should be enough space for every animal to adopt a normal lying posture.
- c) Calculations for the *space allowance* for each animal should be carried out in reference to a relevant national or international document. The size of pens will affect the number of animals in each.
- d) The same principles apply when animals are transported in *containers*.

8. Ability to observe animals during the journey

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

9. Emergency response procedures

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

## Article 3.7.2.6.

**Documentation**

1. Animals should not be loaded until the documentation required to that point is complete.
2. The documentation accompanying the consignment should include:
  - a) *journey* travel plan and an emergency management plan;
  - b) time, date and place of *loading*;
  - c) the *journey* log – a daily record of inspection and important events which includes records of morbidity and mortality and actions taken, climatic conditions, food and water consumed, medication provided, mechanical defects;
  - d) expected time, date and place of arrival and *unloading*;
  - e) veterinary certification, when required;
  - f) *animal identification* to allow *animal traceability* of animals to the premises of departure, and, where possible, to the premises of origin;
  - g) details of any animals considered at particular risk of suffering poor welfare during transport (point 3e) of Article 3.7.2.7.);
  - h) number of *animal handlers* on board, and their competencies; and
  - i) *stocking density* estimate for each load in the consignment.
3. When veterinary certification is required to accompany consignments of animals, it should address:
  - a) when required, details of *disinfection* carried out;
  - b) fitness of the animals to travel;
  - c) *animal identification* (description, number, etc.); and
  - d) health status including any tests, treatments and vaccinations carried out.

## Article 3.7.2.7.

**Pre-journey period**1. General considerations

- a) Before each *journey*, *vessels* should be thoroughly cleaned and, if necessary, treated for animal and public health purposes, using chemicals approved by the *Competent Authority*. When cleaning is necessary during a *journey*, this should be carried out with the minimum of stress and risk to the animals.
- b) In some circumstances, animals may require pre-*journey* assembly. In these circumstances, the following points should be considered:
  - i) Pre-*journey* rest is necessary if the welfare of animals has become poor during the collection period because of the physical environment or the social behaviour of the animals.

**Community comment:**

**The point 1 (b) (ii) should be totally deleted**

**Justification:**

**(1) It is possible to reduce urine and faeces by proceeding to regular cleaning of the pens, using proper drainage facilities or adding new litter.**

**(2) Now that part of the sentence has been deleted the remaining sentence is confusing.**

- ii) For animals such as pigs which are susceptible to motion sickness, and in order to reduce urine and faeces production during the *journey*, ~~a species specific short period of feed deprivation prior to loading is desirable.~~
- iii) When animals are to be provided with a novel diet or unfamiliar methods of supplying feed or water, they should be preconditioned.
- c) Where an *animal handler* believes that there is a significant *risk of disease* among the animals to be loaded or significant doubt as to their fitness to travel, the animals should be examined by a *veterinarian*.
- d) Pre-*journey* assembly / holding areas should be designed to:
  - i) securely contain the animals;
  - ii) maintain an environment safe from hazards, including predators and *disease*;
  - iii) protect animals from exposure to adverse weather conditions;
  - iv) allow for maintenance of social groups; and
  - v) allow for rest, watering and feeding.

2. Selection of compatible groups

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

- a) animals of different species should not be mixed unless they are judged to be compatible;
- b) animals of the same species can be mixed unless there is a significant likelihood of aggression; aggressive individuals should be segregated (recommendations for specific species are described in detail in Article 3.7.2.12.). For some species, animals from different groups should not be mixed because poor welfare occurs unless they have established a social structure;

- c) young or small animals may need to be separated from older or larger animals, with the exception of nursing mothers with young at foot;
- d) animals with horns or antlers should not be mixed with animals lacking horns or antlers, unless judged to be compatible; and
- e) animals reared together should be maintained as a group; animals with a strong social bond, such as a dam and offspring, should be transported together.

### 3. Fitness to travel

- a) Animals should be inspected by a *veterinarian* or an *animal handler* to assess fitness to travel. If its fitness to travel is in doubt, it is the responsibility of a *veterinarian* to determine its ability to travel. Animals found unfit to travel should not be loaded onto a *vessel*.
- b) Humane and effective arrangements should be made by the owner or agent for the handling and care of any animal rejected as unfit to travel.
- c) Animals that are unfit to travel include, but may not be limited to:
  - i) those that are sick, injured, weak, disabled or fatigued;
  - ii) those that are unable to stand unaided or bear weight on each leg;
  - iii) those that are blind in both eyes;
  - iv) those that cannot be moved without causing them additional suffering;
  - v) newborn with an unhealed navel;
  - vi) females travelling without young which have given birth within the previous 48 hours;

#### **Community comment:**

**The point 3 (c) (vii) should be replaced as follows: "pregnant animals for whom 90% or more of the expected gestation period has already passed, or females who have given birth in the previous week.**

#### **Justification:**

**It is easier to verify and is also important to consider the period after birth where the female is usually weak and can not be considered to be fit for transport.**

- vii) pregnant animals which would be in the final 10% of their gestation period at the planned time of *unloading*.
- viii) animals with unhealed wounds from recent surgical procedures such as dehorning.
- d) Risks during transport can be reduced by selecting animals best suited to the conditions of travel and those that are acclimatised to expected weather conditions.
- e) Animals at particular risk of suffering poor welfare during transport and which require special conditions (such as in the design of facilities and *vehicles*, and the length of the *journey*) and additional attention during transport, may include::
  - i) very large or obese individuals;

- ii) very young or old animals;
  - iii) excitable or aggressive animals;
  - iv) animals subject to motion sickness;
  - v) animals which have had little contact with humans;
  - vi) females in the last third of pregnancy or in heavy lactation.
- f) Hair or wool length should be considered in relation to the weather conditions expected during transport.

#### Article 3.7.2.8.

### Loading

#### 1. Competent supervision

- a) *Loading* should be carefully planned as it has the potential to be the cause of poor welfare in transported animals.
- b) *Loading* should be supervised by the *Competent Authority* and conducted by *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.

#### 2. Facilities

- a) The facilities for *loading*, including the collecting area at the wharf, races and loading ramps should be designed and constructed to take into account ~~of~~ the needs and abilities of the animals with regard to dimensions, slopes, surfaces, absence of sharp projections, flooring, sides, etc.
- b) Ventilation during *loading* and the *journey* should provide for fresh air, and the removal of excessive heat, humidity and noxious fumes (such as ammonia and carbon monoxide). Under warm and hot conditions, ventilation should allow for the adequate convective cooling of each animal. In some instances, adequate ventilation can be achieved by increasing the *space allowance* for animals.
- c) *Loading* facilities should be properly illuminated to allow the animals to be easily inspected by *animal handlers*, and to allow the ease of movement of animals at all times. Facilities should provide uniform light levels directly over approaches to sorting pens, chutes, loading ramps, with brighter light levels inside *vehicles/containers*, in order to minimise baulking. Dim light levels may be advantageous for the catching of some animals. Artificial lighting may be required.

#### 3. Goads and other aids

When moving animals, their species specific behaviour should be used (see Article 3.7.2.12.). If goads and other aids are necessary, the following principles should apply:

- a) Animals that have little or no room to move should not be subjected to physical force or goads and other aids which compel movement. Electric goads and prods should only be used in extreme cases and not on a routine basis to move animals. The use and the power output should be restricted to that necessary to assist movement of an animal and only when an animal has a clear path ahead to move. Goads and other aids should not be used repeatedly if the animal fails to respond or move. In such cases it should be investigated whether some physical or other impediment is preventing the animal from moving.

- b) The use of such devices should be limited to battery-powered goads on the hindquarters of pigs and large ruminants, and never on sensitive areas such as the eyes, mouth, ears, anogenital region or belly. Such instruments should not be used on horses, sheep and goats of any age, or on calves or piglets.
- c) 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 rattles; they should be used in a manner sufficient to encourage and direct movement of the animals without causing undue stress.
- d) Painful procedures (including whipping, tail twisting, use of nose twitches, pressure on eyes, ears or external genitalia), or the use of goads or other aids which cause pain and suffering (including large sticks, sticks with sharp ends, lengths of metal piping, fencing wire or heavy leather belts), should not be used to move animals.
- e) Excessive shouting at animals or making loud noises (e.g. through the cracking of whips) to encourage them to move should not occur as such actions may make the animals agitated, leading to crowding or falling.
- f) The use of well trained dogs to help with the *loading* of some species may be acceptable.
- g) 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 animals only by their wool, hair, feathers, feet, neck, ears, tails, head, horns, limbs causing pain or suffering should not be permitted, except in an emergency where animal welfare or human safety may otherwise be compromised.
- h) Conscious animals should not be thrown, dragged or dropped.
- i) Performance standards should be established in which numerical scoring is used to evaluate the use of such instruments, and to measure the percentage of animals moved with an electric instrument and the percentage of animals slipping or falling as a result of their usage.

#### Article 3.7.2.9.

### Travel

#### 1. General considerations

- a) *Animal handler(s)* should check the consignment immediately before departure to ensure that the animals have been loaded according to the load plan. Each consignment should be checked following any incident or situation likely to affect their welfare and in any case within 12 hours of departure.
- b) If necessary and where possible adjustments should be made to the *stocking density* as appropriate during the *journey*.
- c) Each pen of animals should be observed on a daily basis for normal behaviour, health and welfare, and the correct operation of ventilation, watering and feeding systems. There should also be a night patrol. Any necessary corrective action should be undertaken promptly.
- d) Adequate access to suitable feed and water should be ensured for all animals in each pen.
- e) Where cleaning or *disinfestation* is necessary during travel, it should be carried out with the minimum of stress to the animals.

#### 2. Sick or injured animals

- a) Sick or injured animals should be segregated.

- b) Sick or injured animals should be appropriately treated or humanely killed, in accordance with a predetermined emergency response plan (Article 3.7.2.5). Veterinary advice should be sought if necessary. All drugs and products should be used according to recommendations from a *veterinarian* and in accordance with the manufacturer's instructions.
- c) A record of treatments carried out and their outcomes should be kept.-
- d) When humane killing is necessary, the *animal handler* must ensure that it is carried out humanely. Recommendations for specific species are described in Appendix 3.7.6. on killing of animals for *disease* control purposes. Veterinary advice regarding the appropriateness of a particular method of euthanasia should be sought as necessary.

Article 3.7.2.10.

### Unloading and post-journey handling

#### 1. General considerations

- a) The required facilities and the principles of animal handling detailed in Article 3.7.2.8. apply equally to *unloading*, but consideration should be given to the likelihood that the animals will be fatigued.
- b) *Unloading* should be carefully planned as it has the potential to be the cause of poor welfare in transported animals.
- c) A livestock *vessel* should have priority attention when arriving in port and have priority access to a berth with suitable *unloading* facilities. As soon as possible after the *vessel's* arrival at the port and acceptance of the consignment by the *Competent Authority*, animals should be unloaded into appropriate facilities.
- d) The accompanying veterinary certificate and other documents should meet the requirements of the *importing country*. Veterinary inspections should be completed as quickly as possible.
- e) *Unloading* should be supervised by the *Competent Authority* and conducted by *animal handler(s)*. The *animal handlers* should ensure that animals are unloaded as soon as possible after arrival but sufficient time should be allowed for *unloading* to proceed quietly and without unnecessary noise, harassment or force, and that untrained assistants or spectators do not impede the process.

#### 2. Facilities

- a) The facilities for *unloading* including the collecting area at the wharf, races and unloading ramps should be designed and constructed to take into account of the needs and abilities of the animals with regard to dimensions, slopes, surfaces, absence of sharp projections, flooring, sides, etc.
- b) All *unloading* facilities should have sufficient lighting to allow the animals to be easily inspected by the *animal handlers*, and to allow the ease of movement of animals at all times.
- c) There should be facilities to provide animals with appropriate care and comfort, adequate space, access to quality feed and clean drinking water, and shelter from extreme weather conditions.

#### 3. Sick or injured animals

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

- b) In some cases, where animals are non-ambulatory due to fatigue, injury or sickness, it may be in the best welfare interests of the animal to be treated or humanely killed aboard the *vessel*.
  - c) If *unloading* is in the best welfare interests of animals that are fatigued, injured or sick, there should be appropriate facilities and equipment for the humane *unloading* of such animals. These animals should be unloaded in a manner that causes the least amount of suffering. After *unloading*, separate pens and other appropriate facilities and treatments should be provided for sick or injured animals.
4. Cleaning and disinfection
- a) *Vessels* and *containers* used to carry the animals should be cleaned before re-use through the physical removal of manure and bedding, by scraping, washing and flushing *vessels* and *containers* with water until visibly clean. This should be followed by *disinfection* when there are concerns about *disease* transmission.
  - b) Manure, litter and bedding should be disposed of in such a way as to prevent the transmission of *disease* and in compliance with all relevant health and environmental legislation.

#### Article 3.7.2.11.

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

1. The welfare of the animals should be the first consideration in the event of a refusal to import.
2. When animals have been refused import, the *Competent Authority* of the *importing country* should make available suitable isolation facilities to allow the *unloading* of animals from a *vessel* and their secure holding, without posing a risk to the health of the national herd, pending resolution of the situation. In this situation, the priorities should be:
  - a) The *Competent Authority* of the *importing country* should provide urgently in writing the reasons for the refusal.
  - b) In the event of a refusal for animal health reasons, the *Competent Authority* of the *importing country* should provide urgent access to an OIE-appointed *veterinarian(s)* to assess the health status of the animals with regard to the concerns of the *importing country*, and the necessary facilities and approvals to expedite the required diagnostic testing.
  - c) The *Competent Authority* of the *importing country* should provide access to allow continued assessment of the ongoing health and welfare situation.
  - d) If the matter cannot be promptly resolved, the *Competent Authority* of the *exporting* and *importing countries* should call on the OIE to mediate.
3. In the event that the animals are required to remain on the *vessel*, the priorities should be:
  - a) The *Competent Authority* of the *importing country* should allow provisioning of the *vessel* with water and feed as necessary.
  - b) The *Competent Authority* of the *importing country* should provide urgently in writing the reasons for the refusal.
  - c) In the event of a refusal for animal health reasons, the *Competent Authority* of the *importing country* should provide urgent access to an OIE-appointed *veterinarian(s)* to assess the health status of the animals with regard to the concerns of the *importing country*, and the necessary facilities and approvals to expedite the required diagnostic testing.
  - d) The *Competent Authority* of the *importing country* should provide access to allow continued assessment of the ongoing health and other aspects of the welfare of the animals, and the necessary actions to deal with any issues which arise.



- e) If the matter cannot be urgently resolved, the *Competent Authorities* of the *exporting* and *importing countries* should call on the OIE to mediate.
4. The OIE should utilise its dispute settlement mechanism to identify a mutually agreed solution which will address the animal health and welfare issues in a timely manner.

#### Article 3.7.2.12.

### Species specific issues

**Camelids** of the new world 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.

**Cattle** are sociable animals and may become agitated if they are singled out. Social order is usually established at about two years of age. When groups are mixed, social order has to be re-established and aggression may occur until a new order is established. Crowding of cattle may also increase aggression as the animals try to maintain personal space. Social behaviour varies with age, breed and sex; *Bos indicus* and *B. indicus*-cross animals are usually more temperamental than European breeds. Young bulls, when moved in groups, show a degree of playfulness (pushing and shoving) but become more aggressive and territorial with age. Adult bulls have a minimum personal space of six square metres. Cows with young calves can be very protective, and handling calves in the presence of their mothers can be dangerous. Cattle tend to avoid “dead end” in passages.

**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.

**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 *animal 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.

**Pigs** have poor eyesight, and may move reluctantly in unfamiliar. They benefit from well lit *loading* bays. Since they negotiate ramps with difficulty, these should be as level as possible and provided with secure footholds. Ideally, a hydraulic lift should be used for greater heights. Pigs also negotiate steps with difficulty. A good ‘rule-of-thumb’ is that no step should be higher than the pig’s front knee. Serious aggression may result if unfamiliar animals are mixed. Pigs are highly susceptible to heat stress.

**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.

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 — text deleted

## APPENDIX 3.7.3.

## GUIDELINES FOR THE TRANSPORT OF ANIMALS BY LAND

**Preamble:** These guidelines apply to the following live domesticated animals: cattle, buffalo, camels, sheep, goats, pigs, poultry and equines. They 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.

## Article 3.7.3.1.

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

## Article 3.7.3.2.

1. 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 harm each other in a group situation should not be mixed.

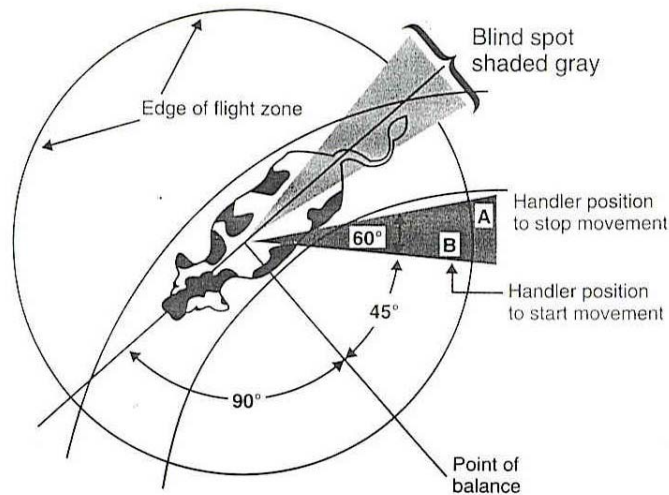
The desire of some animals to control their personal space should be taken into account in designing *loading* and *unloading* facilities, transport *vehicles* and *containers*.

|  |
|--|
| <p><b>Community comment:</b></p> <p><b>The following words should be added at the end of the paragraph:" and compromise the welfare of the animals".</b></p> |
|--|

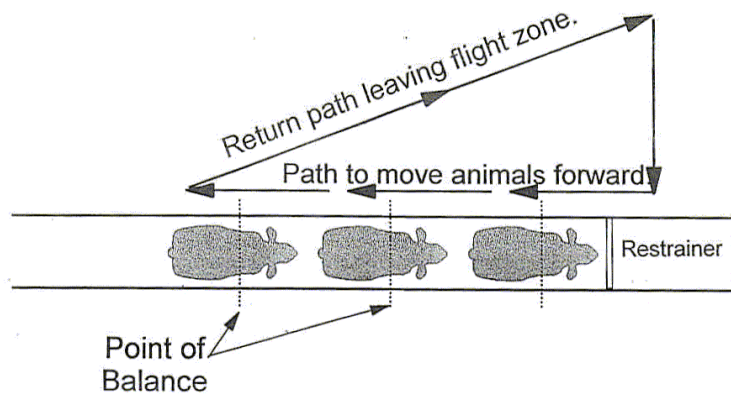
Domestic animals will try to escape if any person approaches closer than a certain distance. This critical distance, which defines the flight zone, varies among species and individuals of the same species, and depends upon previous contact with humans. Animals reared in close proximity to

humans (i.e. tame) have a smaller 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)



### Animal handler movement pattern to move cattle forward



### **To delete fear or oder**

*Animal handlers* should use the point of balance at the 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.

### **Community comment:**

**Words "fear or other" in the second sentence should be deleted as they are vague and confusing. In addition "fear" is already included in the concept of "negative response" that it used in the same sentence.**

Although all domestic animals have a highly sensitive sense of smell, they may react differently to the smells encountered during travel. Smells which cause fear or other negative responses should be taken into consideration when managing animals.

Domestic animals can hear over a greater range of frequencies than humans and are more sensitive to higher frequencies. They tend to be alarmed by constant loud noise and by sudden noises, which may cause them to panic. Sensitivity to such noises should also be taken into account when handling animals.

## 2. Distractions and their removal

Distractions that may cause approaching animals to stop, baulk or turn back should be designed out from new *loading* and *unloading* facilities or removed from existing ones. Below are examples of common distractions and methods for eliminating them:

- a) reflections on shiny metal or wet floors - move a lamp or change lighting;
- b) dark entrances - illuminate with indirect lighting which does not shine directly into the eyes of approaching animals;
- c) animals seeing moving people or equipment up ahead - install solid sides on chutes and races or install shields;
- d) dead ends-avoid if possible by curving the passage, or make an illusory passage;
- e) chains or other loose objects hanging in chutes or on fences - remove them;
- f) uneven floors or a sudden drop in floor levels – avoid uneven floor surfaces or install a solid false floor to provide an illusion of a solid and continuous walking surface;
- g) sounds of air hissing from pneumatic equipment - install silencers or use hydraulic equipment or vent high pressure to the external environment using flexible hosing;
- h) clanging and banging of metal objects - install rubber stops on gates and other devices to reduce metal to metal contact;
- i) air currents from fans or air curtains blowing into the face of animals - redirect or reposition equipment.

### Article 3.7.3.3.

## Responsibilities

Once the decision to transport the animals has been made, the welfare of the animals during their *journey* is the paramount consideration and is the joint responsibility of all people involved. The individual responsibilities of persons involved will be described in more detail in this Article.

The roles of each of those responsible are defined below:

1. The owners and managers of the animals are responsible for:
  - a) the general health, overall welfare and fitness of the animals for the *journey*;
  - b) ensuring compliance with any required veterinary or other certification;

- c) the presence of an *animal handler* competent for the species being transported during the *journey* with the authority to take prompt action; in case of transport by individual trucks, the truck driver may be the sole *animal handler* during the *journey*;
  - d) the presence of an adequate number of *animal handlers* during *loading* and *unloading*;
  - e) ensuring that equipment and veterinary assistance are provided as appropriate for the species and the *journey*.
2. Business agents or buying/selling agents are responsible for:
    - a) selection of animals that are fit to travel;
    - b) availability of suitable facilities at the start and at the end of the *journey* for the assembly; *loading*, transport, *unloading* and holding of animals, including for any stops at *resting points* during the *journey* and for emergencies.
  3. Animal handlers are responsible for the humane handling and care of the animals, especially during *loading* and *unloading*, and for maintaining a journey log. To carry out their responsibilities, they should have the authority to take prompt action. In the absence of a separate *animal handler*, the driver is the *animal handler*.
  4. Transport companies, *vehicle* owners and drivers are responsible for planning the *journey* to ensure the care of the animals; in particular they are responsible for:
    - a) choosing appropriate *vehicles* for the species transported and the *journey*;
    - b) ensuring that properly trained staff are available for *loading* / *unloading* of animals;
    - c) ensuring adequate competency of the driver in matters of animal welfare for the species being transported in case a separate *animal handler* is not assigned to the truck;
    - d) developing and keeping up-to-date contingency plans to address emergencies (including adverse weather conditions) and minimise stress during transport;
    - e) producing a *journey* plan which includes a *loading* plan, *journey* duration, itinerary and location of resting places;
    - f) *loading* only those animals which are fit to travel, for their correct *loading* into the *vehicle* and their inspection during the *journey*, and for appropriate responses to problems arising. If its fitness to travel is in doubt, the animal should be examined by a *veterinarian* in accordance with point 3a) of Article 3.7.3.7.;
    - g) welfare of the animals during the actual transport.
  5. Managers of facilities at the start and at the end of the *journey* and at *resting points* are responsible for:
    - a) providing suitable premises for *loading*, *unloading* and securely holding the animals, with water and feed when required, until further transport, sale or other use (including rearing or *slaughter*);
    - b) providing an adequate number of *animal handlers* to load, unload, drive and hold animals in a manner that causes minimum stress and injury; in the absence of a separate *animal handler*, the driver is the *animal handler*.
    - c) minimising the opportunities for *disease* transmission;
    - d) providing appropriate facilities, with water and feed when required;

- e) providing appropriate facilities for emergencies;
  - f) providing facilities for washing and disinfecting *vehicles* after *unloading*;
  - g) providing facilities and competent staff to allow the humane killing of animals when required
  - h) ensuring proper rest times and minimal delay during stops.
6. The responsibilities of *Competent Authorities* include:
- a) establishing minimum standards for animal welfare, including requirements for inspection of animals before, during and after their travel, defining 'fitness to travel' and appropriate certification and record keeping;
  - b) setting standards for facilities, *containers* and *vehicles* for the transport of animals;
  - c) setting standards for the competence of *animal handlers*, drivers and managers of facilities in relevant issues in animal welfare;
  - d) ensuring appropriate awareness and training of *animal handlers*, drivers and managers of facilities in relevant issues in animal welfare;
  - e) implementation of the standards, including through accreditation of / interaction with other organisations;
  - f) monitoring and evaluating the effectiveness of standards of health and other aspects of welfare;
  - g) monitoring and evaluating the use of veterinary medications;
  - h) giving animal consignments priority at frontiers in order to allow them to pass without unnecessary delay.
7. All individuals, including *veterinarians*, involved in transporting animals and the associated handling procedures should receive appropriate training and be competent to meet their responsibilities.
8. The receiving *Competent Authority* should report back to the sending *Competent Authority* on significant animal welfare problems which occurred during the *journey*.

#### Article 3.7.3.4.

#### Competence

1. All people responsible for animals during *journeys*, should be competent according to their responsibilities listed in Article 3.7.3.3. Competence may be gained through formal training and/or practical experience.
2. The assessment of the competence of *animal handlers* should at a minimum address knowledge, and ability to apply that knowledge, in the following areas:
  - a) planning a *journey*, including appropriate *space allowance*, and feed, water and ventilation requirements;
  - b) responsibilities for animals during the *journey*, including *loading* and *unloading*;
  - c) sources of advice and assistance;

- d) animal behaviour, general signs of *disease*, and indicators of poor animal welfare such as stress, pain and fatigue, and their alleviation;
- e) assessment of fitness to travel; if fitness to travel is in doubt, the animal should be examined by a *veterinarian*;
- f) relevant authorities and applicable transport regulations, and associated documentation requirements;
- g) general *disease* prevention procedures, including cleaning and *disinfection*;
- h) appropriate methods of animal handling during transport and associated activities such as assembling, *loading*, and *unloading*;
- i) methods of inspecting animals, managing situations frequently encountered during transport such as adverse weather conditions, and dealing with emergencies, including humane killing;
- j) species-specific aspects and age-specific aspects of animal handling and care, including feeding, watering and inspection; and
- k) maintaining a *journey* log and other records.

#### Article 3.7.3.5.

### Planning the journey

#### 1. General considerations

- a) Adequate planning is a key factor affecting the welfare of animals during a *journey*.
- b) Before the *journey* starts, plans should be made in relation to:
  - i) preparation of animals for the *journey*;
  - ii) choice of road, ~~or~~ rail; roll-on roll-off *vessels* or *containers*;
  - iii) nature and duration of the *journey*;
  - iv) *vehicle/ container* design and maintenance, including roll-on roll-off *vessels*;
  - v) required documentation;
  - vi) *space allowance*;
  - vii) rest, water and feed;
  - viii) observation of animals en route;
  - ix) control of *disease*;
  - x) emergency response procedures;
  - xi) forecast weather conditions (e.g. conditions being too hot or too cold to travel during certain periods of the day);
  - xii) transfer time when changing mode of transport, and
  - xiii) waiting time at frontiers and inspection points.

- c) Regulations concerning drivers (for example, maximum driving periods) should take into account animal welfare whenever is possible.

## 2. Preparation of animals for the journey

- a) When animals are to be provided with a novel diet or method of water provision during transport, an adequate period of adaptation should be planned. For all animals it is extra important that the rest stops during long journeys are long enough to fulfil the needs of the animals of feed and water. Species-specific short period of feed deprivation prior to *loading* may be desirable.
- b) Animals more accustomed to contact with humans and with being handled are likely to be less fearful of being loaded and transported. *Animal handlers* should handle and load animals in a manner that reduces their fearfulness and improves their approachability.
- c) Behaviour-modifying compounds (such as tranquillisers) or other medication 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*.

## 3. Nature and duration of the journey

The maximum duration of a *journey* should be determined taking into account factors, such as:

- a) the ability of the animals to cope with the stress of transport (such as very young, old, lactating or pregnant animals);
- b) the previous transport experience of the animals;
- c) the likely onset of fatigue;
- d) the need for special attention;
- e) the need for feed and water;
- f) the increased susceptibility to injury and *disease*;
- g) *space allowance*, *vehicle* design, road conditions and driving quality;
- h) weather conditions;
- i) *vehicle* type used, terrain to be traversed, road surfaces and quality, skill and experience of the driver.

## 4. Vehicle and container design and maintenance

- a) *Vehicles* and *containers* used for the transport of animals should be designed, constructed and fitted as appropriate for the species, size and weight of the animals to be transported. Special attention should be paid to avoid injury to animals through the use of secure smooth fittings free from sharp protrusions. The avoidance of injury to drivers, and *animal handlers* while carrying out their responsibilities should be emphasised.
- b) *Vehicles* and *containers* should be designed with the structures necessary to provide protection from adverse weather conditions and to minimise the opportunity for animals to escape.



- c) In order to minimise the likelihood of the spread of infectious *disease* during transport, *vehicles* and *containers* should be designed to permit thorough cleaning and *disinfection*, and the containment of faeces and urine during a *journey*.
  - d) *Vehicles* and *containers* should be maintained in good mechanical and structural condition.
  - e) *Vehicles* and *containers* should have adequate ventilation to meet variations in climate and the thermo-regulatory needs of the animal species being transported; the ventilation system (natural or mechanical) should be effective when the *vehicle* is stationary, and the airflow should be adjustable.
  - f) *Vehicles* should be designed so that the faeces or urine from animals on upper levels do not soil animals on lower levels, nor their feed and water.
  - g) When *vehicles* are carried on board ferries, facilities for adequately securing them should be available.
  - h) If feeding or watering while the *vehicle* is moving is required, adequate facilities on the *vehicle* should be available.
  - i) When appropriate, suitable bedding should be added to *vehicle* floors to assist absorption of urine and faeces, to minimise slipping by animals, and protect animals (especially young animals) from hard flooring surfaces and adverse weather conditions.
5. Special provisions for transport in vehicles (road and rail) on roll-on/roll-off vessels or for containers
- a) *Vehicles* and *containers* should be equipped with a sufficient number of adequately designed, positioned and maintained securing points enabling them to be securely fastened to the *vessel*.
  - b) *Vehicles* and *containers* should be secured to the *vessel* before the start of the sea *journey* to prevent them being displaced by the motion of the *vessel*.
  - c) Roll-on/roll-off *vessels* should have adequate ventilation to meet variations in climate and the thermo-regulatory needs of the animal species being transported, especially where the animals are transported in a secondary *vehicle/container* on enclosed decks.
6. Space allowance
- a) The number of animals which should be transported on a *vehicle* or in a *container* and their allocation to compartments should be determined before *loading*.
  - b) The space required on a *vehicle* or in a *container* depends upon whether or not the animals need to lie down (for example, pigs, camels and poultry), or to stand (horses). Animals which will need to lie down often stand when first loaded or when the *vehicle* is driven with too much lateral movement or sudden braking.
  - c) When animals lie down, they should all be able to adopt a normal lying posture which allows necessary thermoregulation.
  - d) When animals are standing, they should have sufficient space to adopt a balanced position as appropriate to the climate and species transported.
  - e) The amount of headroom necessary depends on the species of animal. Each animal should be able to assume its natural position for transport (including during *loading* and *unloading*) without coming into contact with the roof or upper deck of the *vehicle*, and there should be sufficient headroom to allow adequate airflow over the animals.

- f) Calculations for the *space allowance* for each animal should be carried out using the figures given in a relevant national or international document. The number and size of pens on the *vehicle* should be varied to where possible accommodate already established groups of animals while avoiding group sizes which are too large.
- g) Other factors which may influence *space allowance* include:
  - i) *vehicle/container* design;
  - ii) length of *journey*;
  - iii) need to provide feed and water on the *vehicle*;
  - iv) quality of roads;
  - v) expected weather conditions;
  - vi) category and sex of the animals.

#### 7. Rest, water and feed

- a) Suitable water and feed should be available as appropriate and needed for the species, age, and condition of the animals, as well as the duration of the *journey*, climatic conditions, etc.
- b) Animals should be allowed to rest at *resting points* at appropriate intervals during the *journey*. The type of transport, the age and species of the animals being transported, and climatic conditions should determine the frequency of rest stops and whether the animals should be unloaded. Water and feed should be available during rest stops.

#### 8. Ability to observe animals during the journey

- a) Animals should be positioned to enable each animal to be observed regularly during the *journey* to ensure their safety and good welfare.
- b) If the animals are in crates or on multi-tiered *vehicles* which do not allow free access for observation, for example where the roof of the tier is too low, animals cannot be inspected adequately, and serious injury or *disease* could go undetected. In these circumstances, a shorter *journey* duration should be allowed, and the maximum duration will vary according to the rate at which problems arise in the species and under the conditions of transport.

#### 9. Control of disease

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

- a) mixing of animals from different sources in a single consignment should be minimised;
- b) contact at *resting points* between animals from different sources should be avoided;
- c) when possible, animals should be vaccinated against *diseases* to which they are likely to be exposed at their destination;

#### **Previous Community comment:**

**Under point 9 (d) the words "exporting or" should be added before the words "importing country".**

#### **Justification:**

**It is unlikely to be aware of all medicine registration and licensing procedures in all the countries and the exported animals may have been treated before export not knowing their destination. The medications should of course be approved in the exporting country.**

- d) medications used prophylactically or therapeutically should be approved by the *Veterinary Authority* of the *importing country* and should only be administered by a *veterinarian* or other person who has been instructed in their use by a *veterinarian*.

10. Emergency response procedures

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

11. Other considerations

- a) Extreme weather conditions are hazardous for animals undergoing transport and require appropriate *vehicle* design to minimise risks. Special precautions should be taken for animals that have not been acclimatised or which are unsuited to either hot or cold conditions. In some extreme conditions of heat or cold, animals should not be transported at all.
- b) In some circumstances, transportation during the night may reduce thermal stress or the adverse effects of other external stimuli.

Article 3.7.3.6.

**Documentation**

1. Animals should not be loaded until the documentation required to that point is complete.
2. The documentation accompanying the consignment should include:
  - a) *journey* travel plan and an emergency management plan;
  - b) date, time, and place of *loading* and *unloading*;
  - c) veterinary certification, when required;
  - d) animal welfare competencies of the driver; (under study)
  - e) *animal identification* to allow *animal traceability* to the premises of departure and, where possible, to the premises of origin;
  - f) details of any animals considered at particular risk of suffering poor welfare during transport (point 3e) of Article 3.7.3.7.);
  - g) documentation of the period of rest, and access to feed and water, prior to the *journey*;
  - h) *stocking density* estimate for each load in the consignment;
  - i) the *journey* log - daily record of inspection and important events, including records of morbidity and mortality and actions taken, climatic conditions, rest stops, travel time and distance, feed and water offered and estimates of consumption, medication provided, and mechanical defects.

3. When veterinary certification is required to accompany consignments of animals, it should address:
  - a) fitness of animals to travel;
  - b) *animal identification* (description, number, etc.);
  - c) health status including any tests, treatments and vaccinations carried out;
  - d) when required, details of *disinfection* carried out.

At the time of certification, the *veterinarian* should notify *animal handler* or the driver of any factors affecting the fitness of animals to travel for a particular *journey*.

#### Article 3.7.3.7.

### Pre-journey period

#### 1. General considerations

- a) *Pre-journey* rest is necessary if the welfare of animals has become poor during the collection period because of the physical environment or the social behaviour of the animals. The need for rest should be judged by a *veterinarian* or other competent person.
- b) *Pre-journey* assembly/holding areas should be designed to:
  - i) securely hold the animals;
  - ii) maintain a safe environment from hazards, including predators and *disease*;
  - iii) protect animals from exposure to severe weather conditions;
  - iv) allow for maintenance of social groups;
  - v) allow for rest, and appropriate water and feed;
- c) Consideration should be given to the previous transport experience, training and conditioning of the animals, if known, as these may reduce fear and stress in animals.
- d) Feed and water should be provided *pre-journey* if the *journey* duration is greater than the normal inter-feeding and drinking interval for the animal. Recommendations for specific species are described in detail in Article 3.7.3.12.
- e) When animals are to be provided with a novel diet or method of feed or water provision during the *journey*, an adequate period of adaptation should be allowed.
- f) Before each *journey*, *vehicles* and *containers* should be thoroughly cleaned and, if necessary, treated for animal health and public health purposes, using methods approved by the *Competent Authority*. When cleaning is necessary during a *journey*, this should be carried out with the minimum of stress and risk to the animals.
- g) Where an *animal handler* believes that there is a significant *risk of disease* among the animals to be loaded or significant doubt as to their fitness to travel, the animals should be examined by a *veterinarian*.

#### 2. Selection of compatible groups

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

- a) Animals reared together should be maintained as a group; animals with a strong social bond, such as a dam and offspring, should be transported together.
- b) Animals of the same species can be mixed unless there is a significant likelihood of aggression; aggressive individuals should be segregated (recommendations for specific species are described in detail in Article 3.7.3.12.). For some species, animals from different groups should not be mixed because poor welfare occurs unless they have established a social structure.
- c) Young or small animals should be separated from older or larger animals, with the exception of nursing mothers with young at foot.
- d) Animals with horns or antlers should not be mixed with animals lacking horns or antlers unless judged to be compatible.
- e) Animals of different species should not be mixed unless they are judged to be compatible.

### 3. Fitness to travel

- a) Each animal should be inspected by a *veterinarian* or an *animal handler* to assess fitness to travel. If its fitness to travel is in doubt, the animal should be examined by a *veterinarian*. Animals found unfit to travel should not be loaded onto a *vehicle*, except for transport to receive veterinary treatment.
- b) Humane and effective arrangements should be made by the owner and the agent for the handling and care of any animal rejected as unfit to travel.
- c) Animals that are unfit to travel include, but may not be limited to:
  - i) those that are sick, injured, weak, disabled or fatigued;
  - ii) those that are unable to stand unaided and bear weight on each leg;
  - iii) those that are blind in both eyes;
  - iv) those that cannot be moved without causing them additional suffering;
  - v) newborn with an unhealed navel;

**The Community reiterates its previous comment:**

**The point 3 (c) (vi) should be replaced as follows: "pregnant animals for whom 90% or more of the expected gestation period has already passed, or females who have given birth in the previous week.**

**Justification:**

**It is easier to verify and is important also to consider the period after birth where the female is usually weak and can not be considered to be fit for transport.**

- vi) pregnant animals which would be in the final 10% of their gestation period at the planned time of *unloading*;
- vii) females travelling without young which have given birth within the previous 48 hours;
- viii) those whose body condition would result in poor welfare because of the expected climatic conditions.

- d) Risks during transport can be reduced by selecting animals best suited to the conditions of travel and those that are acclimatised to expected weather conditions.
- e) Animals at particular risk of suffering poor welfare during transport and which require special conditions (such as in the design of facilities and *vehicles*, and the length of the *journey*) and additional attention during transport, may include:
  - i) large or obese individuals;
  - ii) very young or old animals;
  - iii) excitable or aggressive animals;
  - iv) animals which have had little contact with humans;
  - v) animal subject to motion sickness;
  - vi) females in late pregnancy or heavy lactation, dam and offspring;
  - vii) animals with a history of exposure to stressors or pathogenic agents prior to transport;
  - viii) animals with unhealed wounds from recent surgical procedures such as dehorning.

#### 4. Specific species requirements

Transport procedures should be able to take account of variations in the behaviour of the species. Flight zones, social interactions and other behaviour vary significantly among species and even within species. Facilities and handling procedures that are successful with one species are often ineffective or dangerous with another.

Recommendations for specific species are described in detail in Article 3.7.3.12.

#### Article 3.7.3.8.

### **Loading**

#### 1. Competent supervision

- a) *Loading* should be carefully planned as it has the potential to be the cause of poor welfare in transported animals.
- b) *Loading* should be supervised and/or conducted by *animal handlers*. The animals are to be loaded quietly and without unnecessary noise, harassment or force. Untrained assistants or spectators should not impede the process.
- c) When *containers* are loaded onto a *vehicle*, this should be carried out in such a way to avoid poor animal welfare.

#### 2. Facilities

- a) The facilities for *loading* including the collecting area, races and loading ramps should be designed and constructed to take into account the needs and abilities of the animals with regard to dimensions, slopes, surfaces, absence of sharp projections, flooring, etc.
- b) *Loading* facilities should be properly illuminated to allow the animals to be observed by *animal handler(s)*, and to allow the ease of movement of the animals at all times. Facilities should provide uniform light levels directly over approaches to sorting pens, chutes, loading ramps, with brighter light levels inside *vehicles/containers*, in order to minimise baulking. Dim light levels may be advantageous for the catching of poultry and some other animals. Artificial lighting may be required.

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

### 3. Goads and other aids

When moving animals, their species specific behaviour should be used (see Article 3.7.3.12.). If goads and other aids are necessary, the following principles should apply:

- a) Animals that have little or no room to move should not be subjected to physical force or goads and other aids which compel movement. Electric goads and prods should only be used in extreme cases and not on a routine basis to move animals. The use and the power output should be restricted to that necessary to assist movement of an animal and only when an animal has a clear path ahead to move. Goads and other aids should not be used repeatedly if the animal fails to respond or move. In such cases it should be investigated whether some physical or other impediment is preventing the animal from moving.
- b) The use of such devices should be limited to battery-powered goads on the hindquarters of pigs and large ruminants, and never on sensitive areas such as the eyes, mouth, ears, anogenital region or belly. Such instruments should not be used on horses, sheep and goats of any age, or on calves or piglets.
- c) 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 rattles; they should be used in a manner sufficient to encourage and direct movement of the animals without causing undue stress.
- d) Painful procedures (including whipping, tail twisting, use of nose twitches, pressure on eyes, ears or external genitalia), or the use of goads or other aids which cause pain and suffering (including large sticks, sticks with sharp ends, lengths of metal piping, fencing wire or heavy leather belts), should not be used to move animals.
- e) Excessive shouting at animals or making loud noises (e.g., through the cracking of whips) to encourage them to move should not occur, as such actions may make the animals agitated, leading to crowding or falling.
- f) The use of well trained dogs to help with the *loading* of some species may be acceptable.
- g) 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 animals only by their wool, hair, feathers, feet, neck, ears, tails, head, horns, limbs causing pain or suffering should not be permitted, except in an emergency where animal welfare or human safety may otherwise be compromised.
- h) Conscious animals should not be thrown, dragged or dropped.
- i) Performance standards should be established in which numerical scoring is used to evaluate the use of such instruments, and to measure the percentage of animals moved with an electric instrument and the percentage of animals slipping or falling as a result of their usage.

Article 3.7.3.9.

## Travel

## 1. General considerations

- a) Drivers and *animal handlers* should check the load immediately before departure to ensure that the animals have been properly loaded. Each load should be checked again early in the trip and adjustments made as appropriate. Periodic checks should be made throughout the trip, especially at rest or refuelling stops or during meal breaks when the *vehicle* is stationary.
- b) Drivers should utilise smooth, defensive driving techniques, without sudden turns or stops, to minimise uncontrolled movements of the animals.

## 2. Methods of restraining or containing animals

- a) Methods of restraining animals should be appropriate to the species and age of animals involved and the training of the individual animal.
- b) Recommendations for specific species are described in detail in Article 3.7.3.12.

## 3. Regulating the environment within vehicles or containers

- a) Animals should be protected against harm from hot or cold conditions during travel. Effective ventilation procedures for maintaining the 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.
- b) The environment within *vehicles* or *containers* in hot and warm 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 adequate and appropriate ventilation.
- c) To minimise slipping and soiling, and maintain a healthy environment, urine and faeces should be removed from floors when necessary and disposed of in such a way as to prevent the transmission of *disease* and in compliance with all relevant health and environmental legislation.

## 4. Sick, injured or dead animals

- a) A driver or *animal handler* finding sick, injured or dead animals should act according to a predetermined emergency response plan.
- b) Sick or injured animals should be segregated.
- c) Ferries (roll-on roll-off) should have procedures to treat sick or injured animals during the *journey*.
- d) In order to reduce the likelihood that animal transport will increase the spread of infectious *disease*, contact between transported animals, or the waste products of the transported animals, and other farm animals should be minimised.
- e) During the *journey*, when disposal of a dead animal becomes necessary, this should be carried out in such a way as to prevent the transmission of *disease* and in compliance with all relevant health and environmental legislation.
- f) When killing is necessary, it should be carried out as quickly as possible and assistance should be sought from a *veterinarian* or other person(s) competent in humane killing procedures. Recommendations for specific species are described in Appendix 3.7.6. on killing of animals for *disease* control purposes.

## 5. Water and feed requirements



- a) If *journey* duration is such that feeding or watering is required or if the species requires feed or water throughout, access to suitable feed and water for all the animals (appropriate for their species and age) carried in the *vehicle* should be provided. There should be adequate space for all animals to move to the feed and water sources and due account taken of likely competition for feed.
  - b) Recommendations for specific species are described in detail in Article 3.7.3.12.
6. Rest periods and conditions including hygiene
- a) Animals that are being transported should be rested at appropriate intervals during the *journey* and offered feed and water, either on the *vehicle* or, if necessary, unloaded into suitable facilities.
  - b) Suitable facilities should be used en route, when resting requires the *unloading* of the animals. These facilities should meet the needs of the particular animal species and should allow access of all animals to feed and water.
7. In-transit observations
- a) Animals being transported by road should be observed soon after a *journey* is commenced and whenever the driver has a rest stop. After meal breaks and refuelling stops, the animals should be observed immediately prior to departure.
  - b) Animals being transported by rail should be observed at each scheduled stop. The responsible rail transporter should monitor the progress of trains carrying animals and take all appropriate action to minimise delays.
  - c) During stops, it should be ensured that the animals continue to be properly confined, have appropriate feed and water, and their physical condition is satisfactory.

Article 3.7.3.10.

### Unloading and post-journey handling

1. General considerations

- a) The required facilities and the principles of animal handling detailed in Article 3.7.3.8. apply equally to *unloading*, but consideration should be given to the likelihood that the animals will be fatigued.
- b) *Unloading* should be supervised and/or conducted by an *animal handler* with knowledge and experience of the behavioural and physical characteristics of the species being unloaded. Animals should be unloaded from the *vehicle* into appropriate facilities as soon as possible after arrival at the destination but sufficient time should be allowed for *unloading* to proceed quietly and without unnecessary noise, harassment or force.
- c) Facilities should provide all animals with appropriate care and comfort, adequate space and ventilation, access to feed (if appropriate) and water, and shelter from extreme weather conditions.
- d) For details regarding the *unloading* of animals at a *slaughterhouse*, see Appendix 3.7.5. on slaughter of animals for human consumption.

2. Sick ~~and~~ or injured animals

- a) An animal that has become sick, injured or disabled during a *journey* should be appropriately treated or humanely killed (see Appendix 3.7.6. on killing of animals for disease control

purposes). If necessary, veterinary advice should be sought in the care and treatment of these animals. In some cases, where animals are non-ambulatory due to fatigue, injury or sickness, it may be in the best welfare interests of the animal to be treated or killed aboard the *vehicle*. Assistance should be sought from a *veterinarian* or other person(s) competent in humane killing procedures.

- b) At the destination, the *animal handler* or the driver during transit should ensure that responsibility for the welfare of sick, injured or disabled animals is transferred to a veterinarian or other suitable person.
- c) If treatment or humane killing is not possible aboard the *vehicle*, there should be appropriate facilities and equipment for the humane *unloading* of animals that are non-ambulatory due to fatigue, injury or sickness. These animals should be unloaded in a manner that causes the least amount of suffering. After *unloading*, separate pens and other appropriate facilities should be available for sick or injured animals.
- d) Feed, if appropriate, and water should be available for each sick or injured animal.

### 3. Addressing disease risks

The following should be taken into account in addressing the greater *risk* of *disease* due to animal transport and the possible need for segregation of transported animals at the destination:

- a) increased contact among animals, including those from different sources and with different *disease* histories;
- b) increased shedding of pathogens and increased susceptibility to *infection* related to stress and impaired defences against *disease*, including immunosuppression;
- c) exposure of animals to pathogens which may contaminate *vehicles*, *resting points*, *markets*, etc.

### 4. Cleaning and disinfection

- a) *Vehicles*, crates, *containers*, etc. used to carry the animals should be cleaned before re-use through the physical removal of manure and bedding by scraping, washing and flushing with water and detergent. This should be followed by *disinfection* when there are concerns about *disease* transmission.
- b) Manure, litter, bedding and the bodies of any animals which die during the *journey* should be disposed of in such a way as to prevent the transmission of *disease* and in compliance with all relevant health and environmental legislation.
- c) Establishments like livestock *markets*, *slaughterhouses*, *resting sites*, railway stations, etc. where animals are unloaded should be provided with appropriate areas for the cleaning and *disinfection* of *vehicles*.

#### Article 3.7.3.11.

#### **Actions in the event of a refusal to allow the completion of the journey**

1. The welfare of the animals should be the first consideration in the event of a refusal to allow the completion of the *journey*.
2. When the animals have been refused import, the *Competent Authority* of the *importing country* should make available suitable isolation facilities to allow the *unloading* of animals from a *vehicle* and their secure holding, without posing a risk to the health of national herd or flock, pending resolution of the situation. In this situation, the priorities should be:

- a) The *Competent Authority* of the *importing country* should provide urgently in writing the reasons for the refusal.
  - b) In the event of a refusal for animal health reasons, the *Competent Authority* of the *importing country* should provide urgent access to a *veterinarian*, where possible an OIE *veterinarian(s)* appointed by the Director General, to assess the health status of the animals with regard to the concerns of the *importing country*, and the necessary facilities and approvals to expedite the required diagnostic testing.
  - c) The *Competent Authority* of the *importing country* should provide access to allow continued assessment of the health and other aspects of the welfare of the animals.
  - d) If the matter cannot be promptly resolved, the *Competent Authorities* of the *exporting* and *importing countries* should call on the OIE to mediate.
3. In the event that a *Competent Authority* requires the animals to remain on the *vehicle*, the priorities should be:
    - a) to allow re-provisioning of the *vehicle* with water and feed as necessary;
    - b) to provide urgently in writing the reasons for the refusal;
    - c) to provide urgent access to an independent *veterinarian(s)* to assess the health status of the animals, and the necessary facilities and approvals to expedite the required diagnostic testing in the event of a refusal for animal health reasons;
    - d) to provide access to allow continued assessment of the health and other aspects of the welfare of the animals, and the necessary actions to deal with any animal issues which arise.
  4. The OIE should utilise its dispute settlement mechanism to identify a mutually agreed solution which will address animal health and any other welfare issues in a timely manner.

#### Article 3.7.3.12.

### Species specific issues

**Camelids** of the new world 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.

**Cattle** are sociable animals and may become agitated if they are singled out. Social order is usually established at about two years of age. When groups are mixed, social order has to be re-established and aggression may occur until a new order is established. Crowding of cattle may also increase aggression as the animals try to maintain personal space. Social behaviour varies with age, breed and sex; *Bos indicus* and *B. indicus*-cross animals are usually more temperamental than European breeds. Young bulls, when moved in groups, show a degree of playfulness (pushing and shoving) but become more aggressive and territorial with age. Adult bulls have a minimum personal space of six square metres. Cows with young calves can be very protective, and handling calves in the presence of their mothers can be dangerous. Cattle tend to avoid “dead end” in passages.

**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 and can reflect demands for personal space. Housing strange goats together could result in fatalities, either through physical violence, or subordinate goats being refused access to food and water.

**Horses** in this context include, donkeys, mules and hinnies. 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 *animal 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. Horses are prone to respiratory *disease* if they are restricted by period by tethers that prevent the lowering and lifting of their heads.

**Pigs** have poor eyesight, and may move reluctantly in strange surroundings. They benefit from well lit loading bays. Since they negotiate ramps with difficulty, these should be as level as possible and provided with secure footholds. Ideally, a hydraulic lift should be used for greater heights. Pigs also negotiate steps with difficulty. A good ‘rule-of-thumb’ is that no step should be higher than the pig’s front knee. Serious aggression may result if unfamiliar animals are mixed. Pigs are highly susceptible to heat stress.

**Sheep** are sociable animals with good eyesight, a relatively subtle and undemonstrative behaviour and a tendency 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. Crowding of sheep may lead to damaging aggressive and submissive behaviours as animals try to maintain personal space. Sheep may become agitated if they are singled out for attention, or kept alone, and will strive to rejoin the group. Activities which frighten, injure or cause agitation to sheep should be avoided. They can negotiate steep ramps.

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## APPENDIX 3.7.5.

**GUIDELINES FOR THE SLAUGHTER OF ANIMALS**

## Article 3.7.5.1.

**General principles**1. Object

These guidelines address the need to ensure the welfare of food animals during pre-*slaughter* and *slaughter* processes, until they are dead.

These guidelines apply to the *slaughter* in *slaughterhouses* of the following domestic animals: cattle, buffalo, bison, sheep, goats, camelids, deer, horses, pigs, ratites, rabbits and poultry. Other animals, wherever they have been reared, and all animals slaughtered outside *slaughterhouses* should be managed to ensure that their *transport, lairage, restraint* and *slaughter* is carried out without causing undue stress to the animals; the principles underpinning these guidelines apply also to these animals.

2. Personnel

Persons engaged in the *unloading, moving, lairage, care, restraint, stunning, slaughter* and bleeding of animals play an important role in the welfare of those animals. For this reason, there should be a sufficient number of personnel, who should be patient, considerate, competent and familiar with the guidelines outlined in the present Appendix and their application within the national context.

Competence may be gained through formal training and/or practical experience. This competence should be demonstrated through a current certificate from the *Competent Authority* or from an independent body accredited by the *Competent Authority*.

The management of the *slaughterhouse* and the *Veterinary Services* should ensure that *slaughterhouse* staff are competent and carry out their tasks in accordance with the principles of animal welfare.

3. Animal behaviour

*Animal handlers* should be experienced and competent in handling and moving farm livestock and understand the behaviour patterns of animals and the underlying principles necessary to carry out their tasks.

The behaviour of individual animals or groups of animals will vary, depending on their breed, sex, temperament and age and the way in which they have been reared and handled. Despite these differences, the following behaviour patterns which are always present to some degree in domestic animals, should be taken into consideration in handling and moving the animals.

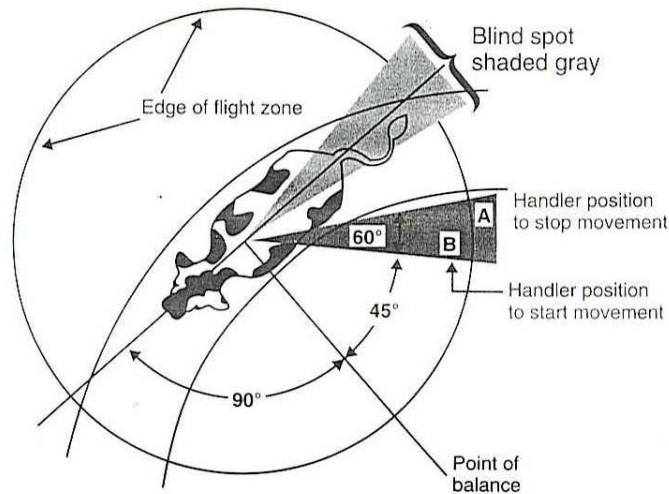
Most domestic livestock are kept in herds and follow a leader by instinct.

Animals which are likely to harm each other in a group situation should not be mixed at *slaughterhouses*.

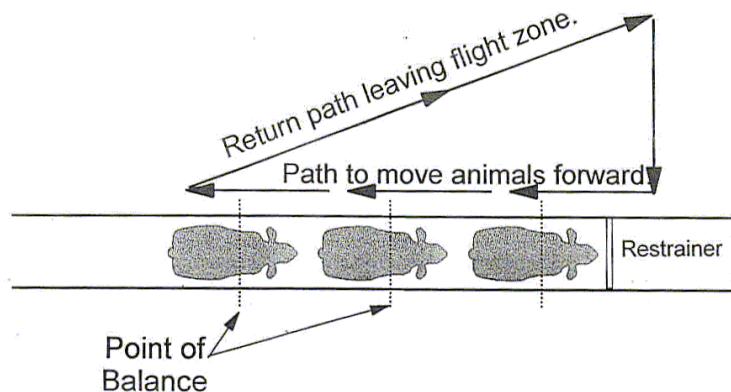
The desire of some animals to control their personal space should be taken into account in designing facilities.

Domestic animals will try to escape if any person 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 a smaller 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)



#### Animal handler movement pattern to move cattle forward



*Animal handlers* should use the point of balance at the animal's shoulder to move animals, adopting a position behind the point of balance to move an animal forward and in front of the point of balance to move it backward.

Domestic animals have wide-angle vision but only have limited forward binocular vision and poor perception of depth. This means that they can detect objects and movements beside and behind them, but can only judge distances directly ahead.

Although all domestic animals have a highly sensitive sense of smell, they react in different ways to the smells of *slaughterhouses*. Smells which cause fear or other negative responses should be taken into consideration when managing animals.

Domestic animals can hear over a greater range of frequencies than humans and are more sensitive to higher frequencies. They tend to be alarmed by constant loud noise and by sudden noises, which may cause them to panic. Sensitivity to such noises should also be taken into account when handling animals.

#### 4. Distractions and their removal

Distractions that may cause approaching animals to stop, baulk or turn back should be designed out from new facilities or removed from existing ones. Below are examples of common distractions and methods for eliminating them:

- a) reflections on shiny metal or wet floors - move a lamp or change lighting;
- b) dark entrances to chutes, races, stun boxes or conveyor restrainers - illuminate with indirect lighting which does not shine directly into the eyes of approaching animals;
- c) animals seeing moving people or equipment up ahead - install solid sides on chutes and races or install shields;
- d) dead ends-avoid if possible by curving the passage, or make an illusory passage;
- e) chains or other loose objects hanging in chutes or on fences - remove them;
- f) 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;
- g) sounds of air hissing from pneumatic equipment - install silencers or use hydraulic equipment or vent high pressure to the external environment using flexible hosing;
- h) clanging and banging of metal objects - install rubber stops on gates and other devices to reduce metal to metal contact;
- i) air currents from fans or air curtains blowing into the face of animals - redirect or reposition equipment.

Article 3.7.5.2.

### **Moving and handling animals**

#### 1. General considerations

Animals should be transported to *slaughter* in a way that minimises adverse animal health and welfare outcomes, and the transport should be conducted in accordance with the OIE guidelines for the transportation of animals (Appendices 3.7.2 and 3.7.3).

The following principles should apply to *unloading* animals, moving them into *lairage* pens, out of the *lairage* pens and up to the *slaughter* point:

- a) The conditions of the animals should be assessed upon their arrival for any animal welfare and health problems.

#### **Community comment:**

**In paragraph (b) the words "for the killing of animals for disease control purposes (Appendix 3.7.6)" should be deleted.**



**Justification:**

**Sick or injured animals can be also slaughtered for human consumption and therefore both guidelines could be used.**

- b) Injured or sick animals, requiring immediate *slaughter*, should be killed humanely and without delay, at the site where they are found in accordance with the relevant OIE guidelines for the killing of animals for *disease* control purposes (Appendix 3.7.6).

**The Community reiterates its previous comment:**

**In paragraph (c) the following two changes should be introduced:**

**(1) In the second sentence, after the words "Performance standards" the word "should" should be replaced by "could".**

**(2) The wording "99% of" should be deleted.**

**Justification:**

**(1) Performance standards could be useful to improve animal welfare conditions but are not always necessary.**

**(2) As an objective no animals should be falling from animal welfare point of view.**

- c) 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.
- d) Animals for *slaughter* should not be forced to walk over the top of other animals.
- e) Animals should be handled in such a way as to avoid harm, distress or injury. Under no circumstances should *animal handlers* resort to violent acts to move animals, such as crushing or breaking tails of animals, grasping their eyes or pulling them by the ears. *Animal handlers* should never apply an injurious object or irritant substance to animals and especially not to sensitive areas such as eyes, mouth, ears, anogenital region or belly. The throwing or dropping of animals, or their lifting or dragging by body parts such as their tail, head, horns, ears, limbs, wool, hair or feathers, should not be permitted. The manual lifting of small animals is permissible.
- f) When using goads and other aids, the following principles should apply:
- i) Animals that have little or no room to move should not be subjected to physical force or goads and other aids which compel movement. Electric goads and prods should only be used in extreme cases and not on a routine basis to move animals. The use and the power output should be restricted to that necessary to assist movement of an animal and only when an animal has a clear path ahead to move. Goads and other aids should not be used repeatedly if the animal fails to respond or move. In such cases it should be investigated whether some physical or other impediment is preventing the animal from moving.
  - ii) The use of such devices should be limited to battery-powered goads on the hindquarters of pigs and large ruminants, and never on sensitive areas such as the eyes, mouth, ears, anogenital region or belly. Such instruments should not be used on horses, sheep and goats of any age, or on calves or piglets.

- iii) 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 rattles; they should be used in a manner sufficient to encourage and direct movement of the animals without causing undue stress.
- iv) Painful procedures (including whipping, tail twisting, use of nose twitches, pressure on eyes, ears or external genitalia), or the use of goads or other aids which cause pain and suffering (including large sticks, sticks with sharp ends, lengths of metal piping, fencing wire or heavy leather belts), should not be used to move animals.
- v) Excessive shouting at animals or making loud noises (e.g. through the cracking of whips) to encourage them to move should not occur, as such actions may make the animals agitated, leading to crowding or falling.
- vi) 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 animals only by their wool, hair, feathers, feet, neck, ears, tails, head, horns, limbs causing pain or suffering should not be permitted, except in an emergency where animal welfare or human safety may otherwise be compromised.
- vii) Conscious animals should not be thrown, dragged or dropped.

**The Community reiterates its previous comment:**

**SAME AS 3.7.5.2. (1) (c)**

**In paragraph (viii), first sentence, after the words "Performance standards", the word "should" should be replaced by "could".**

**Justification:**

**Performance based standards are useful but not always necessary.**

- viii) Performance standards should be established to evaluate the use of such instruments. Numerical scoring may be used and to measure the percentage of animals moved with an electric instrument and the percentage of animals slipping or falling at a point in the *slaughterhouse*. Any risk of compromising animal welfare, for example slippery floor, should be investigated immediately and the defect rectified to eliminate the problem.-

2. Provisions relevant to animals delivered in *containers*

- a) *Containers* in which animals are transported should be handled with care, and should not be thrown, dropped or knocked over. Where possible, they should be horizontal while being loaded and unloaded mechanically, and stacked to ensure ventilation. In any case they should be moved and stored in an upright position as indicated by specific marks.
- b) Animals delivered in *containers* with perforated or flexible bottoms should be unloaded with particular care in order to avoid injury. Where appropriate, animals should be unloaded from the *containers* individually.
- c) Animals which have been transported in *containers* should be slaughtered as soon as possible; mammals and ratites which are not taken directly upon arrival to the place of *slaughter* should have drinking water available to them from appropriate facilities at all times. Delivery of poultry for *slaughter* should be scheduled such that they are not deprived of water at the premises for longer than 12 hours. Animals which have not been slaughtered within 12 hours of their arrival should be fed, and should subsequently be given moderate amounts of food at appropriate intervals.

### 3. Provisions relevant to restraining and containing animals

**The Community reiterates its previous comment:**

**The following text should be added under this section:**

**"(a) Appropriate restraint shall be applied to the animals before they are stunned or immediately killed. In particular individual restraint is necessary when captive-bolt is used or when animals are slaughtered without prior stunning."**

**Justification:**

**The use of the above-mentioned methods of stunning or slaughter needs to be applied with high accuracy by the operator and can not be performed correctly under commercial conditions without individual restraint.**

- a) Provisions relevant to restraining animals for *stunning* or *slaughter* without *stunning*, to help maintain animal welfare, include:
  - i) provision of a non-slip floor;
  - ii) avoidance of excessive pressure applied by restraining equipment that causes struggling or vocalisation in animals;
  - iii) equipment engineered to reduce noise of air hissing and clanging metal;
  - iv) absence of sharp edges in restraining equipment that would harm animals;
  - v) avoidance of jerking or sudden movement of restraining device.
- b) Methods of *restraint* causing avoidable suffering should not be used in conscious animals. Such methods include the following:
  - i) suspending or hoisting animals (other than poultry) by the feet or legs;
  - ii) indiscriminate and inappropriate use of *stunning* equipment;
  - iii) mechanical clamping of the legs or feet of the animals (other than shackles used in poultry and ostriches) as the sole method of *restraint*;
  - iv) breaking legs, cutting leg tendons or blinding animals in order to immobilise them;
  - v) severing the spinal cord, for example using a puntilla or dagger, to immobilise animals; using electric currents to immobilise animals, except for proper *stunning*.

Article 3.7.5.3.

### **Lairage design and construction**

#### 1. General considerations

The *lairage* should be designed and constructed to hold an appropriate number of animals in relation to the throughput rate of the *slaughterhouse* without compromising the welfare of the animals.

In order to permit operations to be conducted as smoothly and efficiently as possible without injury or undue stress to the animals, the *lairage* should be designed and constructed so as to allow the animals to move freely in the required direction, using their behavioural characteristics and without undue penetration of their flight zone.

The following guidelines may help to achieve this.

#### 2. Design of *lairages*

- a) The *lairage* should be designed to allow a one-way flow of animals from *unloading* to the point of *slaughter*, with a minimum number of abrupt corners to negotiate.

- b) In red meat *slaughterhouses*, pens, passageways and races should be arranged in such a way as to permit inspection of animals at any time, and to permit the removal of sick or injured animals when considered to be appropriate, for which separate appropriate accommodation should be provided.
- c) Each animal should have room to stand up and lie down and, when confined in a pen, to turn around, except where the animal is reasonably restrained for safety reasons (e.g. fractious bulls). Fractious animals should be slaughter as soon as possible after arrival at the *slaughterhouse* to avoid welfare problems.\_

The *lairage* should have sufficient accommodation for the number of animals intended to be held. Drinking water should always be available to the animals, and the method of delivery should be appropriate to the type of animal held. Troughs should be designed and installed in such a way as to minimise the risk of fouling by faeces, without introducing risk of bruising and injury in animals, and should not hinder the movement of animals.

- d) Holding pens should be designed to allow as many animals as possible to stand or lie down against a wall. Where feed troughs are provided, they should be sufficient in number and feeding space to allow adequate access of all animals to feed. The feed trough should not hinder the movement of animals.
- e) Where tethers, ties or individual stalls are used, these should be designed so as not to cause injury or distress to the animals and should also allow the animals to stand, lie down and access any food or water that may need to be provided.
- f) Passageways and races should be either straight or consistently curved, as appropriate to the animal species. Passageways and races should have solid sides, but when there is a double race, the shared partition should allow adjacent animals to see each other. For pigs and sheep, passageways should be wide enough to enable two or more animals to walk side by side for as long as possible. At the point where passageways are reduced in width, this should be done by a means which prevents excessive bunching of the animals.
- g) *Animal handlers* should be positioned alongside races and passageways on the inside radius of any curve, to take advantage of the natural tendency of animals to circle an intruder. Where one-way gates are used, they should be of a design which avoids bruising. Races should be horizontal but where there is a slope, they should be constructed to allow the free movement of animals without injury.
- h) There should be a waiting pen, with a level floor and solid sides, between the holding pens and the race leading to the point of *stunning* or *slaughter*, to ensure a steady supply of animals for *stunning* or *slaughter* and to avoid having *animal 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.
- i) Ramps or lifts should be used for *loading* and *unloading* of animals where there is a difference in height or a gap between the floor of the *vehicle* and the unloading area. Unloading ramps should be designed and constructed so as to permit animals to be unloaded from *vehicles* on the level or at the minimum gradient achievable. Lateral side protection should be available to prevent animals escaping or falling. They should be well drained, with secure footholds and adjustable to facilitate easy movement of animals without causing distress or injury.

### 3. Construction of lairages

- a) *Lairages* should be constructed and maintained so as to provide protection from unfavourable climatic conditions, using strong and resistant materials such as concrete and metal which has

been treated to prevent corrosion. Surfaces should be easy to clean. There should be no sharp edges or protuberances which may injure the animals.

- b) Floors should be well drained and not slippery; they should not cause injury to the feet of the animals. Where necessary, floors should be insulated or provided with appropriate bedding. Drainage grids should be placed at the sides of pens and passageways and not where animals would have to cross them. Discontinuities or changes in floor patterns or texture which could cause baulking in the movement of animals should be avoided.
- c) *Lairages* should be provided with adequate lighting, but care should be taken to avoid harsh lights and shadows, which frighten the animals or affect their movement. The fact that animals will move more readily from a darker area into a well-lit area might be exploited by providing for lighting that can be regulated accordingly.
- d) *Lairages* should be adequately ventilated to ensure that waste gases (e.g. ammonia) do not build up and that draughts at animal height are minimised. Ventilation should be able to cope with the range of expected climatic conditions and the number of animals the *lairage* will be expected to hold.
- e) Care should be taken to protect the animals from excessively or potentially disturbing noises, for example by avoiding the use of noisy hydraulic or pneumatic equipment, and muffling noisy metal equipment by the use of suitable padding, or by minimising the transmission of such noise to the areas where animals are held and slaughtered.
- f) Where animals are kept in outdoor *lairages* without natural shelter or shade, they should be protected from the effects of adverse weather conditions.

#### Article 3.7.5.4.

### Care of animals in lairages

Animals in *lairages* should be cared for in accordance with the following guidelines:

1. As far as possible, established groups of animals should be kept together. Each animal should have enough space to stand up, lie down and turn around. Animals hostile to each other should be separated.
2. Where tethers, ties or individual stalls are used, they should allow animals to stand up and lie down without causing injury or distress.
3. Where bedding is provided, it should be maintained in a condition that minimises risks to the health and safety of the animals, and sufficient bedding should be used so that animals do not become soiled with manure.
4. Animals should be kept securely in the *lairage*, and care should be taken to prevent them from escaping and from predators.
5. Suitable drinking water should be available to the animals on their arrival and at all times to animals in *lairages* unless they are to be slaughtered without delay.
6. If animals are not to be slaughtered as soon as possible, suitable feed should be available to the animals on arrival and at intervals appropriate to the species. Unweaned animals should be slaughtered as soon as possible.
7. In order to prevent heat stress, animals subjected to high temperatures, particularly pigs and poultry, should be cooled by the use of water sprays, fans or other suitable means. However, the potential for water sprays to reduce the ability of animals to thermoregulate (especially poultry) should be

considered in any decision to use water sprays. The risk of animals being exposed to very cold temperatures or sudden extreme temperature changes should also be considered.

8. The *lairage* area should be well lit in order to enable the animals to see clearly without being dazzled. During the night, the lights should be dimmed. Lighting should also be adequate to permit inspection of all animals. Subdued lighting, and for example, blue light may be useful in poultry *lairages* in helping to calm birds.
9. The condition and state of health of the animals in a *lairage* should be inspected at least every morning and evening by a *veterinarian* or, under the *veterinarian's* responsibility, by another competent person, such as an *animal handler*. Animals which are sick, weak, injured or showing visible signs of distress should be separated, and veterinary advice should be sought immediately regarding treatment or euthanasia, or the animals should be humanely killed immediately if necessary.
10. Lactating dairy animals should be slaughtered as soon as possible. Dairy animals with obvious udder distension should be milked to minimise udder discomfort.
11. Animals which have given birth during the *journey* or in the *lairage* should be slaughtered as soon as possible or provided with conditions which are appropriate for suckling, for their welfare and the welfare of the newborn. Under normal circumstances, animals which are expected to give birth during a *journey* should not be transported.
12. Animals with horns, antlers or tusks capable of injuring other animals, if aggressive, should be penned separately.

Recommendations for specific species are described in detail in Articles 3.7.5.5. to 3.7.5.8.

#### Article 3.7.5.5.

#### **Management of fetuses during slaughter of pregnant animals**

Under normal circumstances, pregnant animals that would be in the final 10% of their gestation period at the planned time of *unloading* at the *slaughterhouse* should neither be transported nor slaughtered. If such an event occurs, an *animal handler* should ensure that females are handled separately and the specific procedures described below are applied. In all cases, the welfare of fetuses and dams during *slaughter* should be safeguarded.

1. Fetuses should not be removed from the uterus sooner than five minutes after the maternal neck or chest cut, to ensure absence of consciousness. A foetal heartbeat will usually still be present and foetal movements may occur at this stage, but these are only a cause for concern if the exposed foetus successfully breathes air.
2. If a live mature foetus is removed from the uterus, it should be prevented from inflating its lungs and breathing air (e.g. by clamping the trachea).
3. When uterine, placental or foetal tissues, including foetal blood, are not to be collected as part of the post-slaughter processing of pregnant animals, all fetuses should be left inside the unopened uterus until they are dead. When uterine, placental or foetal tissues are to be collected, where practical, fetuses should not be removed from the uterus until at least 15-20 minutes after the maternal neck or chest cut.
4. If there is any doubt about consciousness, the foetus should be killed with a captive bolt of appropriate size 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 fetuses 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 colostrums.





Annex XXIII (contd)

## Article 3.7.5.6.

**Summary analysis of handling and restraining methods and the associated animal welfare issues**

|                     | <b>Presentation of animals</b> | <b>Specific procedure</b>                              | <b>Specific purpose</b>   | <b>AW concerns/implications</b>  | <b>Key AW requirements</b>   | <b>Applicable species</b>  |
|---------------------|--------------------------------|--|---|--|--|--|
| 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   | Inaccurate targeting and inappropriate ballistics not achieving outright kill with first shot  | Operator competence  | Deer   |
|                     |                                | Group stunning pen                                     | Head-only electrical<br>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<br>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<br>Electrical-head-only<br>Free bullet<br>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<br>Free bullet   | Ineffective control of animal movement, misdirected shots  | Competent animal handlers  | Breeding pigs (boars and sows)                                       |

Annex XXIII (contd)

## Article 3.7.5.6.

**Summary analysis of handling and restraining methods and the associated animal welfare issues**

|                             | <b>Presentation of animals</b>           | <b>Specific procedure</b>                                 | <b>Specific purpose</b>  | <b>AW concerns/implications</b>                                    | <b>Key AW requirements</b>               | <b>Applicable species</b>                             |
|-----------------------------|--|---|--|--|--|---|
| Restraining methods (contd) | Upright restraint                        | Beak holding  | Captive bolt<br>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 handlers                | Ostriches   |
|                             | Holding body upright- manual             | Manual restraint  | Captive bolt<br>Electrical-head-only<br>Slaughter without stunning | Stress of capture and restraint;<br>accuracy of stunning/slaughter | Competent animal handlers                | Sheep, goats, calves, raites, small camelids, poultry |
|                             | Holding body upright mechanical          | Mechanical clamp / crush / squeeze/ V-restrainer (static) | Captive bolt<br>Electrical methods<br>Slaughter without stunning   | Loading of animal and overriding;<br>excessive pressure            | Proper design and operation of equipment | Cattle, buffalo, sheep, goats, deer, pigs, ostriches  |
|                             | Lateral restraint – manual or mechanical | Restrainer/cradle/c rush                                  | Slaughter without stunning   | Stress of restraint  | Competent animal handlers                | Sheep, goats, calves, camelids, cattle                |
|                             | Upright restraint mechanical             | Mechanical straddle (static)                              | Slaughter without stunning<br>Electrical methods<br>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   |

Annex XXIII (contd)

## Article 3.7.5.6.

**Summary analysis of handling and restraining methods and the associated animal welfare issues**

|                                       | <b>Presentation of animals</b> | <b>Specific procedure</b>  | <b>Specific purpose</b>  | <b>AW concerns/implications</b>   | <b>Key AW requirements</b>  | <b>Applicable species</b>          |
|---------------------------------------|--------------------------------|--|--|---|---|------------------------------------|
| Restraining and /or conveying methods | Mechanical – upright           | V-restrainer   | Electrical methods<br>Captive bolt<br>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<br>Captive bolt<br>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<br>Tipped out of <i>containers</i> on to conveyors | Presentation of birds for shackling prior to electrical stunning<br>Gas stunning | Stress and injury due to tipping in dump-module systems<br>height of tipping conscious poultry<br>broken bones and dislocations | Proper design and operation of equipment                            | Poultry                            |
|                                       | Suspension and/or inversion    | Poultry shackle  | Electrical stunning<br>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<br>Captive bolt<br>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                          |

Annex XXIII (contd)

## Article 3.7.5.6.

**Summary analysis of handling and restraining methods and the associated animal welfare issues**

|                       | <b>Presentation of animals</b> | <b>Specific procedure</b>         | <b>Specific purpose</b>                                   | <b>AW concerns/implications</b>   | <b>Key AW requirements</b>               | <b>Applicable species</b>                  |
|-----------------------|--------------------------------|-----------------------------------|---|---|--|--|
| Restrain by inversion | Rotating box                   | Fixed dide(s) (e.g. Weinberg pen) | Slaughter without stunning                                | Inversion stress; stress of resisting restraint, prolonged restraint, inhalation of blood and ingesta.<br><del>Keep restraint as brief as possible</del><br><u>Not recommended</u>              | Proper design and operation of equipment | Cattle                                     |
|                       |                                | Compressible side(s)              | Slaughter without stunning                                | Inversion stress, stress of resisting restraint, prolonged restraint<br>Preferable to rotating box with fixed sides<br><del>Keep restraint as brief as possible</del><br><u>Not recommended</u> | Proper design and operation of equipment | Cattle                                     |
| Body restraint        | Casting/hobbling               | Manual                            | Mechanical stunning methods<br>Slaughter without stunning | Stress of resisting restraint; animal temperament; bruising.<br>Keep restraint as short as possible   | Competent animal handlers                | Sheep, goats, calves, small camelids, pigs |
| Leg restraints        |                                | Rope casting                      | Mechanical stunning methods<br>Slaughter without stunning | Stress of resisting restraint; prolonged restraint, animal temperament; bruising<br>Keep restraint as short as possible   | Competent animal handlers                | Cattle, camelids                           |
|                       |                                | Tying of 3 or 4 legs              | Mechanical stunning methods<br>Slaughter without stunning | Stress of resisting restraint; prolonged restraint, animal temperament; bruising<br>Keep restraint as short as possible   | Competent animal handlers                | Sheep, goats, small camelids, pigs         |

Annex XXIII (contd)

## Article 3.7.5.7.

**Stunning methods**1. General considerations

The competence of the operators, and the appropriateness, and effectiveness of the method used for *stunning* and the maintenance of the equipment are the responsibility of the management of the *slaughterhouse*, and should be checked regularly by a *Competent Authority*.

Persons carrying out *stunning* should be properly trained and competent, and should ensure that:

- a) the animal is adequately restrained;
- b) animals in *restraint* are stunned as soon as possible;
- c) the equipment used for *stunning* is maintained and operated properly in accordance with the manufacturer's recommendations, in particular with regard to the species and size of the animal;
- d) the instrument is applied correctly;
- e) stunned animals are bled out (slaughtered) as soon as possible;
- f) animals should not be stunned when slaughter is likely to be delayed; and
- g) backup *stunning* devices are available for immediate use if the primary method of *stunning* fails.

In addition, such persons should be able to recognise when an animal is not correctly stunned and should take appropriate action.

**Community comment:**

**Since free bullet is mentioned as a method of slaughter in Article 3.7.5.8 the corresponding details applicable for free bullet that are laid down in the guidelines for killing for disease control purposes should be inserted here as well.**

2. Mechanical stunning

A mechanical device should be applied usually to the front of the head and perpendicular to the bone surface. The following diagrams illustrate the proper application of the device for certain species.

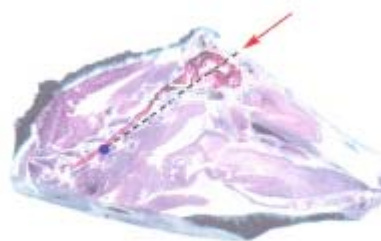
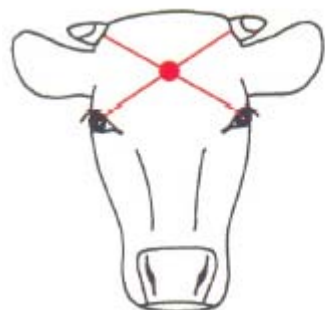
**Cattle**

Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom ([www.hsa.org.uk](http://www.hsa.org.uk)).

The optimum position for cattle is at the intersection of two imaginary lines drawn from the rear of the eyes to the opposite horn buds.

## Pigs



Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom ([www.hsa.org.uk](http://www.hsa.org.uk)).

The optimum position for pigs is on the midline just above eye level, with the shot directed down the line of the spinal cord.

## Sheep

The optimum position for hornless sheep and goats is on the midline.

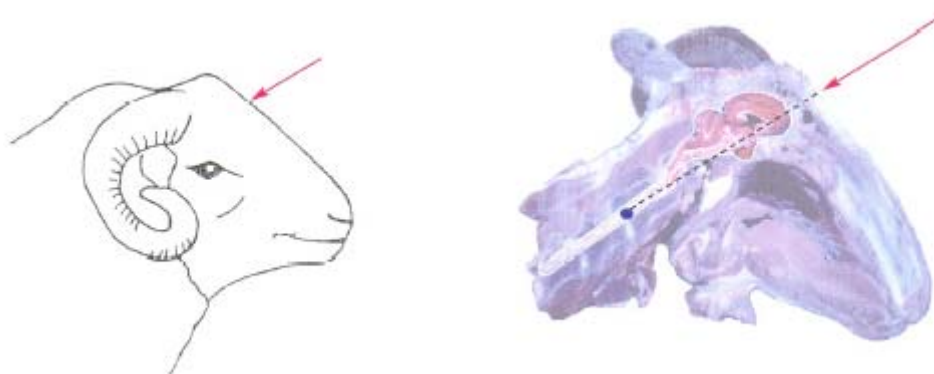


Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom ([www.hsa.org.uk](http://www.hsa.org.uk)).

### Goats

The optimum position for heavily horned sheep and horned goats is behind the poll, aiming towards the angle of the jaw.

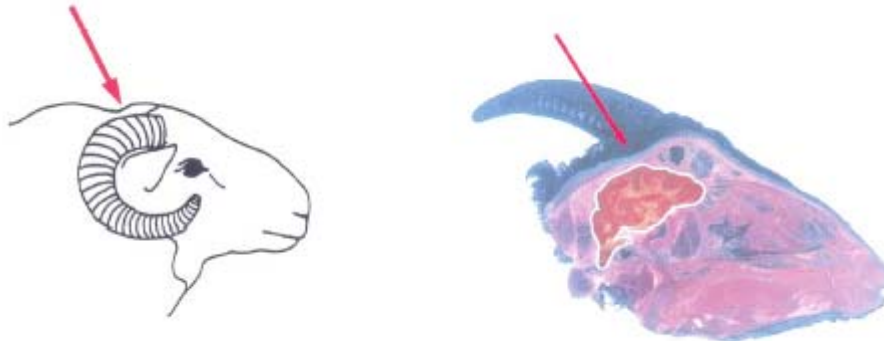


Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom ([www.hsa.org.uk](http://www.hsa.org.uk)).

### Horses



Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom ([www.hsa.org.uk](http://www.hsa.org.uk)).

The optimum position for horses is at right angles to the frontal surface, well above the point where imaginary lines from eyes to ears cross.

Signs of correct *stunning* using a mechanical instrument are as follows:

- a) the animal collapses immediately and does not attempt to stand up;
- b) the body and muscles of the animal become tonic (rigid) immediately after the shot;
- c) normal rhythmic breathing stops; and
- d) the eyelid is open with the eyeball facing straight ahead and is not rotated.

### 3. Electrical stunning

#### a) General considerations

An electrical device should be applied to the animal in accordance with the following guidelines.

Electrodes should be designed, constructed, maintained and cleaned regularly to ensure that the flow of current is optimal and in accordance with manufacturing specifications. They should be placed so that they span the brain. The application of electrical currents which bypass the brain is unacceptable unless the animal has been stunned. The use of a single current leg-to-leg is unacceptable as a *stunning* method.

If, in addition, it is intended to cause cardiac arrest, the electrodes should either span the brain and immediately thereafter the heart, on the condition that it has been ascertained that the animal is adequately stunned, or span brain and heart simultaneously.

Electrical *stunning* equipment should not be applied on animals as a means of guidance, movement, *restraint* or immobilisation, and shall not deliver any shock to the animal before the actual *stunning* or *killing*.

Electrical *stunning* apparatus should be tested prior to application on animals using appropriate resistors or dummy loads to ensure the power output is adequate to stun animals.

The electrical *stunning* apparatus should incorporate a device that monitors and displays voltage (true RMS) and the applied current (true RMS) and that such devices are regularly calibrated at least annually.

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 Community reiterates its previous comment:**

**The following sentence should be added here:**

***"In all cases electrodes should be applied rapidly and firmly and appropriate pressure maintained to facilitate proper contact and effective stunning".***

**Justification:**

**Correct operator technique in applying the electrodes is very important to achieve effective stunning.**

The *stunning* apparatus required for electrical *stunning* should be provided with adequate power to achieve continuously the minimum current level recommended for *stunning* as indicated in the table below:

| Species                                      | Minimum current levels for head-only stunning |
|--|---|
| Cattle                                       | 1.5 amps                                      |
| Calves (bovines of less than 6 month of age) | 1.0 amps                                      |
| Pigs   | 1.25 amps                                     |
| Sheep and goats                              | 1.0 amps                                      |
| Lambs  | 0.7 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 three seconds and in accordance with the manufacturer's instructions.

#### b) Electrical *stunning* of birds using a waterbath

There should be no sharp bends or steep gradients in the shackle line and the shackle line should be as short as possible consistent with achieving acceptable line speeds, and ensuring that birds have settled by the time they reach the water bath. A breast comforter can be used



effectively to reduce wing flapping and calm birds. The angle at which the shackle line approaches the entrance to the water bath, and the design of the entrance to the water bath, and the draining of excess 'live' water from the bath are all important considerations in ensuring birds are calm as they enter the bath, do not flap their wings, and do not receive pre-stun electric shocks.

In the case of birds suspended on a moving line, measures should be taken to ensure that the birds are not wing flapping at the entrance of the stunner. The birds should be secure in their shackle, but there should not be undue pressure on their shanks.

Waterbaths for poultry should be adequate in size and depth for the type of bird being slaughtered, and their height should be adjustable to allow for the head of each bird to be immersed. The electrode immersed in the bath should extend the full length of the waterbath.. Birds should be immersed in the bath up to the base of their wings.

The waterbath should be designed and maintained in such a way that when the shackles pass over the water, they are in continuous contact with the earthed rubbing bar.

The control box for the waterbath stunner should incorporate an ammeter which displays the total current flowing through the birds.

The shackle-to-leg contact should be wetted preferably before the birds are inserted in the shackles. In order to improve electrical conductivity of the water it is recommended that salt be added in the waterbath as necessary. Additional salt should be added regularly as a solution to maintain suitable constant concentrations in the waterbath.

Using waterbaths, birds are stunned in groups and different birds will have different impedances. The voltage should be adjusted so that the total current is the required current per bird as shown in the table hereafter, multiplied by the number of birds in the waterbath at the same time. The following values have been found to be satisfactory when employing a 50 Hertz sinusoidal alternating current.

Birds should receive the current for at least 4 seconds.

| Species             | Current (milliamperes per bird) |
|---------------------|---------------------------------|
| Broilers            | 100                             |
| Layers (spent hens) | 100                             |
| 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.

| Frequency (Hz)      | Chickens | Turkeys |
|---------------------|----------|---------|
| < 200 Hz            | 100 mA   | 250 mA  |
| From 200 to 400 Hz  | 150 mA   | 400 mA  |
| From 400 to 1500 Hz | 200 mA   | 400 mA  |

Every effort shall be made to ensure that no conscious or live birds enter the scalding tank.

In the case of automatic systems, until fail-safe systems of *stunning* and bleeding have been introduced, a manual back-up system should be in place to ensure that any birds which have missed the waterbath stunner and/or the automatic neck-cutter are immediately stunned and/or killed immediately, and they are dead before entering scald tank.

To lessen the number of birds that have not been effectively stunned reaching neck cutters, steps should be taken to ensure that small birds do not go on the line amongst bigger birds and that these small birds are stunned separately.

#### 4. Gas stunning (under study)

##### a) Stunning of pigs by exposure to carbon dioxide (CO<sub>2</sub>)

The concentration of CO<sub>2</sub> for *stunning* should be preferably 90% by volume but in any case no less than 80% by volume. After entering the *stunning* chamber, the animals should be conveyed to the point of maximum concentration of the gas as rapidly as possible and be kept until they are dead or brought into a state of insensibility which lasts until *death* occurs due to bleeding. Ideally, pigs should be exposed to this concentration of CO<sub>2</sub> for 3 minutes. Sticking should occur as soon as possible after exit from the gas chamber.

In any case, the concentration of the gas should be such that it minimises as far as possible all stress of the animal prior to loss of consciousness.

The chamber in which animals are exposed to CO<sub>2</sub> 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.

#### **The Community reiterates its previous comment:**

**At the end of the sentence, the text "and to have access to the animals in emergency cases" should be deleted.**

#### **Justification:**

**Access to animals in a gas chamber is of little interest from a welfare point of view, as, due to safety reason, operators will not be in a position to intervene in this particular area.**

It should be possible to inspect the CO<sub>2</sub> 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<sub>2</sub> concentration and the time of exposure, and to give a clearly visible and audible warning if the concentration of CO<sub>2</sub> falls below the required level.

Emergency stunning equipment should be available at the point of exit from the *stunning* chamber and used on any pigs that do not appear to be dead or completely stunned.

##### b) Inert gas mixtures for stunning pigs

Inhalation of high concentrations of carbon dioxide is aversive and can be distressing to animals. Therefore, the use of non-aversive gas mixtures is being developed.

Such gas mixtures include:

- i) a maximum of 2% by volume of oxygen in argon, nitrogen or other inert gases, or
- ii) a maximum of 30% by volume of carbon dioxide and a maximum of 2% by volume of oxygen in mixtures with carbon dioxide and argon, nitrogen or other inert gases.

Exposure time to the gas mixtures should be sufficient to ensure that no pigs regain consciousness before *death* supervenes through bleeding or cardiac arrest is induced.

c) Gas stunning of poultry

The main objective of gas *stunning* is to avoid the pain and suffering associated with shackling conscious poultry under water bath *stunning* and *killing* systems. Therefore, gas *stunning* should be limited to birds contained in crates or on conveyors only. The gas mixture should be non-aversive to poultry.

Gas *stunning* of poultry in their transport *containers* will eliminate the need for live bird handling at the processing plant and all the problems associated with the electrical *stunning*. Gas *stunning* of poultry on a conveyor eliminates the problems associated with the electrical water bath *stunning*.

Live poultry should be conveyed into the gas mixtures either in transport crates or on conveyor belts.

The following gas procedures have been properly documented for chickens and turkeys but do not necessarily apply for other domestic birds. In any case the procedure should be designed as to ensure that all animals are properly stunned without unnecessary suffering.

- i) Gas mixtures used for *stunning* poultry include:
  - a minimum of 2 minutes exposure to 40% carbon dioxide, 30% oxygen and 30% nitrogen, followed by a minimum of one minute exposure to 80% carbon dioxide in air; or
  - a minimum of 2 minutes exposure to any mixture of argon, nitrogen or other inert gases with atmospheric air and carbon dioxide, provided that the carbon dioxide concentration does not exceed 30% by volume and the residual oxygen concentration does not exceed 2% by volume; or
  - a minimum of 2 minutes exposure to argon, nitrogen, other inert gases or any mixture of these gases in atmospheric air with a maximum of 2% residual oxygen by volume; or
  - a minimum of 2 minutes exposure to a minimum of 55% carbon dioxide in air.
- ii) Requirements for effective use are as follows:
  - Compressed gases should be vaporised prior to administration into the chamber and should be at room temperature to prevent any thermal shock. Under no circumstances, should solid gases with freezing temperatures enter the chamber.
  - Gas mixtures should be humidified.
  - Appropriate gas concentrations of oxygen and carbon dioxide should be monitored and displayed continuously at the level of the birds inside the chamber to ensure that anoxia ensues.

Under no circumstances, should birds exposed to gas mixtures be allowed to regain consciousness. If necessary, the exposure time should be extended.

## 5. Bleeding

From the point of view of animal welfare, animals which are stunned with a reversible method should be bled without delay. Maximum stun-stick interval depends on the parameters of the *stunning* method applied, the species concerned and the bleeding method used (full cut or chest stick when possible). As a consequence, depending on those factors, the *slaughterhouse* operator should set up a maximum stun-stick interval that ensures that no animals recover consciousness during bleeding. In any case the following time limits should be applied.

| Stunning method                                     | Maximum delay for bleeding to be started |
|---|--|
| Electrical methods and non penetrating captive bolt | 20 seconds                               |
| CO <sub>2</sub>                                     | 60 seconds (after leaving the chamber)   |

All animals should be bled out by incising both carotid arteries, or the vessels from which they arise (e.g., chest stick). However, when the *stunning* method used cardiac arrest, the incision of all of these *vessels* is not necessary from the point of view 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 re-stunned.

After incision of the blood vessels, no scalding carcass treatment or dressing procedures should be performed on the animals for at least 30 seconds, or in any case until all brain-stem reflexes have ceased.

## Annex XXIII (contd)

## Article 3.7.5.8.

## Summary analysis of 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   | Operator competence, 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).<br>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. This method should only be used for cattle and sheep when alternative methods are not available. |
|            | Manual percussive blow   | Inaccurate targeting; insufficient power; size of instrument  | Competent animal handlers; restraint; accuracy.<br>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:<br>1. across head then head to chest;<br>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.                                       |
|            | Single application:<br>1. head only;<br>2. head to body;<br>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                         |  |
|            | Waterbath  | Restraint, accidental pre-stun electric shocks; inadequate current and voltage; recovery of consciousness   | Competent operation and maintenance of equipment                                   | Poultry only   |  |

## Article 3.7.5.8.

## Summary analysis of stunning methods and the associated animal welfare issues

| Method  | Specific method  | AW concerns/implications  | Key AW requirements applicable  | Species   | Comment   |
|---|--|---|---|---|---|
| Gaseous   | CO <sub>2</sub> air/O <sub>2</sub> mixture;<br>CO <sub>2</sub> inert gas mixture | Aversiveness of high CO <sub>2</sub> concentrations, respiratory distress; inadequate exposure                | Concentration; duration of exposure; design, maintenance and operation of equipment; stocking density management  | Pigs, poultry   |   |
|   | Inert gases  | Recovery of consciousness   | Concentration; duration of exposure; design, maintenance and operation of equipment; stocking density management  | Pigs, poultry   |   |
| 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. <u>pain during and after the cut.</u> | High level of operator competency.<br>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.<br>An incision which does not close over the knife during the throat cut. | Cattle, buffalo, horses, camelids, sheep, goats, poultry, ratites | No further procedure should be carried out before the bleeding out is completed (i.e. at least <del>30</del> 60 seconds for mammals)<br>The practice to remove hypothetical blood clots just after the bleeding should be discouraged since this may increase animal suffering. |

## Annex XXIII (contd)

## Article 3.7.5.9.

## Summary analysis of slaughter methods and the associated animal welfare issues

| Slaughter methods            | Specific method   | AW concerns / implications   | Key requirements  | Species  | Comments |
|------------------------------|---|--|---|--|----------|
| Bleeding with prior stunning | Full frontal cutting across the throat                          | Failure to cut both common carotid arteries; occlusion of cut arteries; pain during and after the cut.                                 | A very sharp blade or knife, of sufficient length so that the point of the knife remains outside the incision during the cut; the point of the knife should not be used to make the incision.<br>An incision which does not close over the knife during the throat cut. | Cattle, buffalo, horses, camelids, sheep, goats, |          |
|                              | Neck stab followed by forward cut                               | Ineffective stunning; failure to cut both common carotid arteries; impaired blood flow; delay in cutting after reversible stunning     | Prompt and accurate cutting   | Camelids, sheep, goats, poultry, ratites         |          |
|                              | Neck stab 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 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   |          |

## Article 3.7.5.9.

## Summary analysis of slaughter methods and the associated animal welfare issues (contd)

| Slaughter methods                              | Specific method  | AW concerns / implications   | Key requirements   | Species               | Comments  |
|--|--|--|--|-----------------------|---|
| 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   |                       |   |
| Bleeding with prior stunning (contd)           | 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 slaughter  |
|  | Manual neck dislocation and decapitation   | Pain due to loss of consciousness not being immediate; difficult to achieve in large birds | Neck dislocation should be performed in one stretch to sever the spinal cord | Poultry only          | Slaughter by neck dislocation should be performed in one stretch to sever the spinal cord. Acceptable only when slaughtering small numbers of small birds |
| Cardiac arrest in a waterbath electric stunner | Bleeding by evisceration   |  | Induction of cardiac arrest  | Quail                 |   |
|  | Bleeding by neck cutting   |  |  | Poultry               |   |



Annex XXIII (contd)

Article 3.7.5.10.

**Methods, procedures or practices unacceptable on animal welfare grounds**

1. The restraining methods which work through immobilisation by injury such as breaking legs, leg tendon cutting, and severing the spinal cord (e.g. using a puntilla or dagger) cause severe pain and stress in animals. Those methods are not acceptable in any species.
2. The use of the electrical *stunning* method with a single application leg to leg is ineffective and unacceptable in any species.
3. The *slaughter* method of brain stem severance by piercing through the eye socket or skull bone without prior *stunning*, is not acceptable in any species.

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## APPENDIX 3.7.6.

**GUIDELINES FOR THE KILLING OF ANIMALS FOR DISEASE CONTROL PURPOSES**

## Article 3.7.6.1.

**General principles**

These guidelines are based on the premise that a decision to kill the animals has been made, and address the need to ensure the welfare of the animals until they are dead.

1. All personnel involved in the humane *killing* of animals should have the relevant skills and competencies. Competence may be gained through formal training and/or practical experience.
2. As necessary, operational procedures should be adapted to the specific circumstances operating on the premises and should address, apart from animal welfare, aesthetics of the method of euthanasia, cost of the method, operator safety, biosecurity and environmental aspects, aesthetics of the method of euthanasia and cost of the method.
3. Following the decision to kill the animals, *killing* should be carried out as quickly as possible and normal husbandry should be maintained until the animals are killed.
4. The handling and movement of animals should be minimised and when done, it should be done in accordance with the guidelines described below.
5. Animal *restraint* should be sufficient to facilitate effective *killing*, and in accordance with animal welfare and operator safety requirements; when *restraint* is required, *killing* should follow with minimal delay.

**The Community reiterates its previous comment:****The paragraph 6 should be amended in the following way:**

**6. When animals are killed for disease control purposes, methods used should result in immediate death or immediate loss of consciousness lasting until death; when loss of consciousness is not immediate, induction of unconsciousness should be non-aversive or as least aversive as possible and should not cause avoidable anxiety, pain, distress or suffering in the animals.**

**Justification: Total non-aversiveness is technically difficult to guarantee especially under disease control situation.**

6. When animals are killed for *disease* control purposes, methods used should result in immediate death or immediate loss of consciousness lasting until death; when loss of consciousness is not immediate, induction of unconsciousness should be non-aversive and should not cause anxiety, pain, distress or suffering in the animals.
7. For animal welfare considerations, young animals should be killed before older animals; for biosecurity considerations, infected animals should be killed first, followed by in-contact animals, and then the remaining animals.
8. There should be continuous monitoring of the procedures by the *Competent Authorities* to ensure they are consistently effective with regard to animal welfare, operator safety and biosecurity.
9. When the operational procedures are concluded, there should be a written report describing the practices adopted and their effect on animal welfare, operator safety and biosecurity.

10. These general principles should also apply when animals need to be killed for other purposes such as after natural disasters or for culling animal populations.

**Article 3.7.6.2.**

**Organisational structure**

*Disease* control contingency plans should be in place at a national level and should contain details of management structure, *disease* control strategies and operational procedures; animal welfare considerations should be addressed within these disease control contingency plans. The plans should also include a strategy to ensure that an adequate number of personnel competent in the humane *killing* of animals is available. Local level plans should be based on national plans and be informed by local knowledge.

*Disease* control contingency plans should address the animal welfare issues that may result from animal movement controls.

The operational activities should be led by an *official veterinarian* who has the authority to appoint the personnel in the specialist teams and ensure that they adhere to the required animal welfare and biosecurity standards. When appointing the personnel, he/she should ensure that the personnel involved have the required competencies.

The *official veterinarian* should be responsible for all activities across one or more affected premises and should be supported by coordinators for planning (including communications), operations and logistics to facilitate efficient operations.

The *official veterinarian* should provide overall guidance to personnel and logistic support for operations on all affected premises to ensure consistency in adherence to the OIE animal welfare and animal health guidelines.

A specialist team, led by a team leader answerable to the *official veterinarian*, should be deployed to work on each affected premises. The team should consist of personnel with the competencies to conduct all required operations; in some situations, personnel may be required to fulfil more than one function. Each team should contain a *veterinarian* or have access to veterinary advice at all times.

In considering the animal welfare issues associated with the *killing* of animals, the key personnel, their responsibilities and competencies required are described in Article 3.7.6.3.

**Article 3.7.6.3.**

**Responsibilities and competencies of the specialist team**

1. Team leader

a) Responsibilities:

- i) plan overall operations on ~~an~~ affected premises;
- ii) determine and address requirements for animal welfare, operator safety and biosecurity;
- iii) organise, brief and manage team of people to facilitate humane *killing* of the relevant animals on the premises in accordance with national regulations and these guidelines;
- iv) determine logistics required;
- v) monitor operations to ensure animal welfare, operator safety and biosecurity requirements are met;
- vi) report upwards on progress and problems;
- vii) provide a written report at the conclusion of the *killing*, describing the practices adopted and their effect on the animal welfare, operator safety and biosecurity outcomes.

b) Competencies

- i) appreciation of normal animal husbandry practices;
- ii) appreciation of animal welfare and the underpinning behavioural, anatomical and physiological processes involved in the *killing* process;
- iii) skills to manage all activities on premises and deliver outcomes on time;
- iv) awareness of psychological effects on farmers, team members and general public;
- v) effective communication skills;
- vi) appreciation of the environmental impacts caused by their operation.

## 2. Veterinarian

### a) Responsibilities

- i) determine and supervise the implementation of the most appropriate *killing* method to ensure that animals are killed without avoidable pain and distress;
- ii) determine and implement the additional requirements for animal welfare, including the order of *killing*;
- iii) ensure that confirmation of animals deaths is carried out by competent persons at appropriate times after the *killing* procedure;
- iv) minimise the *risk of disease* spread within and from the premises through the supervision of biosecurity procedures;
- v) continuously monitor animal welfare and biosecurity procedures;
- vi) in cooperation with the leader, prepare a written report at the conclusion of the *killing*, describing the practices adopted and their effect on animal welfare.

### b) Competencies

- i) ability to assess animal welfare, especially the effectiveness of *stunning* and *killing*, and to correct any deficiencies;
- ii) ability to assess biosecurity risks.

## 3. Animal handlers

### a) Responsibilities

- i) review on-site facilities in terms of their appropriateness;
- ii) design and construct temporary animal handling facilities, when required;
- iii) move and restrain animals;
- iv) continuously monitor animal welfare and biosecurity procedures.

### b) Competencies

- i) animal handling in emergency situations and in close confinement is required;
- ii) an appreciation of biosecurity and containment principles.

## 4. Animal killing personnel

### a) Responsibilities

Humane *killing* of the animals through effective *stunning* and *killing* should be ensured.

### b) Competencies

- i) when required by regulations, licensed to use necessary equipment;
- ii) competent to use and maintain relevant equipment;
- iii) competent to use techniques for the species involved;

iv) competent to assess effective *stunning* and *killing*.

5. Carcass disposal personnel

a) Responsibilities

An efficient carcass disposal (to ensure *killing* operations are not hindered) should be ensured.

b) Competencies

The personnel should be competent to use and maintain available equipment and apply techniques for the species involved.

6. Farmer/owner/manager

a) Responsibilities

i) assist when requested.

b) Competencies

i) specific knowledge of his/her animals and their environment.

Article 3.7.6.4.

**Considerations in planning the humane killing of animals**

Many activities will need to be conducted on affected premises, including the humane *killing* of animals. The team leader should develop a plan for humanely *killing* animals on the premises which should include consideration of:

1. minimising handling and movement of animals;
2. *killing* the animals on the affected premises; however, there may be circumstances where the animals may need to be moved to another location for *killing*; when the *killing* is conducted at an *abattoir*, the guidelines in Appendix 3.7.6. on *slaughter* of animals should be followed;
3. the species, number, age and size of animals to be killed, and the order of *killing* them;
4. methods of *killing* the animals, and their cost;
5. housing, husbandry, location of the animals, as well as accessibility of the farm;
6. the availability and effectiveness of equipment needed for *killing* of the animals, as well as the time necessary to kill the required number of animals using such methods;
7. the facilities available on the premises that will assist with the *killing* including any additional facilities that may need to be brought on and then removed from the premises;
8. biosecurity and environmental issues;
9. the health and safety of personnel conducting the *killing*;
10. any legal issues that may be involved, for example where restricted veterinary drugs or poisons may be used, or where the process may impact on the environment;
11. the presence of other nearby premises holding animals;
12. possibilities for removal, disposal and destruction of carcasses.

The plan should minimise the negative welfare impacts of the killing by taking into account the different phases of the procedures to be applied for killing (choice of the killing sites, killing methods, etc.) and the measures restricting the movements of the animals.

Competences and skills of the personnel handling and killing animals

In designing a *killing* plan, it is essential that the method chosen be consistently reliable to ensure that all animals are humanely and quickly killed.

## Article 3.7.6.5.

Table summarising killing methods described in Articles 3.7.6.6.-3.7.6.17.

| Species         | Age range           | Procedure   | Restraint necessary | Animal welfare concerns with inappropriate application          | Article reference |
|-----------------|---------------------|---|---------------------|---|-------------------|
| Cattle          | all                 | free bullet   | no                  | non-lethal wounding   | 3.7.6.6.          |
|                 | all except neonates | captive bolt - penetrating, followed by pithing or bleeding | yes                 | ineffective stunning  | 3.7.6.7.          |
|                 | adults only         | captive bolt - non-penetrating, followed by bleeding        | yes                 | ineffective stunning, regaining of consciousness before killing | 3.7.6.8.          |
|                 | calves only         | electrical, two stage application                           | yes                 | pain associated with cardiac arrest after ineffective stunning  | 3.7.6.10.         |
|                 | calves only         | electrical, single application (method 1)                   | yes                 | ineffective stunning  | 3.7.6.11.         |
|                 | all                 | injection with barbiturates and other drugs                 | yes                 | non-lethal dose, pain associated with injection site            | 3.7.6.15.         |
| Sheep and goats | all                 | free bullet   | no                  | non-lethal wounding   | 3.7.6.6.          |
|                 | all except neonates | captive bolt - penetrating, followed by pithing or bleeding | yes                 | ineffective stunning, regaining of consciousness before death   | 3.7.6.7.          |
|                 | all except neonates | captive bolt - non-penetrating, followed by bleeding        | yes                 | ineffective stunning, regaining of consciousness before death   | 3.7.6.8.          |
|                 | neonates            | captive bolt - non-penetrating                              | yes                 | non-lethal wounding   | 3.7.6.8.          |
|                 | all                 | electrical, two stage application                           | yes                 | pain associated with cardiac arrest after ineffective stunning  | 3.7.6.10.         |
|                 | all                 | electrical, single application (Method 1)                   | yes                 | ineffective stunning  | 3.7.6.11.         |
|                 | neonates only       | CO <sub>2</sub> / air mixture                               | yes                 | slow induction of unconsciousness, aversiveness of induction    | 3.7.6.12.         |
|                 | neonates only       | nitrogen and/or inert gas mixed with CO <sub>2</sub>        | yes                 | slow induction of unconsciousness, aversiveness of induction    | 3.7.6.13.         |
|                 | neonates only       | nitrogen and/or inert gases                                 | yes                 | slow induction of unconsciousness                               | 3.7.6.14.         |

## Annex XXIII (contd)

Table summarising killing methods described in Articles 3.7.6.6.-3.7.6.17. (Cont)

| Species                | Age range              | Procedure   | Restraint Necessary | Animal welfare concerns with inappropriate application         | Article reference |
|------------------------|------------------------|---|---------------------|--|-------------------|
| Sheep and goats (cont) | all                    | injection of barbiturates and other drugs                     | yes                 | non-lethal dose, pain associated with injection site           | 3.7.6.15.         |
| Pigs                   | all, except neonates   | free bullet   | no                  | Non-lethal wounding  | 3.7.6.6.          |
|                        | all except neonates    | captive bolt - penetrating, followed by pithing or bleeding   | yes                 | ineffective stunning, regaining of consciousness before death  | 3.7.6.7.          |
|                        | neonates only          | captive bolt - non-penetrating                                | yes                 | Non-lethal wounding  | 3.7.6.8.          |
|                        | all §                  | electrical, two stage application                             | yes                 | pain associated with cardiac arrest after ineffective stunning | 3.7.6.10.         |
|                        | all                    | electrical, single application (Method 1)                     | yes                 | ineffective stunning   | 3.7.6.11.         |
|                        | neonates only          | CO <sub>2</sub> / air mixture                                 | yes                 | slow induction of unconsciousness, aversiveness of induction   | 3.7.6.12.         |
|                        |                        |   |                     |  |                   |
|                        | neonates only          | nitrogen and/or inert gas mixed with CO <sub>2</sub>          | yes                 | slow induction of unconsciousness, aversiveness of induction   | 3.7.6.13.         |
|                        | neonates only          | nitrogen and/or inert gases                                   | yes                 | slow induction of unconsciousness,                             | 3.7.6.14.         |
|                        | all                    | injection with barbiturates and other drugs                   | yes                 | non-lethal dose, pain associated with injection site           | 3.7.6.15.         |
| Poultry                | adults only            | captive bolt - non-penetrating                                | yes                 | ineffective stunning   | 3.7.6.8.          |
|                        | day-olds and eggs only | Maceration  | no                  | non-lethal wounding, non- immediacy;                           | 3.7.6.9.          |
|                        | adults only            | electrical single application (Method 2)                      | yes                 | ineffective stunning   | 3.7.6.11.         |
|                        | adults only            | electrical single application, followed by killing (Method 3) | yes                 | ineffective stunning; regaining of consciousness before death  | 3.7.6.11.         |

Annex XXIII (contd)**Table summarising killing methods described in Articles 3.7.6.6.-3.7.6.17. (Cont)**

|                |             |   |           |   |           |
|----------------|-------------|---|-----------|---|-----------|
| Poultry (cont) | all         | CO <sub>2</sub> / air mixture<br>Method 1<br>Method 2   | yes<br>no | slow induction of<br>unconsciousness,<br>aversiveness of<br>induction | 3.7.6.12. |
|                | all         | nitrogen and/or inert gas<br>mixed with CO <sub>2</sub>                                       | yes       | slow induction of<br>unconsciousness,<br>aversiveness of<br>induction | 3.7.6.13. |
|                | all         | nitrogen and/or inert<br>gases  | yes       | slow induction of<br>unconsciousness                                  | 3.7.6.14. |
|                | all         | injection of barbiturates<br>and other drugs  | yes       | Non-lethal dose, pain<br>associated with injection<br>site            | 3.7.6.15. |
|                | adults only | addition of anaesthetics to<br>feed or water, followed by<br>an appropriate killing<br>method | no        | ineffective or slow<br>induction of<br>unconsciousness                | 3.7.6.16. |

- The methods are described in the order of mechanical, electrical and gaseous, not in an order of desirability from an animal welfare viewpoint.
- § The only preclusion against the use of this method for neonates is the design of the stunning tongs that may not facilitate their application across such a small-sized head/body.

**Article 3.7.6.6.****Free bullet****1. Introduction**

- a) A free bullet is a projectile fired from a shotgun, rifle, handgun or purpose-made humane killer.
- b) The most commonly used firearms for close range use are:
  - i) humane killers (specially manufactured/adapted single-shot weapons);
  - ii) shotguns (12, 16, 20, 28 bore and .410);
  - iii) rifles (.22 rimfire);
  - iv) handguns (various calibres from .32 to .45).
- c) The most commonly used firearms for long range use are rifles (.22, .243, .270 and .308).
- d) A free bullet used from long range should be aimed to penetrate the skull or soft tissue at the top of the neck of the animal (high neck shot), to cause irreversible concussion and death and should only be used by properly trained and competent marksmen.



## 2. Requirements for effective use

- a) The marksman should take account of human safety in the area in which he/she is operating. Appropriate vision and hearing protective devices should be worn by all personnel involved.
- b) The marksman should ensure that the animal is not moving and in the correct position to enable accurate targeting and the range should be as short as possible (5 –50 cm for a shotgun) but the barrel should not be in contact with the head of the animal.
- c) The correct cartridge, calibre and type of bullet for the different species age and size should be used. Ideally the ammunition should expand upon impact and dissipate its energy within the cranium.
- d) Shot animals should be checked to ensure the absence of brain stem reflexes.

**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 Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire, AL4 8AN, United Kingdom ([www.hsa.org.uk](http://www.hsa.org.uk)).

**Figure 2.** The optimum position for hornless sheep and goats is on the midline, with the shot aiming at the angle of the jaw.

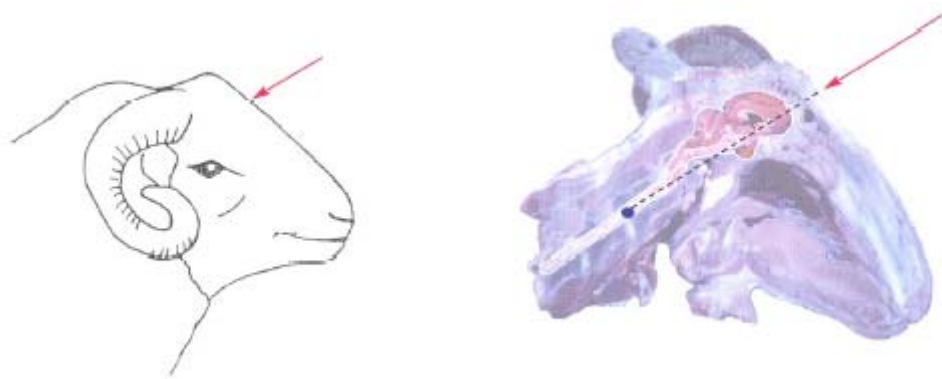


Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire, AL4 8AN, United Kingdom ([www.hsa.org.uk](http://www.hsa.org.uk)).

**Figure 3.** The optimum shooting position for heavily horned sheep and horned goats is behind the poll aiming towards the angle of the jaw.

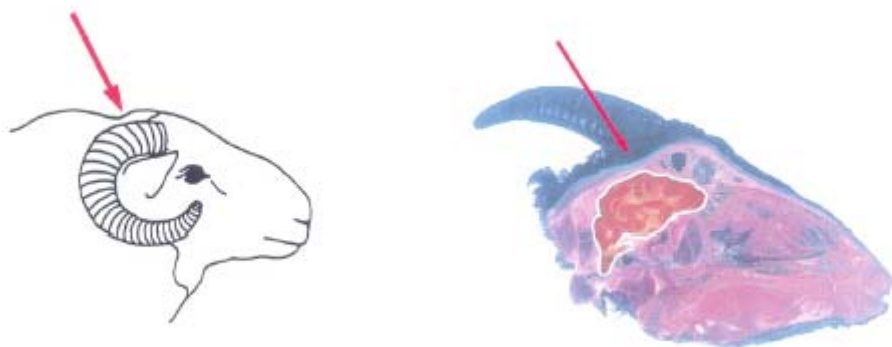


Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire, AL4 8AN, United Kingdom ([www.hsa.org.uk](http://www.hsa.org.uk)).

**Figure 4.** The optimum shooting position for pigs is just above eye level, with the shot directed down the line of the spinal cord.



Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire, AL4 8AN, United Kingdom ([www.hsa.org.uk](http://www.hsa.org.uk)).

### 3. Advantages

- a) Used properly, a free bullet provides a quick and effective method for *killing*.
- b) It requires minimal or no *restraint* and can be use to kill from a distance by properly trained and competent marksmen.
- c) It is suitable for *killing* agitated animals in open spaces.

### 4. Disadvantages

- a) The method is potentially dangerous to humans and other animals in the area.

- b) It has the potential for non-lethal wounding.
- c) Destruction of brain tissue may preclude diagnosis of some *diseases*.
- d) Leakage of bodily fluids may present a biosecurity *risk*.
- e) Legal requirements may preclude or restrict use.
- f) There is a limited availability of competent personnel.

#### 4. Conclusions

The method is suitable for cattle, sheep, goats and pigs, including large animals in open spaces.

#### Article 3.7.6.7.

### **Penetrating captive bolt**

#### 1. Introduction

A penetrating captive bolt is fired from a gun powered by either compressed air or a blank cartridge. There is no free projectile.

The captive bolt should be aimed on the skull in a position to penetrate the cortex and mid-brain of the animal. The impact of the bolt on the skull produces unconsciousness. Physical damage to the brain caused by penetration of the bolt may result in death, however pithing or bleeding should be performed as soon as possible after the shot to ensure the death of the animal.

#### 2. Requirements for effective use

- a) For cartridge powered and compressed air guns, the bolt velocity and the length of the bolt should be appropriate to the species and type of animal, in accordance with the recommendations of the manufacturer.
- b) Captive bolt guns should be frequently cleaned and maintained in good working condition.
- c) More than one gun may be necessary to avoid overheating and a back-up gun should be available in the event of an ineffective shot.
- d) Animals should be restrained; at a minimum they should be penned for cartridge powered guns and in a race for compressed air guns.
- e) The operator should ensure that the head of the animal is accessible.
- f) The operator should fire the captive bolt at right angles to the skull in the optimal position (see figures 1, 3 & 4. The optimum shooting position for hornless sheep is on the highest point of the head, on the midline and aim towards the angle of the jaw).
- g) To ensure the death of the animal, pithing or bleeding should be performed as soon as possible after *stunning*.
- h) Animals should be monitored continuously after *stunning* until death to ensure the absence of brain stem reflexes.

#### 3. Advantages

- a) Mobility of cartridge powered equipment reduces the need to move animals.
- b) The method induces an immediate onset of a sustained period of unconsciousness.

#### 4. Disadvantages

- a) Poor gun maintenance and misfiring, and inaccurate gun positioning and orientation may result in poor animal welfare.
- b) Post stun convulsions may make pithing difficult and hazardous.
- c) The method is difficult to apply in agitated animals.
- d) Repeated use of a cartridge powered gun may result in over-heating.
- e) Leakage of bodily fluids may present a biosecurity risk.
- f) Destruction of brain tissue may preclude diagnosis of some *diseases*.

#### 5. Conclusions

The method is suitable for cattle, sheep, goats and pigs (except neonates), when followed by pithing or bleeding.

#### Article 3.7.6.8.

### **Captive bolt – non-penetrating**

#### 1. Introduction

A non-penetrating captive bolt is fired from a gun powered by either compressed air or a blank cartridge. There is no free projectile.

The gun should be placed on the front of the skull to deliver a percussive blow which produces unconsciousness in cattle (adults only), sheep, goats and pigs, and death in poultry and neonate sheep, goats and pigs up to a maximum live weight of 10 kg. Bleeding should be performed as soon as possible after the blow to ensure the death of the animal.

#### 2. Requirements for effective use

- a) For cartridge powered and compressed air guns, the bolt velocity should be appropriate to the species and type of animal, in accordance with the recommendations of the manufacturer.
- b) Captive bolt guns should be frequently cleaned and maintained in good working condition.
- c) More than one gun may be necessary to avoid overheating and a back-up gun should be available in the event of an ineffective shot.
- d) Animals should be restrained; at a minimum mammals should be penned for cartridge powered guns and in a race for compressed air guns; birds should be restrained in cones, shackles, crushes or by hand.
- e) The operator should ensure that the head of the animal is accessible.
- f) The operator should fire the captive bolt at right angles to the skull in the optimal position (figures 1-4).
- g) To ensure death in non-neonate mammals, bleeding should be performed as soon as possible after *stunning*.

- h) Animals should be monitored continuously after *stunning* until death to ensure the absence of brain stem reflexes.

### 3. Advantages

- a) The method induces an immediate onset of unconsciousness, and death in birds and neonate mammals.
- b) Mobility of equipment reduces the need to move animals.

### 4. Disadvantages

- a) As consciousness can be regained quickly in non-neonate mammals, they should be bled as soon as possible after *stunning*.
- b) Laying hens in cages have to be removed from their cages and most birds have to be restrained.
- c) Poor gun maintenance and misfiring, and inaccurate gun positioning and orientation may result in poor animal welfare.
- d) Post stun convulsions may make bleeding difficult and hazardous.
- e) Difficult to apply in agitated animals; such animals may be sedated in advance of the *killing* procedure.
- f) Repeated use of a cartridge powered gun may result in over-heating.
- g) Bleeding may present a biosecurity risk.

### 5. Conclusions

- a) The method is suitable for poultry, and neonate sheep, goats and pigs up to a maximum weight of 10 kg.

#### Article 3.7.6.9.

### **Maceration**

#### 1. Introduction

Maceration, utilising a mechanical apparatus with rotating blades or projections, causes immediate fragmentation and death in day-old poultry and embryonated eggs.

#### 2. Requirements

- a) Maceration requires specialised equipment which should be kept in excellent working order.
- b) The rate of introducing the birds should not allow the equipment to jam, birds to rebound from the blades or the birds to suffocate before they are macerated.

#### 3. Advantages

- a) Procedure results in immediate death.

b) Large numbers can be killed quickly.

4. Disadvantages

- a) Specialised equipment is required.
- b) Macerated tissues may present a biosecurity or human health risks.
- c) The cleaning of the equipment can be a source of contamination.

5. Conclusion

The method is suitable for *killing* day-old poultry and embryonated eggs.

Article 3.7.6.10.

**Electrical – two-stage application**

1. Introduction

A two stage application of electric current comprises firstly an application of current to the head by scissor-type tongs, immediately followed by an application of the tongs across the chest in a position that spans the heart.

The application of sufficient electric current to the head will induce ‘tonic/clonic’ epilepsy and unconsciousness. Once the animal is unconscious, the second stage will induce ventricular fibrillation (cardiac arrest) resulting in death. The second stage (the application of low frequency current across the chest) should only be applied to unconscious animals to prevent unacceptable levels of pain.



Figure 5. Scissor-type stunning tongs.

2. Requirements for effective use

- a) The stunner control device should generate a low frequency (AC sine wave 50 Hz) current with a minimum voltage and current as set out in the following table:

| Animal         | Minimum voltage (V) | Minimum current (A) |
|----------------|---------------------|---------------------|
| Cattle         | 220                 | 1.5                 |
| Sheep          | 220                 | 1.0                 |
| Pigs > 6 weeks | 220                 | 1.3                 |
| Pigs < 6 weeks | 125                 | 0.5                 |

- b) Appropriate protective clothing (including rubber gloves and boots) should be worn.
- c) Animals should be restrained, at a minimum free-standing in a pen, close to an electrical supply.
- d) Two team members are required, the first to apply the electrodes and the second to manipulate the position of the animal to allow the second application to be made.
- e) A *stunning* current should be applied via scissor-type stunning tongs in a position that spans the brain for a minimum of 3–10 seconds; immediately following the application to the head, the electrodes should be transferred to a position that spans the heart and the electrodes applied for a minimum of 3 seconds.

- f) Electrodes should be cleaned regularly and after use, to enable optimum electrical contact to be maintained.
- g) Animals should be monitored continuously after *stunning* until death to ensure the absence of brain stem reflexes.
- h) Electrodes should be applied firmly for the intended duration of time and pressure not released until the stun is complete.

### 3. Advantages

- a) The application of the second stage minimises post-stun convulsions and therefore the method is particularly effective with pigs.
- b) Non-invasive technique minimises biosecurity risk.

### 4. Disadvantages

- a) The method requires a reliable supply of electricity.
- b) The electrodes must be applied and maintained in the correct positions to produce an effective stun and kill.
- c) Most stunner control devices utilise low voltage impedance sensing as an electronic switch prior to the application of high voltages; in unshorn sheep, contact impedance may be too high to switch on the required high voltage (especially during stage two).
- d) The procedure may be physically demanding, leading to operator fatigue and poor electrode placement.

### 5. Conclusion

The method is suitable for calves, sheep and goats, and especially for pigs (over one week of age).

Article 3.7.6.11.

## Electrical – single application

### 1. Method 1

Method 1 comprises the single application of sufficient electrical current to the head and back, to simultaneously stun the animal and fibrillate the heart. Provided sufficient current is applied in a position that spans both the brain and heart, the animal will not recover consciousness.

#### **Community comment:**

**The frequency mentioned under (a) (i) should be modified to (50-60 Hz).**

#### **Justification:**

**The Community is not aware of scientific data supporting the use of lower frequency than 50 Hz.**

- a) Requirements for effective use
- i) The stunner control device should generate a low frequency (30 – 60 Hz) current with a minimum voltage of 250 volts true RMS under load.
  - ii) Appropriate protective clothing (including rubber gloves and boots) should be worn.
  - iii) Animals should be individually and mechanically restrained close to an electrical supply as the maintenance of physical contact between the stunning electrodes and the animal is necessary for effective use.
  - iv) The rear electrode should be applied to the back, above or behind the heart, and then the front electrode in a position that is forward of the eyes, with current applied for a minimum of  $\geq 10$  seconds.
  - v) Electrodes should be cleaned regularly between animals and after use, to enable optimum electrical contact to be maintained.
  - vi) Water or saline may be necessary to improve electrical contact with sheep.
  - vii) An effective stun and kill should be verified by the absence of brain stem reflexes.
- b) Advantages
- i) Method 1 stuns and kills simultaneously.
  - ii) It minimises post-stun convulsions and therefore is particularly effective with pigs.
  - iii) A single team member only is required for the application.
  - iv) Non-invasive technique minimises biosecurity risk.
- c) Disadvantages
- i) Method 1 requires individual mechanical animal *restraint*.
  - ii) The electrodes must be applied and maintained in the correct positions to produce an effective stun and kill.
  - iii) Method 1 requires a reliable supply of electricity.
- d) Conclusion

Method 1 is suitable for calves, sheep, goats, and pigs (over 1 week of age).

## 2. Method 2

Method 2 stuns and kills by drawing inverted and shackled poultry through an electrified waterbath stunner. Electrical contact is made between the 'live' water and earthed shackle and, when sufficient current is applied, poultry will be simultaneously stunned and killed.

- a) Requirements for effective use
- i) A mobile waterbath stunner and a short loop of processing line are required.
  - ii) A low frequency (50-60 Hz) current applied for a minimum of 3 seconds is necessary to stun and kill the birds.
  - iii) Poultry need to be manually removed from their cage, house or yard, inverted and shackled onto a line which conveys them through a waterbath stunner with their heads fully immersed.
  - iv) The required minimum currents to stun and kill dry birds are:
    - Quail - 100 mA/bird



- Chickens – 160 mA/bird
- Ducks & Geese – 200 mA/bird
- Turkeys – 250 mA/bird.

A higher current is required for wet birds.

v) An effective stun and kill should be verified by the absence of brain stem reflexes.

b) Advantages

- i) Method 2 stuns and kills simultaneously.
- ii) It is capable of processing large numbers of birds reliably and effectively.
- iii) This non-invasive technique minimises biosecurity risk.

c) Disadvantages

- i) Method 2 requires a reliable supply of electricity.
- ii) Handling, inversion and shackling of birds are required.

d) Conclusion

Method 2 is suitable for large numbers of poultry.

3. Method 3

Method 3 comprises the single application of sufficient electrical current to the head of poultry in a position that spans the brain, causing unconsciousness; this is followed by a *killing* method (Article 3.7.6.17.).

a) Requirements for effective use

- i) The stunner control device should generate sufficient current (more than 600 mA/ duck, more than 300 mA/bird) to stun.
- ii) Appropriate protective clothing (including rubber gloves and boots) should be worn.
- iii) Birds should be restrained, at a minimum manually, close to an electrical supply.
- iv) A *stunning* current should be applied in a position that spans the brain for a minimum of ~~3~~<sup>7</sup> seconds; immediately following this application, the birds should be killed (Article 3.7.6.17.).
- v) Electrodes should be cleaned regularly and after use, to enable optimum electrical contact to be maintained.
- vi) Birds should be monitored continuously after *stunning* until death to ensure the absence of brain stem reflexes.

b) Advantages

Non-invasive technique (when combined with cervical dislocation) minimises biosecurity risk.

c) Disadvantages

- i) Method 3 requires a reliable supply of electricity and is not suitable for large-scale operations.
- ii) The electrodes must be applied and maintained in the correct position to produce an effective stun.

- iii) Birds must be individually restrained.
- iv) It must be followed by a *killing* method.
- d) Conclusion  
Method 3 is suitable for small numbers of poultry.

Article 3.7.6.12.  
(under study)

#### CO<sub>2</sub> / air mixture

##### 1. Introduction

Community comment

**The following paragraph should be changed by the following text:**

**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) or by placing birds in transport modules and placing them in a gas tight container and introducing a gas mixture( method 3 – under study) ~~Method 2 should be used whenever possible, as it eliminates welfare issues resulting from the need to manually remove live birds~~ Method 3 (under study) requires only handling and crating of the birds and reduces stress of manually moving birds to containers and immersion in gas mixture used for method 1. Inhalation of carbon dioxide (CO<sub>2</sub>) induces respiratory and metabolic acidosis and hence reduces the pH of cerebrospinal fluid (CSF) and neurones thereby causing unconsciousness and, after prolonged exposure, death.**

##### **Justification:**

**This method 3 has been tested in the UK and has provided improved welfare for the animals as they are handled under usual conditions. Furthermore, another advantage of this method is that there are usually staff and equipment available for this type of handling birds.**

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). Method 2 ~~should be used whenever possible, as it eliminates welfare issues resulting from the need to manually remove live birds.~~

##### 2. Method 1

The animals are placed in a gas-filled *container* or apparatus.

- a) Requirements for effective use in a *container* or apparatus
- i) *Containers* or apparatus should allow the required gas concentration to be maintained and accurately measured.
  - ii) When animals are exposed to the gas individually or in small groups in a *container* or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the animals and allow them to be observed.
  - iii) Animals can also be introduced to low concentrations [as low concentrations are not aversive] and the concentration could be increased afterwards and the animals then held in the higher concentration until death is confirmed.
  - iv) Team members should ensure that there is sufficient time allowed for each batch of animals to die before subsequent ones are introduced into the *container* or apparatus.
  - iv) *Containers* or apparatus should not be overcrowded and measures are needed to avoid animals suffocating by climbing on top of each other.
- b) Advantages
- i) CO<sub>2</sub> is readily available.
  - ii) Application methods are simple.
- c) Disadvantages
- i) The need for properly designed *container* or apparatus.
  - ii) The aversive nature of high CO<sub>2</sub> concentrations.
  - iii) No immediate loss of consciousness.
  - iv) The risk of suffocation due to overcrowding.
  - v) Difficulty in verifying death while the animals are in the *container* or apparatus.
- d) Conclusion

Method 1 is suitable for use in poultry and neonatal sheep, goats and pigs.

### 3. Method 2

The gas is introduced into a poultry house.

- a) Requirements for effective use in a poultry house
- i) Prior to introduction of the CO<sub>2</sub> the poultry house should be appropriately sealed to allow control over the gas concentration.
  - ii) The house should be gradually filled with CO<sub>2</sub> so that all birds are exposed to a concentration of >40% until they are dead; a vaporiser may be required to prevent freezing.
  - iii) Devices should be used to accurately measure the gas concentration at the maximum height accommodation of birds.
- b) Advantages
- i) Applying gas to birds *in situ* eliminates the need to manually remove live birds.

- ii) CO<sub>2</sub> is readily available.
  - iii) Gradual raising of CO<sub>2</sub> concentration minimises the aversiveness of the induction of unconsciousness.
- c) Disadvantages
- i) It is difficult to determine volume of gas required to achieve adequate concentrations of CO<sub>2</sub> in some poultry houses.
  - ii) It is difficult to verify death while the birds are in the poultry house.
- d) Conclusion
- Method 2 is suitable for use in poultry in closed-environment sheds.

**Community comment:**

**The following text should be added**

**Method 3. (under study)**

**The birds are placed in crates and loaded into a container and gas is introduced into the container.**

**a) Requirements for effective use of containerised gassing units (CGU)**

**i) Each CGU consists of a purpose-built, gas-tight steel chamber measuring 3 metres in length, 1.5 metres in height and 1.5 metres wide and manufactured from 3mm steel sheet. There is a lockable access door, designed to accommodate industry standard poultry transport module. The chamber is pre-fitted with gas lines and diffusers, with silencers which in turn are connected via a system of manifolds and gas regulators to four gas cylinders. Either a meter is used to monitor the level of oxygen to ensure that the level of Oxygen is less than 2% or to monitor carbon dioxide levels to ensure they reach at least 40 %**

**. ii) The birds are caught and placed in crates used for the transport modules of appropriate size and at appropriate stocking densities to allow all birds to sit down and such that they will not be subject to thermal**

**iii) Team members should ensure that there is sufficient time allowed for each batch of animals to die before the door is opened and then all the birds should be checked for death by examining each module.**

**b) Advantages**

**i) .The gas is introduced quickly and quietly resulting in less disturbance of the birds Gradual raising of CO<sub>2</sub> concentration minimises the aversiveness of the induction of unconsciousness**

**ii) This use of transport modules minimises handling. Birds should be handled by trained, experienced catching teams at the time of depopulation of the poultry house and placed into crates, which are then loaded into the modules. The modules are loaded mechanically into the CGU and a lethal mixture of gas is rapidly introduced into the chamber immediately after sealing CO<sub>2</sub> is readily available.**

**iii) .When birds are placed in a container as used for method 1 they frequently flap and move quickly so disrupting other birds. Birds sitting transport modules are likely to have fewer disturbances.**

**iv) The units are operated in tandem for optimum capacity, and throughputs per pair of up to 4,000 chickens per hour are possible .The main limiting factors are speed of catching and availability of gas**

**v) The volume of gas required can be readily calculated and as the units are operated outdoors the gas is dispersed quickly at the end of each cycle by opening the door**

- vi) **The system used the skilled catching teams and catching methods and equipment in daily use by the industry available and readily cleansed and disinfected.**
- c) **Disadvantages**
- i) **.Requires trained operators, trained catchers, transport modules and fork lift but such equipment is usually available and suitable area with hard surface.**
- ii) **It is difficult to verify death while the birds are in the container but sound of vocalisations can be used...**
- d) **Conclusion**
- i) **Method 3 is suitable for use in poultry in a wide range of poultry systems which have access to vehicles to carry containers and handling equipment.**
- ii) **Animals should be introduced into the container or apparatus, which is then sealed and filled as quickly as possible thereafter with the required gas concentrations (with  $\geq 2\%$  O<sub>2</sub>) or more than 40% CO<sub>2</sub> and held in this atmosphere until death is confirmed;**

Article 3.7.6.13.

Nitrogen and/or inert gas mixed with CO<sub>2</sub>

1. Introduction

**Community comment:**

**As the previous method can be used for both mixtures of gas the following text should be amended as follows:**

**CO<sub>2</sub> may be mixed in various proportions with nitrogen or an inert gas (e.g., argon), and the inhalation of such mixtures leads to hypercapnic-hypoxia and death when the oxygen concentration by volume is  $\leq 2\%$ . This method involves either the introduction of animals into a *container* or apparatus containing the gases or the use of a containerised gassing unit (See Article 3.7.6.12. for details) in which birds are placed on transport modules and then into a container which is sealed and a gas mixture added. Mixtures of CO<sub>2</sub> with nitrogen or an inert gas do not induce immediate loss of consciousness, therefore the aversiveness of various gas mixtures containing high concentrations of CO<sub>2</sub> and the respiratory distress occurring during the induction phase, are important animal welfare considerations.**

CO<sub>2</sub> may be mixed in various proportions with nitrogen or an inert gas (e.g., argon), and the inhalation of such mixtures leads to hypercapnic-hypoxia and death when the oxygen concentration by volume is  $\leq 2\%$ . 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<sub>2</sub> 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<sub>2</sub> strongly aversive, and a mixture of nitrogen or argon with  $\leq 30\%$  CO<sub>2</sub> by volume and  $\leq 2\%$  O<sub>2</sub> by volume can be used for *killing* poultry and neonatal sheep, goats and pigs.

2. Requirements for effective use

**Community comment:**

**For sake of consistency the following section should be amended as follows:**

**Requirements for effective use**

- a) **Containers or apparatus should allow the required gas concentrations to be maintained, and the O<sub>2</sub> and/or CO<sub>2</sub> concentrations accurately measured during the *killing* procedure.**
- b) **When animals are exposed to the gases individually or in small groups in a *container* or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the animals and allow them to be observed.**
- c) **Either:**
- i) **Method 1 Animals should be introduced into the *container* or apparatus after it has been filled with the required gas concentrations (with  $\leq 2\%$  O<sub>2</sub>), and held in this atmosphere until death is confirmed; or**
- ii) **Method 2 (under study) Animals should be introduced into the container gassing unit ( CGU) , which is then sealed and filled as quickly as possible thereafter with the required gas concentrations (with  $\geq 2\%$  O<sub>2</sub>) and held in this atmosphere until death is confirmed);**
- d) **For method 1 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.**
- e) **For method 2 (under study) Team members should ensure that there is sufficient time allowed for each batch of animals to die before the door is opened and then all the birds should be checked for death by examining each module.**
3. **Advantages**
- a) **Low concentrations of CO<sub>2</sub> cause little aversiveness and, in combination with nitrogen or an inert gas, produces a fast induction of unconsciousness.**
- b) **The advantages of using CGUS are described in article 3.7.6.12. For details) .**
- c) **Using mixtures of CO<sub>2</sub> and inert gases renders then easier to use than using 100% CO<sub>2</sub> which requires specific measures to prevent blockages due to freezing of pipes due to vaporisation of the gas.**
4. **Disadvantages**
- a) **A properly designed *container* or apparatus is needed.**
- b) **It is difficult to verify death while the animals are in the *container* or apparatus.**
- c) **There is no immediate loss of consciousness.**
- d) **Exposure times required to kill are considerable.**
- e) **The disadvantages of using CGUS are described in article 3.7.6.12. for details)**
5. **Conclusion**
- Methods using Nitrogen and/or inert gas mixed with CO<sub>2</sub> by either introducing animals to a container or using CGUS are suitable for poultry and neonatal sheep, goats and pigs.**

- a) *Containers* or apparatus should allow the required gas concentrations to be maintained, and the O<sub>2</sub> and CO<sub>2</sub> concentrations accurately measured during the *killing* procedure.
- b) When animals are exposed to the gases individually or in small groups in a *container* or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the animals and allow them to be observed.
- c) Animals should be introduced into the *container* or apparatus after it has been filled with the required gas concentrations (with  $\leq 2\%$  O<sub>2</sub>), and held in this atmosphere until death is confirmed.
- d) Team members should ensure that there is sufficient time allowed for each batch of animals to die before subsequent ones are introduced into the *container* or apparatus.
- e) *Containers* or apparatus should not be overcrowded and measures are needed to avoid animals suffocating by climbing on top of each other.

### 3. Advantages

Low concentrations of CO<sub>2</sub> cause little aversiveness and, in combination with nitrogen or an inert gas, produces a fast induction of unconsciousness.

### 4. Disadvantages

- a) A properly designed *container* or apparatus is needed.
- b) It is difficult to verify death while the animals are in the *container* or apparatus.
- c) There is no immediate loss of consciousness.
- d) Exposure times required to kill are considerable.

### 5. Conclusion

The method is suitable for poultry and neonatal sheep, goats and pigs.

#### Article 3.7.6.14.

## **Nitrogen and/or inert gasses**

### 1. Introduction

This method involves the introduction of animals into a *container* or apparatus containing nitrogen or an inert gas such as argon. The controlled atmosphere produced leads to unconsciousness and death from hypoxia.

Research has shown that hypoxia is not aversive to pigs and poultry, and it does not induce any signs of respiratory distress prior to loss of consciousness.

### 2. Requirements for effective use

- a) *Containers* or apparatus should allow the required gas concentrations to be maintained, and the O<sub>2</sub> concentration accurately measured.
- b) When animals are exposed to the gases individually or in small groups in a *container* or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the animals and allow them to be observed.
- c) Animals should be introduced into the *container* or apparatus after it has been filled with the required gas concentrations (with  $\leq 2\%$  O<sub>2</sub>), and held in this atmosphere until death is confirmed.

- d) Team members should ensure that there is sufficient time allowed for each batch of animals to die before subsequent ones are introduced into the *container* or apparatus.
- e) *Containers* or apparatus should not be overcrowded and measures are needed to avoid animals suffocating by climbing on top of each other.

### 3. Advantages

Animals are unable to detect nitrogen or inert gases, and the induction of hypoxia by this method is not aversive to animals.

### 4. Disadvantages

- a) A properly designed *container* or apparatus is needed.
- b) It is difficult to verify death while the animals are in the *container* or apparatus.
- c) There is no immediate loss of consciousness.
- d) Exposure times required to kill are considerable.

### 5. Conclusion

The method is suitable for poultry and neonatal sheep, goats and pigs.

#### Article 3.7.6.15.

## **Lethal injection**

### 1. Introduction

A lethal injection using high doses of anaesthetic and sedative drugs causes CNS depression, unconsciousness and death. In practice, barbiturates in combination with other drugs are commonly used.

### 2. Requirements for effective use

- a) Doses and routes of administration that cause rapid loss of consciousness followed by death should be used.
- b) Prior sedation may be necessary for some animals.
- c) Intravenous administration is preferred, but intraperitoneal or intramuscular administration may be appropriate, especially if the agent is non-irritating.
- d) Animals should be restrained to allow effective administration.
- e) Animals should be monitored to ensure the absence of brain stem reflexes.

### 3. Advantages

- a) The method can be used in all species.
- b) Death can be induced smoothly.

### 4. Disadvantages

- a) *Restraint* and/or sedation may be necessary prior to injection.
- b) Some combinations of drug type and route of administration may be painful, and should only be used in unconscious animals.



- c) Legal requirements and skill/training required may restrict use to *veterinarians*.
- d) Contaminated carcasses may present a risk to other wild or domestic animals.

5. Conclusion

The method is suitable for *killing* small numbers of cattle, sheep, goats, pigs and poultry.

Article 3.7.6.16.

**Addition of anaesthetics to feed or water**

1. Introduction

An anaesthetic agent which can be mixed with poultry feed or water may be used to kill poultry in houses. Poultry which are only anaesthetised need to be killed by another method such as cervical dislocation.

2. Requirements for effective use

- a) Sufficient quantities of anaesthetic need to be ingested rapidly for effective response.
- b) Intake of sufficient quantities is facilitated if the birds are fasted or water is withheld.
- c) Must be followed by *killing* (see Article 3.7.6.17) if birds are anaesthetised only.

3. Advantages

- a) Handling is not required until birds are anaesthetised.
- b) There may be biosecurity advantages in the case of large numbers of diseased birds.

4. Disadvantages

- a) Non-target animals may accidentally access the medicated feed or water when provided in an open environment.
- b) Dose taken is unable to be regulated and variable results may be obtained.
- c) Animals may reject adulterated feed or water due to illness or adverse flavour.
- d) The method may need to be followed by *killing*.
- e) Care is essential in the preparation and provision of treated feed or water, and in the disposal of uneaten treated feed/water and contaminated carcasses.

5. Conclusion

The method is suitable for *killing* large numbers of poultry in houses.

Article 3.7.6.17.

**Cervical dislocation and decapitation**

1. Cervical dislocation (manual and mechanical)

- a) Introduction

Unconscious 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 cerebral anoxia due to cessation of breathing and/or blood supply to the brain.

However, conscious birds of less than 3 kilograms in case of small numbers of birds where other methods are not available or impracticable, may be killed using cervical dislocation in a way that the blood vessels of the neck are severed and death is instantaneous.

b) Requirements for effective use

- i) *Killing* should be performed either by manually or mechanically stretching the neck to sever the spinal cord or by using mechanical pliers to crush the cervical vertebrae with consequent major damage to the spinal cord.
- ii) Consistent results require strength and skill so team members should be rested regularly to ensure consistently reliable results.
- iii) Birds should be monitored continuously until death to ensure the absence of brain stem reflexes.

c) Advantages

- i) It is a non-invasive *killing* method.
- ii) It can be performed manually on small birds.

d) Disadvantages

- i) Operator fatigue.
- ii) The method is more difficult in larger birds. Its use should be avoided in any case for birds over 3 kg of live weight.
- iii) Requires trained personnel to perform humanely.

2. Decapitation

**The Community reiterates its previous comment:**

**The method should only be used for unconscious animals as previously recommended.**

**Justification:**

**There is no clear scientific evidence that this method induces immediate loss of consciousness.**

a) Introduction

Decapitation results in death by cerebral ischaemia using a guillotine or knife.

b) Requirements for effective use

The required equipment should be kept in good working order.

c) Advantages

The technique is effective and does not require monitoring.

## d) Disadvantages

The working area is contaminated with body fluids, which increases biosecurity risks.

## Article 3.7.6.18.

**Pithing and bleeding**1. Pithing

## a) Introduction

Pithing is a method of *killing* animals which have been stunned by a penetrating captive bolt, without immediate death. Pithing results in the physical destruction of the brain and upper regions of the spinal cord, through the insertion of a rod or cane through the bolt hole.

## b) Requirements for effective use

- i) Pithing cane or rod is required.
- ii) An access to the head of the animal and to the brain through the skull is required.
- iii) Animals should be monitored continuously until death to ensure the absence of brain stem reflexes.

## c) Advantages

The technique is effective in producing immediate death.

## d) Disadvantages

- i) A delayed and/or ineffective pithing due to convulsions may occur.
- ii) The working area is contaminated with body fluids, which increases biosecurity risks.

2. Bleeding

## a) Introduction

**The Community reiterates its previous comment:**

**The following sentence should be added at the beginning of the paragraph:**

**"Bleeding should only be used for killing unconscious animals".**

**Justification:**

**Bleeding without prior stunning is not necessary for animal disease control purposes and should not be recommended as acceptable from a welfare point of view.**

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.

Bleeding out should be completed and any incision made should ensure the complete severance off both carotid arteries, or the vessels from which they arise (e.g. chest stick).

## b) Requirements for effective use

- i) A sharp knife is required.

- ii) An access to the neck or chest of the animal is required.
  - iii) Animals should be monitored continuously until death to ensure the absence of brain stem reflexes.
- c) Advantages
- The technique is effective in producing death after an effective *stunning* method which does not permit pithing.
- d) Disadvantages
- a) A delayed and/or ineffective bleeding due to convulsions may occur.
  - b) The working area is contaminated with body fluids, which increases biosecurity risks.

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## DRAFT GUIDELINES ON DOG POPULATION CONTROL

### Community comments:

The Community welcomes this initiative and the positive improvements of the text. In particular, the Community appreciates the improvements of practical information provided as regards control measures listed in Article 5, methods for the euthanasia of dogs listed in Table 1 and methodologies for estimating stray dog populations listed in Annex 1 of the draft guidelines. Furthermore, the Community appreciates the multidisciplinary approach to dog population management programmes where education and promotion of responsible dog ownership are taken into account.

### Nevertheless:

1. For more clarity of the scope of these guidelines, the title should be: "Draft guidelines on Stray Dog Population Control", and the following sentence should be added at the beginning of the preamble: "The scope of these guidelines is to deal with problems caused by stray and feral dogs."

2. The Community reiterates its previous comment: Methodological approach regarding the carrying capacity could be further expanded as well as methods of capture, transport, keeping and killing of dogs. Scientific information regarding the behaviour of stray dogs and their possible practical applications to control their population would be valuable to be added.

**Preamble:** Stray and feral dogs pose serious human health, socio-economic, political and animal welfare problems in many countries of the world. Many of these are developing countries and others fall in the least developed category. Whilst acknowledging human health is a priority including the prevention of zoonotic diseases notably rabies, the OIE recognises the importance of controlling dog populations without causing unnecessary or avoidable animal suffering. Veterinary Services should play a lead role in preventing zoonotic diseases and ensuring animal welfare and should be involved in dog population control.

### Guiding principles

The following guidelines are based on those laid down in Section 3.7 of the *Terrestrial Animal Health Code*. Some additional principles are relevant to these guidelines:

1. The promotion of responsible dog ownership can significantly reduce the numbers of stray dogs and the incidence of zoonotic diseases
2. Because dog ecology is linked with human activities, management of dog populations has to be accompanied by changes in human behaviour to be effective.

### Article 1

#### Definitions

### Community comment:

The definition of Stray dog should be modified as follows:

**"Any dog which does not show physical evidence of identification or ownership and is not under direct control or prevented from roaming."**

**Justification:**

**A hunting dog for example could be not under direct control although not being a stray dog.**

a) ~~Stray Dog~~ **dog**: any dog not under direct control or not prevented from roaming .....

Types of stray dog

**Community comment:**

**The point a) should be replaced as follows: free roaming dog not having physical evidence of ownership.**

**Justification:**

**An owned dog could be not under the direct control of its owner for a short period of time without being a stray dog if it can be easily recognised as owned.**

- a) free roaming owned dog not under direct control or restriction at a particular time;
- b) free roaming dog with no owner;
- c) feral dog: domestic dog that has reverted to the wild state and is no longer directly ~~dependant~~ dependent upon humans for successful reproduction.

**Community comment:**

**In the following definition the words "with physical evidence of ownership or " should be included between the words dog and with.**

**Justification:**

**See previous comments.**

b) ~~Owned Dog~~ **dog**: dog with a person that claims responsibility ~~is responsible~~ for this animal.

e) **Person**: This can include more than one individual, and could comprise family/household members or an organisation.

**Community comment:**

**In the following definition, the word "dog" should be inserted before the word "ownership".**

**The following words "according to the legislation in place and" should be inserted between the words "duties" and "focused".**

**Justification:**

**A responsible ownership would imply the respect of legislation in place (such as for example the identification and registration of dogs.)**

d) ~~Responsible Ownership~~ **ownership**: The situation whereby a person (as defined above) accepts and commits to perform various duties focused on the satisfaction of the psychological, environmental and physical needs of a dog (~~or other pet~~) and to the prevention of *risks* (aggression, *disease* transmission or ~~causing~~ injuries) that the ~~pet~~ dog may cause to the community, other animals or the environment.

e) **Euthanasia:** the act of inducing death in a humane manner.

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

~~The following point should be changed in Stray dog populaion~~

**Community comment:**

**In the following definition the word "Stray" should be added before the word dog.**

**Justification:**

**See comments at the beginning of the chapter.**

~~g) **Dog Ppopulation Ccontrol Pprogramme:** A programme with the objective of reducing the number of stray dogs. A programme with the aim of reducing a dog population to a particular level and/or maintaining it at that level and/or managing it in order to meet a predetermined objective (see Article 2).~~

**The Community reiterates its previous comment:**

**The notion of "carrying capacity" is very valuable but would need to be further developed as to be used more practically. Further references or examples of models to calculate or estimate the carrying capacity should be presented.**

~~h) **Carrying capacity:** is the upper limit of the dog population density that could be supported by the habitat based on the availability of resources (food, water, shelter); and human acceptance.~~

**Article 2**

**Dog population control programme ~~optional~~ objectives**

**The Community partly reiterates its previous comment.**

**At point 2, the words "to an acceptable level" should be inserted at the end of the sentence.**

**At point 3 (the number should not be deleted), the words "or rabies free" should be added after the word "immune".**

**Justification:**

**The level of the reduction in the number of stray dogs can depend on animal health and welfare factors, cost-benefit analysis and local community acceptance.**

**In rabies free areas the dog population will not be rabies immune.**

The objectives of a programme to control the dog population may include the following:

1. improve health and welfare of owned and stray dog population
2. reduce numbers of stray dogs
3. ~~Create~~ assist in the creation and maintenance of a rabies immune dog population
4. promote responsible ownership;



5. reduce the risk of zoonotic diseases other than rabies;
6. manage other risks to human health e.g. parasites;
7. prevent harm to the environment
8. prevent illegal trade and trafficking.

### Article 3

#### Responsibilities and competencies

##### 1. Veterinary Authority Administration

The Veterinary Authority Administration is responsible for the implementation of animal health legislation ~~and for controlling outbreaks of notifiable animal diseases such as foot and mouth disease and avian influenza~~. Control of endemic zoonotic diseases such as rabies and parasitic *infections* (e.g. *Echinococcus spp.*) would require technical advice from the Veterinary Authority Administration, as animal health and some aspects of public health are within this Authority's competence but organising and/or supervising dog control schemes is frequently the responsibility of government agencies other than the Veterinary Authority Administration.

~~In many countries the Veterinary Authority Administration is in the Ministry of Agriculture.~~

##### 2. Other government agencies

The responsibilities of other government agencies will depend on the disease risk being managed and the objective/nature of the dog population control measures employed.

The Ministry or other Agency responsible for Public Health would normally play a leadership role and may have legislative authority in dealing with zoonotic diseases. Control of stray dogs ~~in regards~~ with regard to other human health risks (eg stray dogs on roads; dog attacks within communities) may fall within the responsibility of the Public Health Agency but is more likely to be the responsibility of police or other agencies for public safety/security operating at the State/Provincial or municipal level.

Environment Protection Agencies (normally within a National or State/Provincial Ministry for the Environment) may take responsibility for ~~the~~ controlling problems associated with stray dogs when they present a hazard to the environment (e.g. control of feral dogs in national parks; prevention of dog attacks on wildlife or transmission of diseases to wildlife) or where a lack of environmental controls is giving rise to stray dog populations that threaten human health or access to amenities. For example, Environmental Protection agencies may regulate and enforce measures to prevent dogs (and other wild animals) from accessing waste or human sewage.

##### 3. Private sector veterinarians

The private sector veterinarian is responsible for providing advice to pet owners consulting the veterinarian for advice or treatment of a dog. The private sector veterinarian can play an important role in *disease surveillance* ~~as~~ because he/she might be the first to see a dog suffering from a *notifiable disease* such as rabies. It is necessary that the private sector veterinarian follow the procedure established by the Veterinary Authority for responding to and reporting a suspected rabies case or a dog that is suffering from any other *notifiable disease*. Private sector veterinarians also play an important role (often in liaison with the police) in dealing with cases of neglect that can lead to problems with stray and mismanaged dogs.

The private veterinarian has competence and will normally be involved in pet dog health programmes and population control measures, including health testing and vaccination, kennelling during the absence of the owner, sterilisation and euthanasia. Two-way communication between the private sector veterinarian and *Veterinary Authority*, often via the medium of a veterinary professional organisation, is very important and the *Veterinary Authority* is responsible to set up appropriate mechanisms for this action.

#### 4. Non Governmental Organisations (NGOs)

NGOs are potentially important partners of the *Veterinary Services* in contributing to public awareness and understanding and helping to obtain resources to contribute in a practical way to the design and successful implementation of dog control programmes. NGOs can supply local knowledge on dog populations and features of ownership, as well as expertise in handling and kennelling dogs and the implementation of large scale vaccination and sterilisation programmes. NGOs can also contribute, together with veterinarians and the authorities in educating the public in responsible dog ownership. NGOs can help to obtain funding for control programmes, particularly in countries where governments may depend on support from NGOs for programs carried out to assist poor communities.

#### 5. Local Government Authorities

Local Government Authorities are responsible for many services and programmes that relate to health, safety and public good within their jurisdiction. In many countries the legislative framework gives authority to local government agencies in regard to aspects of public health, environmental health/hygiene and inspection/compliance activities.

In many countries local government agencies are responsible for the control of stray dogs (e.g. dog catching and shelters) and the alleviation of the problems stray dogs cause. This would normally be done with advice from a higher level (national or state/provincial) authority with specialised expertise in regard to public health and animal health. Collaboration with the private sector veterinarians (e.g. in programs to sterilise and vaccinate stray dogs) is a common feature of dog control programs. Regardless of the legislative basis, it is essential to have the co-operation of local government authorities in the control of stray dogs.

#### 6. Dog owners

##### **Community comment:**

**The Community welcomes the identification of owners' responsibilities and competencies and suggests further expanding this part. In particular the owner should ensure that the welfare of the dog and the fulfilments of its needs are respected as well as its health.**

##### **Justification:**

**Responsibility for the dog should include not only protection from infectious diseases and unwanted reproduction but also the respect of the behavioural needs of the dog.**

When a person takes on the ownership of dog there should be an immediate acceptance of responsibility for that dog, and for any offspring it may produce, for the duration of its life or until a subsequent owner is found. The owner must ensure the dog is protected, as far as possible, from infectious diseases (e.g. through vaccination and parasite control) and from unwanted reproduction (e.g. through surgical sterilisation). Owners should ensure that the dog's ownership is clearly identified (preferably with permanent identification such as a tattoo or microchip) and, where required by legislation, registered on a centralised database. All reasonable steps should be taken to ensure that the dog does not roam out of control in a manner that would pose a problem to the community and/or the environment.

#### Article 4

Considerations in planning a dog population control programme ~~measures~~

**The Community partially reiterates its comments.**

**NGOs should be included in the list of relevant stakeholders.**

**Justification:**

**NGOs could play an important role in analysing the causes of the problem and in proposing and developing information campaigns and training programs.**

In the development of a dog population control programme it is recommended that the authorities establish an advisory group, which should include ~~appropriate~~ veterinarians, experts in dog ecology, dog ownership and zoonotic diseases, and representatives of relevant and stakeholders (local authorities, human health services/authorities, environmental control services/authorities and the public). The main purpose of this advisory group would be to analyse the problem, identify the causes and propose the most effective approaches to use in the short and long term.

Important considerations are as follows:

1. Identifying the sources of stray dogs
  - a) Owned animals that roam freely
  - b) Animals that have been abandoned by their owner, including animals resulting from:
    - i) uncontrolled breeding of owned dogs;
    - ii) unowned dogs that reproduce successfully.
2. Estimating the existing number, distribution and ecology ~~(To be completed)~~

**Community comment:**

**In the second sentence of the following paragraph, the words "attitudes and" should be inserted between the words "human" and "behaviour".**

**Justification:**

**For estimating the dog carrying capacity, it is important to understand people's attitude as well as behaviour towards dogs.**

Practical tools that are available include ~~Using available practical tools such as~~ registers of dogs, population estimates, surveys of dogs, owners, dog shelters and associated veterinarians etc. The important factors relevant to the dog carrying capacity of the environment include food, shelter, water and human behaviour.

A methodology, including generalised dog identification and centralised registration, ~~must~~ should be established ~~in order~~ to make an estimate of the total dog population.

**Community comment:**

**The Community welcomes the overview of appropriate methodologies for estimating the size of dog populations and encourages further developments.**

An overview of appropriate methodologies may be found in Annex I.

The same methodology ~~must~~ should be used at appropriate intervals to assess population trends. ~~Find~~

references if possible:

- ~~The Identify the important factors relevant to the dog carrying capacity of the environment. These generally include food, shelter, water, and human behaviour.~~
- ~~Add examples of good methodology if possible.~~

### 3. Legislation

**The Community reiterates its previous comment:**

**The word "should" should be replaced by "could"**

**Justification:**

**These are tools given to OIE Member Countries.**

Legislation that would help authorities establish ~~to establishing~~ successful dog control programmes should include the following key elements:

- a) registration and identification of dogs and licensing of dog breeders ~~owners~~;
- b) rabies vaccination;
- c) veterinary procedures (e.g. surgical procedures);
- d) control of dog movement (restrictions within the country);
- e) control of dog movement (international movement);
- f) control of dangerous dogs;
- g) regulations on the breeding and sale of dogs ~~Commercial dog production~~;
- h) environmental controls (e.g. *abattoirs*, rubbish dumps, dead stock facilities);
- i) dog shelters;
- j) animal welfare, including humane capture and killing methods.

### 4. Resources available to authorities

- a) Human resources
- b) Financial resources
- c) Technical tools
- d) Infrastructure
- e) Cooperative activities
- f) Public-private-NGO partnerships
- g) Central-state or province-local partnerships.

### Article 5

#### Control measures

**The Community reiterates its previous comment:**

**The word "should" should be replaced by "could".**

**Justification: These are non compulsory guidelines.**

**Community comment:**

**The Community welcomes the multidisciplinary approach where the people's attitude towards dog ownership and the promotion of responsible ownership through education and legislation are taken into account.**

**Justification:**

**An efficient dog control population management programme as well as responsible ownership can be achieved only through complementary measures and combination of legislation, education and promotion of public awareness.**

The following control measures should be implemented according to the situation in national context and local circumstances of Member Countries. They can Measures may be used in combination. or singly. Killing of dogs, used alone, is not an effective control measure. If used, it should be combined with other measures to achieve effective long term control. It is also important that authorities gain an understanding of people's attitudes towards dog ownership so that they can develop a cooperative approach to the control of dog populations.

1. Education and promotion legislation of for responsible ownership (To be completed)

The health and welfare of domestic dogs may be improved through the promotion of responsible human ownership. Minimizing stray dogs population, in combination with educating humans, particularly children about specific behaviours, can reduce dog bite injury and prevent some major zoonotic diseases.

Responsible dog ownership includes the control of reproduction of dogs under direct human supervision such that offspring of owned dogs are not abandoned.

**Community comment:**

**In the following paragraph, in the third sentence "*The promotion of responsible dog ownership though.....*", the word "though" should be replaced by "through".**

The owned dog population is a primary source of stray dogs, through the abandonment of unwanted dogs and their offspring, and through allowing owned dogs to roam unrestricted, contributing to the stray population. Encouraging dog owners to be more responsible will reduce the number of dogs allowed to roam, improve the health and welfare of dogs, and minimise the risk that dogs pose to the community. The promotion of responsible dog ownership through legislation and education is a necessary part of a dog population management programme. Collaboration with responsible animal welfare NGOs and private veterinarians will assist Veterinary Authorities in establishing and maintaining programmes.

Education on responsible dog ownership (for the currently owned dog and any offspring it produces) should address the following elements:

**Community comment:**

**The Community appreciates that socialisation and training of dogs are taken into account.**

**Justification:**

**Correct socialization and training of dogs are crucial to avoid the development of behavioural pathologies which could lead to the abandonment of unwanted dogs and consequent negative impact on the community.**

- a) the importance of proper care to ensure the welfare of the dog and any offspring; this may include preparing the dog to cope with its environment through attention to socialisation and training;
- b) registration and identification of dogs (see Article 5. 2.);

**Community comment:**

**Prevention of non zoonotic diseases should be also taken into account.**

**Justification:**

**In order to ensure the welfare of the dogs, non zoonotic diseases should be prevented as well.**

- c) prevention of zoonotic diseases, eg through regular vaccination in rabies endemic areas;
- d) preventing negative impacts of dogs on the community, via pollution (eg faeces and noise), risks to human health through biting or traffic accidents and risks to wildlife, livestock and other companion animal species.
- e) control of dog reproduction

In order to achieve a shift towards responsible ownership, a combination of legislation, public awareness, education, and promotion of these elements will be required. It may also be necessary to improve access to resources supporting responsible ownership, such as veterinary care, identification and registration services and measures for control of zoonotic diseases.

## 2. Registration and identification of dogs (licensing)

A core component of dog population management by the Competent Authorities is the registration and identification of owned dogs. This and may include granting licences to owners. Registration and identification may be emphasized as part of responsible dog ownership and are often linked to animal health programs, for example, mandatory rabies vaccination.

Registration and identification of animals in a centralised database can be used to support the enforcement of legislation, the reuniting of lost animals with owners and may be used as a tool to encourage control of dog reproduction control of owned dogs through financial incentives reduced fee schedule to register neutered sterilise dogs.

## 3. Reproductive control

Controlling reproduction in dogs prevents the birth of unwanted litters of puppies and can help address the balance between demand for dogs and the size of the population. It is advisable to focus efforts to control reproduction on those individuals or groups in the dog population identified as the most productive and the most likely to be the sources of unwanted and stray dogs, as this will to ensure best use of resources. Methods of controlling reproduction will require direct veterinary input to individual animals, involvement of both private and public veterinary sectors may be required to meet demand. The control of reproduction is essentially the responsibility of owners and can be incorporated into education on responsible ownership (section 5 a.). Methods for controlling reproduction in dogs include:

- a) surgical sterilisation;
- b) chemical sterilisation;
- c) chemical contraception;
- d) separation of female dogs during oestrus from ~~entire~~ unsterilised males.

**Community comment:**

**It should be specified that surgical sterilization should be carried out by veterinarians under appropriate general anaesthesia.**

**Justification:**

**Veterinarians' role is crucial to ensure that such method of reproductive control is carried out respecting the welfare and the health of the dogs.**

Surgical sterilisation should be carried out in a humane manner and include appropriate use of pain relief.

Any chemicals or drugs used in controlling reproduction should be shown to have appropriate safety, quality and efficacy for the function required and used according to the ~~manufacturers~~ manufacturer's and Competent ~~Authorities~~ Authority's regulations. In the case of chemical ~~sterilants~~ sterilants and contraceptives, ~~this may require further~~ research and field trials may need to be completed before use.

**Community comment:**

**The "numbering" of the following bullet points should be changed**

2. Removal and handling

**The Community reiterates its previous comment:**

**Basic behaviour and needs of dogs should be defined in order to set up acceptable methods of capture, transport and keeping. Furthermore, more guidance would be needed here concerning acceptable methods of capture and transport of dogs taking into account their basic behaviour and needs.**

**Emphasis should be given on the needs for animals' handlers to be aware of the different aspects of these tasks (e.g. human safe and animal welfare).**

**Justification:**

**Acceptable methods of capture, transport and keeping of dogs depend on their basic behaviour and needs. Furthermore, the behaviour of animals' handlers can influence the effective implementation of such acceptable methods while respecting the welfare of the dogs.**

The *Competent Authority* should collect dogs that are not under direct supervision and verify their ownership. Capture, transport, and holding of the animals should be done humanely. The *Competent Authority* should develop and implement appropriate legislation and training to regulate these activities. Capture should be achieved with the minimum force required and equipment should be used that supports humane handling. Snares and uncovered wire loops should not be used for capture.

3. Management of dogs removed from communities

**The Community reiterates its previous comment:**

**The wording "dogs removed from communities" would need further explanation if different from the management of captured stray dogs.**

Competent authorities have the responsibility to develop minimum standards for the housing (physical facilities) and care of these dogs. There should be a provision for holding the dogs for a reasonable period of time to allow for reunion with the owner and, as appropriate, for rabies observation. ~~A period of 7-10 days is often used for this purpose.~~

a) Minimum standards for housing should include the following provisions:

- i) site selection: Access to drainage, water and electricity are essential and environmental factors such as noise and pollution should be taken into account;

- ii) kennel size, design and occupancy taking exercise into account;
- iii) disease control measures including isolation facilities.
- b) Management should address:
  - i) adequate fresh water and nutritious food;
  - ii) regular hygiene and cleaning;
  - iii) routine inspection of the dogs;
  - iv) monitoring of health and provision of required veterinary treatments;
  - v) policies and procedures for rehoming, sterilisation and euthanasia;
  - vi) record keeping and reporting to authorities.

Dogs that are removed from a community may be reunited with the owner or offered to new owners for adoption (rehoming). This provides an opportunity to promote responsible ownership and good animal health care (including rabies vaccination). ~~including animal health care through vaccination against common diseases of dogs, control of ecto- and endo-parasites, and vaccination against major zoonotic diseases such as rabies. Incentives for dog reproduction control may be provided through the provision of neutering services at a reduced rate or the release for adoption of only neutered animals.~~ Sterilisation of dogs prior to adoption should be considered. The suitability of new owners to adopt dogs should be assessed and owners matched with available animals. The effectiveness of ~~this~~ strategy i.e. offering dogs to new owners rehoming may be limited due to the suitability and number of dogs.

Dogs that are removed from a community may in some cases be provided health care (including rabies vaccination), sterilised, and released to their local community at or near the place of capture. ~~;~~ who agree to take responsibility for the health, welfare and management of the animal. The beneficial effect of this practice for dog welfare and population management is unknown. With regard to disease control, such as for rabies and possibly others, some beneficial effect may be realized. This may be short or long time. This method is more likely to be accepted in the situation where the presence of stray dogs is considered to be inevitable and is well tolerated by the local community.

**Community comment:**

**In the following paragraph, the words " or regions" should be inserted after the word "countries" in the first sentence.**

**In the sentence "*If the local community has owned dogs,.....*", the word "dogs" should be inserted at the end of the sentence.**

**Justification: Since the dog population control could be dealt by the local competent authorities and at regional level, there could be a different approach within the same country.**

This method is not applicable in all situations and may be illegal in countries where legislation prohibits the abandonment of dogs. Problems caused by dogs, such as noise, faecal pollution and traffic accidents, would not be alleviated as dogs are returned to the local community and their movements are not restricted. If the local community has owned dogs, consideration should be given to the potential encouragement of abandonment of unwanted. In the situation where many dogs are owned, a population control programme that focuses on neutering and responsible ownership may be more appropriate.



It is recommended that before adopting this approach, a cost-benefit analysis is conducted. Factors such as the monetary costs, impact on culture of ownership and public safety should be assessed as well as the benefits for *disease* control and animal welfare as well as any societal benefits.

- c) If this method is adopted, the following factors should be addressed:
- i) Raising awareness of the programme within the local community to ensure understanding and support
  - ii) Use of humane methods for catching, transporting and holding dogs
  - iii) Correct surgical technique, anaesthesia and analgesia, followed by post-operative care
  - iv) Disease control may include blanket vaccination (e.g. rabies) and treatments and testing for diseases (e.g. leishmaniasis) followed, as appropriate by treatment or euthanasia of the dog.
  - v) Behavioural observation may be used to assess if dogs are suitable for release. If not suitable for release or re-homing euthanasia should be considered.
  - vi) Permanent marking (e.g. tattoo) to indicate that the animal has been sterilised. Individual identification allows for tracking of vaccination status and treatment history. A visible identification (e.g. collar) may also be used to prevent unnecessary recapture. Identification can also be taken to indicate a level of 'ownership' by the organisation/authority responsible for carrying out this intervention.
  - vii) The dog should be returned to a place that is as near as possible to the place of capture.
  - viii) The welfare of dogs after release should be monitored and action taken if required.

**Community comment:**

**The word “responsible” should be deleted.**

~~Dogs that are removed from a community may, in some cases, be too numerous or may be unsuitable to place responsible ownership. If elimination of the excess animals is the only option, killing should be under regulation by a for any rehoming scheme. If euthanasia of these unwanted animals is the only option, the procedure should be conducted in accordance with the regulations of the Competent Authority and conducted humanely (see Article 4 k).~~

~~A number of selected animals, could be released if “environmentally compatible”, meaning that, once again, the feasibility of this strategy is very much related to the local people attitude/resources availability:-~~

- ~~≡ Risk-benefit evaluation of Catch Neuter Release & Monitoring (CNR&M) in terms of public safety and AW.~~
- ~~≡ Proper behavioural evaluation of dogs when removed for problems related to public nuisance~~
- ~~≡ Monitoring needed to evaluate individual health and welfare~~
- ~~≡ Sufficient level of public tolerance, food and assistance provided by responsible people/community~~
- ~~≡ Permanent identification (i.e. surgical sterilization, rabies vaccination, echinococcosis treatment, Leishmaniasis negative test). These actions clearly recon duct the animal to an “owner”, both intended as public (local municipality, regional government) or private~~
- ~~≡ Possibly clearly visible at distance (i.e. painted collars)~~

~~**Advantages:** Possible strategy in an early stage, when scarce resources are in place, if adopted in very specific situation it may also promote the societal value of animals and the benefits of a positive human-animal relationship (Rome's cat colony, "community" dogs)~~

~~**Disadvantages:** Ineffective over a long term since not promoting responsible ownership concept, possible AW concerns due to persistent intolerance by the community, possible risk to human safety and damage of the private property due to improper selection of animals.~~

~~Preferably to be used as a "spot" solution in specific situations and only in addition to other measures (humane education, door-to-door reuniting programs, adoption programs), possibly not to be used as the sole method of stray dog population control as a long term strategy.~~

#### 7. Environmental controls

#### **The Community reiterates its previous comment:**

**Public policy toward better services for the collection of rubbish associated with stricter rules concerning the release of wastes in the environment should be emphasized here. Synergy of such policy with the fight against rodents and insects could be stressed also here.**

Steps should be taken to reduce the carrying capacity, such as excluding dogs from sources of food (e.g. rubbish dumps and *abattoirs*, and installing animal-proof rubbish containers).

This should be linked to a reduction in the animal population by other methods, to avoid animal welfare problems.

#### 7. Control of dog movement – international (export/import)

Chapter 2.2.5 of the Terrestrial Animal Health Code provides recommendations on the international movement of dogs between rabies free countries and countries considered to be infected with rabies.

#### 8. Control of dog movements – within country (e.g. leash laws, roaming restrictions)

Measures for the control of dog movement in a country are generally invoked for ~~two~~ the following reasons:

- a) for rabies control when the *disease* is present in a country
- b) for public safety reasons
- c) for the safety of "owned dogs" in an area or locality when a stray dog control programme is in place
- d) to protect wildlife and livestock.

~~In both cases it is essential that dogs are registered and permanently identified to control or confine these dogs, reunite them if collected and to keep the relevant sanitary information recorded.~~

~~It is necessary to have empowering legislation to give the necessary power is necessary and a national or local infrastructure comprising of organization, administration, staff and resources is essential to encourage the finders of a stray dog to report to the *Competent Authority*.~~

~~The following 3 grades of movement control can be applied:~~

- ~~Absolute control (confinement, leash and muzzle), feasible during a limited periods such as for an emergency~~
- ~~Partial control (obedience if not on leash during daylight, confinement between the relevant information times of 5pm and 8 am)~~

- Control during specific times (rabies vaccination campaign, stray dog roundup)

#### 9. Regulation of commercial ~~Animal~~ dog dealers

~~While the majority of animal breeders and dealers are committed to raising and selling physically and psychologically healthy pets, regulation is necessary to ensure that all of these operations provide adequate care.~~

~~The law should require the humane care and treatment of certain animals sold as pets in retail stores as well at the wholesale level, transported in commerce, and used in research or exhibits.~~

~~Individuals using or working with such animals should be licensed and they must comply with regulations and standards.~~

- ~~Standards of Care and Recordkeeping~~

~~Businesses in the commercial pet trade must maintain minimum standards for veterinary care and animal management. The requirements should cover housing, handling, sanitation, food, water, and protection against extremes of weather and temperature.~~

~~To prevent lost or stolen animals from entering trade channels, breeders and dealers are required to keep records that identify the source and disposition of all regulated animals that come into their possession.~~

#### Community comment:

**The words “Shipping” and “Handling” should be removed.**

- Shipping and Handling

~~Specific regulations and standards are needed to regulate the transport of animals by commercial carriers. These rules help ensure that licensed dealers, contract carriers, and intermediate handlers treat regulated animals humanely. Transported animals must meet established minimum age and health certification requirements.~~

Regulation is needed to ensure that dog breeders and dealers are identified by the *Competent Authority* and are committed to raising and selling physically and psychologically healthy animals, as unhealthy animals may be more likely to be abandoned to become part of the stray population. Regulations should include specific requirements for accommodation, provision of suitable food, drink and bedding, adequate exercise, veterinary care and *disease* control. Breeders and dealers establishments should be inspected at regular intervals, including veterinary inspections. Advice on proper animal care should be given to all new owners of dogs.

#### 10. Reduction in dog bite incidence

~~Propensity to bite is influenced by heredity, early experience, socialisation & training, health and human behaviour towards the dog. Breed or type specific bans are difficult and costly to enforce, provide a false sense of security to the community and, where enacted, no data currently supports them as effective in reducing incidence of dog bites; therefore, they are not recommended. Specific behaviours or incidences can be used as criteria to facilitate identification of a dog as ‘dangerous’ and appropriate measures taken to control the animal by the competent authority. For example, a dog that has been reported to have bitten someone or something (livestock or pets) may be required by law to be to be confined on the owner’s property and kept on a lead (and if necessary muzzled) when in public. Note that confinement by tethering should be avoided as this can increase the likelihood of aggressive behaviour.~~

The most effective means of reducing prevalence of dog bites are education and placing responsibility on the owner; ~~not the animal~~. Dog owners should be educated ~~trained~~ in principles of responsible pet ownership as described in Article 5.a. Legal mechanisms that enable the competent authorities to impose penalties or otherwise deal with irresponsible owners are necessary. Mandatory registration and identification schemes will facilitate the effective application of such mechanisms.

Young children are the ~~group at highest~~ ~~most at-risk group~~ for dog bites. Education programmes focussed on appropriate dog-directed behaviour have been demonstrated to be effective in reducing dog bite prevalence and these programmes should be encouraged.

#### 11. Euthanasia

##### **Community comment:**

**The Community welcomes the work and the detailed considerations carried out on the different methods for the euthanasia of dogs.**

When euthanasia is practised, the ~~procedures used should comply with general principles the presented~~ laid down in the Terrestrial Animal Health Code — 2006 (Article 3.7.6.4) should be followed, with the emphasis on using the most practical, rapid and humane methods and ensuring operator safety.

##### **Community comment:**

**The following sentence should be deleted since in the table 1 it is not specified which methods should be used in rural or urban areas.**

~~For practical reasons, different procedures may be used in rural and urban areas.~~

~~For reasons of convenience, different procedures could be used in rural and in urban areas. Dogs should only be euthanized after holding for a period of time to allows for the owner to locate his/her dog.~~

~~Table 1 shows a list of methods for the euthanasia of dogs.~~

~~They fall into two major categories based on whether it is necessary to handle or restrain the dog or not in order to euthanize it.~~

~~Where capture or restraint procedures give rise to a risk or potential risk of human exposure to rabies, procedures that do not require restraint of dogs are preferable.~~

~~The methods are not described in any particular order.~~

|  | Procedure            | Capture | Restraint<br>=<br>Handling | Advantages/Disadvantages  |
|--|----------------------|---------|----------------------------|---|
| s<br>o<br>l<br>o<br>n<br>e<br>s<br>t<br>r<br>i<br>c<br>a<br>l<br>a<br>n<br>n<br>o<br>t<br>e<br>s | Electrocution        | Yes     | No                         | Affordable equipment: 220 V mains current;<br>gloves + boots.<br>Instant death.   |
|  | Carbon monoxide (CO) | Yes     | No                         | Needs appropriate premises; puts personnel at risk.<br>Slow death.  |
|  | CO <sub>2</sub>      | Yes     | No                         | As CO <sub>2</sub> is heavier than air, the dogs can lift their heads over the CO <sub>2</sub> layer and death is slow. |

|         |                                  |     |     |   |
|---------|----------------------------------|-----|-----|---|
|         | Barbiturates                     |     |     | Requires an appropriate dose and pre-anaesthetic.                         |
|         | Intravenous                      | Yes | Yes |   |
|         | Intracardial                     | Yes | Yes | Administered under veterinary supervision and requires trained personnel. |
|         | Intraperitoneal                  | Yes | Yes | Slow death.   |
|         | T-61 = Tanax                     |     |     | Dangerous for personnel in the event of accidental injection.             |
|         | Intravenous                      | Yes | Yes |   |
|         | Intracardial                     | Yes | Yes | Slow death.   |
|         | Intrapulmonary                   | Yes | Yes |   |
| Refract | Free bullet used from long range | No  | No  | Fast death.<br>Risk of accident (same as for hunting)                     |

=

Table 1: List of methods for the euthanasia of dogs

| Euthanasia method             | Specific method  | Animal welfare concerns/ implications   | Key animal welfare requirements  | Considerations relating to operator security  | Advantages  | Disadvantages  |
|-------------------------------|--|---|--|---|---|--|
| Chemical<br>-via<br>injection | Barbiturates   | Correct restraint is needed.<br>IP is slow and may be irritant.<br>IC injection is a painful procedure. | Recommend to use IV injection.<br>When using IP injection, the solution may be diluted or local anaesthetic agent used in conjunction.<br>IC should only be performed on unconscious animal and by skilled operator. | Correct restraint is needed.<br>Administered under veterinary supervision and requires trained personnel. | Speed of action generally depends on the dose, concentration, route and rate of injection.<br>Barbiturates induce euthanasia smoothly, with minimal discomfort to the animal.<br>Barbiturates are less expensive than many other euthanasia agents. | Mild aesthetic objection as terminal gasps may occur in unconscious animals. These drugs persist in the carcass and may cause sedation or death in animals that consume the cadaver. |
|                               | Embutramide +Mebezonium +Tetracaine                    | Muscle paralysis may occur before lost of consciousness if injection given rapidly                      | Use slow IV injection with sedation to permit slow rate of injection.  | Correct restraint is needed.<br>To be administered under veterinary supervision and by trained personnel. | Quite low cost.   | Unavailable/unlicensed in some countries   |
|                               | Anaesthetic agent overdose (thiopentone or propofenol) | Underdosing may lead to recovery  | IV injection of a sufficient dose  | Correct restraint is needed.<br>To be administered under veterinary supervision and by trained personnel. | Generally quick action and minimal discomfort to animal.  | Large volume required (cost implications)  |
|                               | Potassium chloride (KCl)                               | K <sup>+</sup> is cardiotoxic and very painful if used without anaesthetic agent.                       | Only use on anaesthetised animals, IV injection  | Requires trained personnel.   | Readily available without veterinary control.   | Prior need for anaesthetic (cost and availability implications)  |

Table 1: List of methods for the euthanasia of dogs

| Euthanasia method | Specific method          | Animal welfare concerns/ implications   | Key animal welfare requirements | Considerations relating to operator security           | Advantages                              | Disadvantages   |
|-------------------|--------------------------|---|---------------------------------|--|---|---|
| Mechanical        | Free bullet              | Can be inhumane if shot is inaccurate and dog is only wounded; dog may also escape. | Skilled operator essential.     | Risk of injury of operator.                            | Not necessary to handle or capture dog. | Brain tissue may be unavailable for rabies diagnosis. Risk of injury to bystanders. Legal constraints on use of firearms..  |
|                   | Penetrating captive bolt | Can be inhumane if shot is inaccurate and dog is only wounded.                      | Skilled operator essential.     | Animal must be restrained. Skilled operator essential. | No risk to operator (cf free bullet)    | Brain tissue may be unavailable for rabies diagnosis. Legal constraints on use of firearms. May raise aesthetic objections. |
|                   | Exsanguination           | Onset of hypovolaemia may cause dog to become anxious.                              | Only use on unconscious animal  | Danger to operator through use of sharp instrument.    | Material requirements minimal.          | Must be done on unconscious animal. Aesthetically objectionable   |

Table 1: List of methods for the euthanasia of dogs (cont)

**Community comments:**

**1. In the Animal welfare concern/implications of the gaseous method with Carbon monoxide the sentence "Gas is aversive" should be deleted since it is in contradiction with what listed in the advantages of this method.**

**2. In the Animal welfare concern/implications of the gaseous method with Carbon dioxide, the word "highly" should be deleted.**

| Euthanasia method | Specific method                   | Animal welfare concerns/ implications   | Key animal welfare requirements   | Considerations relating to operator security  | Advantages  | Disadvantages  |
|-------------------|-----------------------------------|---|---|---|---|--|
| Gaseous           | Carbon monoxide (CO)              | Gas is aversive. Inadequate concentration of CO is not lethal and can cause suffering. Signs of distress (convulsions, vocalization and agitation) may occur.   | Compressed CO in cylinders must be used to achieve and maintain adequate concentration, which must be monitored. Note: fumes from gasoline engines are irritant and this source of CO is not recommended. | Very hazardous for operator - gas is odourless and causes both high and chronic toxicity. Not sure what this means, can we make it clearer? | Dog dies quite rapidly if concentration of 4 to 6% used. No odour (therefore no aversive effect). Gas is not flammable or explosive except at concentration greater than 10%. |  |
|                   | Carbon dioxide (CO <sub>2</sub> ) | Gas is highly aversive. Inadequate concentration of CO <sub>2</sub> is not lethal and can cause suffering. CO <sub>2</sub> is heavier than air, so when incomplete filling of the chamber occurs, dogs may raise their head and avoid exposure. Few studies on adequate concentration and animal welfare. | Compressed CO <sub>2</sub> gas chamber is the only recommended method because the concentration can be monitored and regulated.   | Minimal hazard to operator when properly designed equipment used.   | Gas is not flammable or explosive and causes quite rapid anaesthesia when correct concentrations used. Low cost. Readily available as compressed gas                          | Anaesthesia can be quite rapid but death may take some time. |



|   |  |   |   |  |  |
|---|--|---|---|--|--|
| Inert gas (nitrogen, N <sub>2</sub><br>argon, Ar) | Loss of consciousness is preceded by hypoxemia and ventilatory stimulation, which may be distressing to the dog. Re-establishing a low concentration of O <sub>2</sub> (ie greater than or equal to 6%) in the chamber before death will allow immediate recovery. | Concentration above 98% must be achieved rapidly and maintained. Properly designed equipment must be used | Minimal hazard to operator when properly designed equipment used. | Gas is not flammable or explosive and is odourless. Readily available as compressed gas. | High cost. Little data on animal welfare implications in dogs. |
|---|--|---|---|--|--|

## Annex XXIII (contd)

Table 1: List of methods for the euthanasia of dogs (cont)

| Euthanasia method | Specific method                                   | Animal welfare concerns/ implications   | Key animal welfare requirements   | Considerations relating to operator security   | Advantages   | Disadvantages  |
|-------------------|---|---|---|--|--|--|
| <b>Gaseous</b>    | Anaesthetic gas overdose (halothane or enflurane) | Animal may struggle and become anxious during induction. Vapours may be irritating and can induce excitement.   | Supplementation with air or O <sub>2</sub> required to avoid hypoxemia during induction phase.  | Some gases may be hazardous, especially for pregnant women. General recommendation: Avoid human exposure to greater than or equal to 2ppm to avoid narcosis. | Gas is not flammable or explosive.<br>Valuable for use with small animals. | High cost.<br>Anaesthetic and euthanasia properties of the gas used must be known.<br>Isoflurane has a pungent odour. Methoxyflurane's action is slow and dog may become agitated. |
| <b>Electrical</b> | Electrocution                                     | Cardiac fibrillation occurs before onset of unconsciousness, causing severe pain if dog is conscious. Pain can also be caused by violent extension of the limbs, head and neck.<br>Method may not be effective if insufficient current applied. | Dogs must be unconscious before being electrocuted. This can be accomplished by electrical stunning (current through the brain to produce an instantaneous stun) or anaesthesia. Electrodes should span the brain in order that the current passed through the brain<br>Proper equipment and trained operator is essential. | May be hazardous for operator, who should use protective equipment (boots and gloves).   | Low cost.  | Inhumane if performed on conscious dog.<br>May raise aesthetic objections.   |

KEY to abbreviations used in Table 1:

IV: intravenous

IP: Intraperitoneal

IC: Intracardiac

**To be developed for each method-**

- 1- ~~Introduction~~
- 2- ~~Requirements for effective use~~
- 3- ~~Advantages~~
- 4- ~~Disadvantages~~
- 5- ~~Conclusions~~

a) Summary assessment of Comments on methods for the euthanasia of dogs:i) Restraint

When a dog needs to be restrained for any procedure, including euthanasia, ~~procedure~~, this should always be done with full regard for operator security and animal welfare. In order to use Some euthanasia methods must be used in association with sedation or anaesthesia in order to be considered humane way, may be required.

ii) Special equipment

When special equipment is needed to perform euthanasia (eg. gas chamber) the system should be ~~properly~~ designed for the purpose and regularly maintained in order to achieve operator security and animal welfare.

iii) The following methods, procedures and practices are unacceptable on animal welfare grounds:• Chemical methods:

- Embutramide +Mebezonium +Tetracaine without sedation or by other than IV injection
- Chloral hydrate
- Nitrous oxide : may be used with other inhalants to speed the onset of anaesthesia, but alone it does not induce anaesthesia in dogs
- Ether
- Chloroform
- Cyanide
- Strychnine
- Neuromuscular blocking agents (nicotine, magnesium sulphate, potassium chloride, all curariform agents) : when used alone, respiratory arrest occurs before lost of consciousness, so the dog may perceive pain.
- Formalin
- Household products and solvents

• Mechanical methods:

- Air embolism on conscious animal

- Burning
- Exsanguination of conscious animal
- Decompression: expansion of gas trapped in body cavities may be very painful
- Drowning
- Hypothermia, rapid freezing
- Stunning: stunning is not a euthanasia method, it should always be followed by a method which ensures death.
- Kill-trapping
- Electrocution of conscious animal.

**Community comments:**

**1. A definition of neonatal animal should be foreseen in order to allow a correct application of methods for euthanasia such as gaseous ones, cervical dislocation and concussion.**

**2. Furthermore, the Commission would welcome scientific evidence on the resistance of neonatal animals to hypoxia.**

Because neonatal animals are resistant to hypoxia, methods that depend upon achieving a hypoxic state (eg CO<sub>2</sub>, CO, N<sub>2</sub>, Ar) should not be used. These methods should not be used in animals aged less than 4 months, except to produce loss of consciousness and should be followed by another method to cause death. Cervical dislocation and concussion may be used in neonatal dogs. Operators must be well trained in the use of physical techniques to ensure that they are correctly and humanely carried out. The dog must be exsanguinated immediately after concussion or cervical dislocation.

iv) Confirmation of death

For all methods of euthanasia used, death must be confirmed before animals are disposed of or left unattended. If an animal is not dead, another method of euthanasia must be performed.

v) Carcass disposal

Carcasses should be disposed of in a manner that complies with legislation. Attention must be paid to the risk of residues occurring in the carcass. Incineration is generally the safest way of carcass disposal.

**Article 6**

**Community comment:**

**The Community welcomes the work carried out on the methodology to monitor and evaluate the dog population control programme. In this context, the use of indicators and particularly of animal based ones is very much appreciated.**

**Monitoring and evaluation of dog population control programmes**

Monitoring and evaluation allows for comparison of important indicators against the baselines measured during initial assessment (Article 4). The three main reasons for carrying out monitoring and evaluation are:

1. To help improve performance, by highlighting both problems and successful elements of interventions.
2. For accountability, to demonstrate that the programme is achieving its aims.

3. Assuming methods are standardised, to compare the success of strategies used in different locations and situations.

Monitoring is a continuous process that aims to check the programme progress against targets and allows for regular adjustments. Evaluation is a periodic assessment, usually carried out at particular milestones to check the programme is having the desired and stated impact. These procedures involve the measurement of 'indicators' that are chosen because they reflect important components of the programme at different stages. Selection of suitable indicators requires clear planning of what the programme is aiming to achieve. the best selection of indicators will be one that reflects the interest of all relevant stakeholders. Standardised methodology will facilitate comparison of data from subsequent evaluations and performance between different projects. Indicators can be direct measurements of an area targeted to change (e.g. population of free roaming dogs on public property) or indirect measures that reflect change in a targeted area (e.g. number of reported dog bites as a reflection of rabies prevalence).

4. Elements that should generally be monitored and evaluated ~~most programmes will need to monitor and evaluate~~ include:

- a) Dog population size, separated by into sub-populations according to ownership and restriction of movement (i.e. roaming unrestricted or restricted by an owner);
- b) Dog welfare, in the target population (e.g. body condition score, skin conditions and injuries or lameness) and as a result of the programme (if interventions involve direct handling of dogs, the welfare of the dogs as result of this handling should be monitored);
- c) Prevalence of zoonotic diseases, such as rabies, ~~prevalence~~ in both the animal and human population ~~can be measured~~;
- d) Responsible animal ownership, including measures of attitudes and understanding of responsible ownership and evidence that this is translating into ~~actual~~ responsible behaviour.

5. There are many sources of information for measuring indicators ~~can be widespread~~, including:

**Community comment:**

**In the following point, the "focus group" should be included after the "structured questionnaires".**

**Justification:**

**A focus group is a form of qualitative research in which a group of people are asked about their attitude towards a problem. This method allows studying people attitude in a more natural setting than a one-to-one interview and allows the collection of valid results relatively quickly and with a low cost.**

- a) Feedback from the local community (e.g. through the use of structured questionnaires or 'open format' consultation processes)
- b) Records and opinions obtained from relevant professionals (e.g. veterinarians, medical doctors, law enforcement agencies, educators)
- c) Animal based measurements (e.g. direct observation surveys of population size and welfare status)

The output of activities against budget should be carefully recorded in order to evaluate ~~balance~~ the effort (or cost) against the outcomes and impact (or benefit) that are reflected in the results of monitoring and evaluation ~~results~~.

~~Article 7~~

~~Research needs~~

~~To be completed~~

~~Article 8~~

~~International cooperation~~

~~To be completed~~

Annex XXIII (contd)Annex I:

An overview of appropriate methodologies for estimating the size of dog populations.

Population estimates are necessary for making realistic plans for dog population management and zoonosis control, and for monitoring the success of such interventions. However, for designing effective management plans, data on population sizes alone are insufficient. Additional information is required, such as degrees of supervision of owned dogs, the origin of ownerless dogs, accessibility, etc.

The term “owned” may be restricted to a dog that is registered with licensing authorities, or it may be expanded to unregistered animals that are somewhat supervised and receive shelter and some form of care in individual households. Owned dogs may be well supervised and restrained at all times, or they may be left without control for various time periods and activities. Dogs without owners that claim responsibility may still be accepted or tolerated in the neighbourhood, and individuals may provide food and protection. Such animals are sometimes called “community owned dogs” or “neighbourhood dogs”. For an observer it is frequently impossible to decide if a free roaming dog belongs to someone or not.

The choice of methods for assessing the size of a dog population depends on the ratio of owned versus ownerless dogs, which may not always be easy to judge. For populations with a large proportion of owned dogs it may be sufficient to consult dog registration records or to conduct household surveys. These surveys should establish the number of owned dogs and the dog to human ratio in the area. In addition, questions on dog reproduction and demographics, care provided, zoonosis prevention, dog bite incidence, etc. may be asked. Sample questionnaires can be found in the “Guidelines for Dog Population Management” (WHO/WSPA 1990). Standard polling principles must be applied.

If the proportion of ownerless dogs is high or difficult to assess, then one must resort to more experimental approaches. Methods borrowed from wildlife biology can be applied. These methods are described in WHO/WSPA’s “Guidelines for Dog Population Management” (1990), and in more detail in numerous professional publications and handbooks, such as Bookhout (1994) and Sutherland (2006). Being generally diurnal and tolerant to human proximity, dogs lend themselves to direct observation and the application of mark-recapture techniques. Nevertheless, a number of caveats and limitations have to be taken into account. The methods are relatively labour intensive, they require some understanding of statistics and population biology, and most importantly, they are difficult to apply to very large areas. One must take into account that dog distribution is non-random, that their populations are not static, and that individual dogs are fairly mobile.

Counting of dogs visible in a defined area is the simplest approach to getting information on population size. One has to take into account that the visibility of dogs depends on the physical environment, but also on dog and human activity patterns. The visibility of animals changes with the time of the day and with seasons as a function of food availability, shelter (shade), disturbance, etc. Repeated standardized counting of dogs visible within defined geographical localities (e.g. wards) and specific times will provide indications of population trends. Direct counting is most reliable if it is applied to small and relatively confined dog populations, e.g. in villages, where it might be possible to recognize individual dogs based on their physical appearance.

Methods using mark-recapture procedures are often considered more reliable. However, they also produce trustworthy results only when a number of preconditions are met. Mortality, emigration and recruitment into the population must be minimal during the census period. One may be able to incorporate corrective factors into the calculations.

It is therefore important that the recommended census procedures are applied at times of low dispersal and that one selects study plots of shape and size that minimize the effect of dog movements in and out of the observation area. Census surveys should be completed within a few days to a maximum of two

weeks in order to reduce demographic changes. In addition, all individuals in the population must have an equal chance of being counted. This is a highly improbable condition for dogs, whose visibility depends on ownership status and degrees of supervision. It is therefore recommended that the investigator determines what fraction of the total population he/she might cover with an observational method and how much this part overlaps with the owned dog segment that he/she assesses with household surveys.

There are essentially two ways to obtain a population estimate if it is possible, in a defined area and within a few days, to tag a large number of dogs with a visible mark, e.g. a distinctive collar or a paint smudge. The first method requires that the capture (marking) effort remains reasonably constant for the whole length of the study. By plotting the daily number of dogs marked against the accumulated total of marked dogs for each day one can extrapolate the value representing the total number of dogs in the area. More commonly used in wildlife studies are mark recapture methods (Peterson-Jackson, Lincoln indices). Dogs are marked (tagged) and released back into the population. The population is subsequently sampled by direct observation. The number of marked and unmarked dogs is recorded. One multiplies the number of dogs that were initially marked and released by the number of subsequently observed dogs divided by the number of dogs seen as marked during the re-observation to obtain a total population estimate. Examples for the two methods are given in WHO/WSPA's "Guidelines for Dog Population Management" (1990).

Since the dog populations of entire countries, states, provinces or even cities are much too large for complete assessment, it is necessary to apply the methods summarized above to sample areas. These should be selected (using common sense) so that results can be extrapolated to larger areas.

Bookhout TA (ed), 1994: *Research and Management Techniques for Wildlife and Habitats*, 5th ed. The Wildlife Society, Bethesda, Maryland, 740p.

Sutherland WJ (ed), 2006: *Ecological Census Techniques - A Handbook*, 2nd ed. Cambridge University Press, Cambridge, 448 p.

WHO/WSPA, 1990: *Guidelines for Dog Population Management*. WHO/ZOON/90.165. WHO, Geneva, 116 p.





## CHAPTER 2.9.X.

**AETHINA TUMIDA (SMALL HIVE BEETLE)  
INFESTATION OF HONEY BEES****Community comments:**

**The Community welcomes this draft Chapter and can support this proposal however it would like the points below taken on board. The Community proposes to amend the title to be consistent to other chapter headings.**

**The title should be: *AETHINA TUMIDA* (SMALL HIVE BEETLE)**

**In addition *Veterinary Administration* should be replaced by *Veterinary Authority*.**

**Risk assessment document should be provided by the OiE.**

**Some other comments are integrated in the text.**

## Article 2.9.X.1.

For the purposes of this chapter, small hive beetle (SHB) is an infestation of bee colonies by the beetle *Aethina tumida*, which is an ectoparasite affecting populations of the honey bee *Apis mellifera* L. It can also parasitise bumble bee *Bombus terrestris* colonies under experimental conditions, and although infestation has not been demonstrated in wild populations, *Bombus* spp. must also be considered to be susceptible to infestation.

**Community comments:**

**The Community proposes that the words “For the purpose of this chapter” are deleted and the word “ectoparasite” is replaced by “parasite” because this parasite does not strictly comply with the definition of ectoparasite.**

The adult beetle is attracted to bee colonies to reproduce, although it can survive and reproduce independently in other natural environments, using other food supplies as its nutritional source, including certain types of fruit. Hence once it is established within a localised environment, it is extremely difficult to eradicate.

The life cycle of *Aethina tumida* begins with the adult beetle laying eggs within infested hives- these are usually laid in irregular masses in hive crevices or brood combs. After 2-6 days, the eggs hatch and the emerging larvae begin to feed voraciously on brood comb, bee eggs, pollen and honey within the hive. The SHB has a high reproductive potential. Each female can produce about 1,000 eggs in its four to six months of life. At maturation (approximately 10-29 days after hatching), the larvae exit the hive and burrow into soil around the hive entrance. Adult beetle emerge after an average of 3-4 weeks, although pupation can take between 8 and 60 days depending on temperature and moisture levels (usually takes 3 to 4 weeks).

**Community comments:**

**The Community proposes that the word “voracious” is deleted.**

The life span of an adult beetle depends on environmental conditions such as temperature and humidity, but in practice, adult beetles can live for at least 6 months, and in favourable reproductive conditions, the female is capable of laying new egg batches every 5-12 weeks. The beetle is able to survive at least two weeks without food and 50 days on brood combs.

Early signs of infestation may go unnoticed, but the growth in the beetle population is rapid, leading to high mortality in the hive. Because *Aethina tumida* can be found and can thrive within the natural environment, and can fly up to a distance of 6-13km from its nest site, it is capable of dispersing rapidly and directly colonising hives. This includes following or accompanying swarms. It also does not require direct contact between adult bees to spread infestation. However, the movement of adult bees, honeycomb and other apiculture products may all cause infestations to spread to previously unaffected colonies.

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

#### Article 2.9.X.2.

The *Aethina tumida* status of a country or zone can only be determined after considering the following criteria:

1. a risk assessment has been conducted, identifying all potential factors for *Aethina tumida* occurrence and their historic perspective; including *disease/pest* incidence data from permanent official sanitary surveillance of apiaries programme
2. *Aethina tumida* infestation should be notifiable in the whole country, and all clinical signs suggestive of *Aethina tumida* infestation should be subjected to field and laboratory investigations;
3. On-going awareness and training programmes should be in place to encourage reporting of all cases suggestive of *Aethina tumida* infestation;
4. the *Veterinary Administration* or other competent authority with responsibility for the health of honey bees should have current knowledge of, and authority over, all domesticated apiaries in the country.

#### Community comments:

**The Community suggests deleting the word “current”.**

#### Article 2.9.X.3.

#### Country or zone free from *Aethina tumida*

##### 1) Historically free status

A country or zone may be considered free from the *disease* after conducting a risk assessment as referred to in Article 2.9.X.2. but without formally applying a specific surveillance programme if the country or zone complies with the provisions of Article 3.8.1.2.

##### 2) Free status as a result of an eradication programme

A country or zone which does not meet the conditions of point 1) above may be considered free from *Aethina tumida* infestation after conducting a risk assessment as referred to in Article 2.9.X.2. and when:

- a) the *Veterinary Administration* or other competent authority with responsibility for the health of honey bees has current knowledge of, and authority over, all domesticated apiaries existing in

the country or zone;

**Community comments:**

**The Community suggest deleting the word “current”.**

- b) *Aethina tumida* infestation is notifiable in the whole country or zone, and any clinical cases suggestive of *Aethina tumida* infestation are subjected to field and laboratory investigations; a contingency plan is in place describing controls and inspection activities;
- c) for the 5 years following the last reported case of *Aethina tumida* infestation, an annual survey supervised by the Veterinary Administration, with negative results, have been carried out on a representative sample of apiaries in the country or zone to provide a confidence level of at least 95% of detecting *Aethina tumida* infestation if at least 1% of the apiaries were infected at a within-apiary prevalence rate of at least 5% of the hives; such surveys may be targeted towards areas with a higher likelihood of infestation;
- d) to maintain free status, an annual survey supervised by the *Veterinary Administration*, with negative results, is carried out on a representative sample of apiaries in the country or zone to indicate that there has been no new *cases*; such surveys may be targeted towards areas with a higher likelihood of infestation;
- e) all equipment associated with previously infected apiaries has been destroyed, or cleaned and sterilised to ensure the destruction of *Aethina tumida* spp., in conformity with one of the procedures referred to in Appendix XXX (under study);
- f) the soil and undergrowth in the immediate vicinity of all infected apiaries has been treated with a soil drench or similar suitable treatment that is efficacious in destroying incubating *Aethina tumida* larvae and pupae;

**Community comments:**

**The Community suggests deleting the word “incubating” as it is superfluous.**

- g) the importation of the *commodities* listed in this Chapter into the country or zone is carried out, in conformity with the recommendations of this Chapter.

**Article 2.9.X.4.**

Regardless of the status of the *exporting country* with regard to *Aethina tumida* infestation, *Veterinary Administrations* should authorise without restriction the import or transit through their territory of the following *commodities*:

1. honey bee semen and honey bee venom;
2. extracted honey, refined or rendered beeswax, propolis and royal jelly.

**Community comments:**

**In order to be more precise, the first sentence of article 2.9.X.4 should read:**

**"Veterinary Authorities should authorise without any restrictions in relation to the *Aethina tumida* status of the exporting country, the import or transit through their territory of the following commodities:"**

**Furthermore, without any knowledge about the efficacy of the treatment applied to these products, the Community thinks that their use in apiculture could be a risk of introduction of the disease. Thus, the point 2 should read:**

**"extracted honey, refined or rendered propolis, bees wax and royal jelly not intended for use in apiculture."**

Article 2.9.X.5.

*Veterinary Administrations of importing countries* should require:

for individual consignments containing a single live queen honey bee, accompanied by a small number of associated attendants (a maximum of 20 attendants per queen)

**Community comments:**

**The words "or queen bumble bee" should be added after the words "queen honey bee".**

the presentation of an *international veterinary certificate* attesting that the bees come from a country or zone officially free from *Aethina tumida* infestation,

or

the presentation of an *international veterinary certificate* including an attestation from the competent authority of the exporting third country stating that:

1. the bees come from hives or colonies which were inspected immediately prior to dispatch and show no clinical signs or suspicion of the presence of *Aethina tumida* or its eggs, larvae or pupae;
2. come from an area of at least 100km radius where no apiary has been subject to any restrictions associated with the occurrence of *Aethina tumida* for the previous 6 months, and
3. the bees and accompanying packaging presented for export have been thoroughly and individually inspected and do not contain *Aethina tumida* or its eggs, larvae or pupae.

**Community comments:**

**The certificate should be amended to be more precise and applicable.**

**A point 1 in the certificate should be added:**

**"1. the bees come from a breeding apiary, which is supervised and controlled by the competent authority"**

**Point 2 would become point 3, and should read:**

**"come from an area of at least 100km radius which is not the subject of any restrictions associated with the occurrence of *Aethina tumida*, and where these infestations are absent, and"**

Article 2.9.X.6.

*Veterinary Administrations of importing countries* should require:

for live worker bees, drone bees or bee colonies with or without associated brood combs

the presentation of an *international veterinary certificate* attesting that the bees come from a country or zone officially free from *Aethina tumida* infestation, and the bees and accompanying packaging presented for export have been inspected and do not contain *Aethina tumida* or its eggs, larvae or pupae.

**Community comments:**

**In order to include bumble bees, an article should be inserted (and the further articles renumbered in consequence):**

**Article 2.9.X.7.**

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

**for live bumble bees**

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

**1. the bumble bees come from a country or zone officially free from *Aethina tumida* infestation, and**

**2. the bumble bees, and accompanying packaging presented for export have been inspected and do not contain *Aethina tumida* or its eggs, larvae or pupae.**

**or**

**3. the bumble bees have been bred and kept under a controlled environment within a recognised establishment which is supervised and controlled by the competent authority,**

**4. the establishment referred to above was inspected immediately prior to dispatch and all eggs, larvae and pupae show no clinical signs or suspicion of the presence of *Aethina tumida* or its eggs or larvae or pupae and**

**5. the packaging material, containers, accompanying products and food are new and all precautions have been taken to prevent contamination with *Aethina tumida* or its eggs, larvae or pupae.**

Article 2.9.X.7.

*Veterinary Administrations of importing countries* should require:

for eggs, larvae and pupae of honey bees

**Community comments:**

**The words "or bumble bees" should be added after the words "honey bees".**

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

1. were sourced from a free country or zone (under study);

or

2. have been isolated from queens in a quarantine station, and
3. are from hives or come from hives or colonies which were inspected immediately prior to entry into the quarantine station and show no clinical signs or suspicion of the presence of *Aethina tumida* or its eggs or larvae or pupae then and during the quarantine period.

**Community comments:**

**The certificate should be amended to be based upon risk management measures at source rather than in a quarantine station. Points 2 and 3 should be replaced by the following:**

- 2. have been bred and kept under a controlled environment within a recognised establishment which is supervised and controlled by the competent authority,**
- 3. the establishment referred to above was inspected immediately prior to dispatch and all eggs, larvae and pupae show no clinical signs or suspicion of the presence of *Aethina tumida* or its eggs or larvae or pupae and**
- 4. the packaging material, containers, accompanying products and food are new and all precautions have been taken to prevent contamination with *Aethina tumida* or its eggs, larvae or pupae.**

Article 2.9.X.8.

*Veterinary Administrations of importing countries* should require:

for used equipment associated with beekeeping

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

1. the equipment:
  - EITHER
  - a) comes from a country or zone free from *Aethina tumida* infestation; and
  - b) contains no live honey bees or bee brood;
  - OR
  - c) contains no live honey bees or bee brood;
  - d) has been thoroughly cleaned, and treated to ensure the destruction of *Aethina tumida* spp., in conformity with one of the procedures referred to in Appendix XXX (under study); and

**Community comments:**

**The word "and" should be added at the end of point c).**

2. all precautions have been taken to prevent infestation/contamination.

Article 2.9.X.9.

*Veterinary Administrations of importing countries* should require:

for honey-bee collected pollen and beeswax (in the form of honeycomb)

**Community comments:**

**The certificate should be amended to be consistent with the previous comments, and only concern the products intended for apiculture. Thus the sentence above should read:**

**for apiculture products intended for use in apiculture**

**Furthermore, it should take into account the possibility of presence of eggs or larvae of *Aethina tumida*. Latest scientific and practical evidence show that *Aethina tumida* is inactivated by a cold treatment of -12°C during at least 24 hours. So it should be amended as such:**

**1. the products:**

**EITHER**

- a) **come from a country or zone free from *Aethina tumida* infestation; and**
- b) **contain no live honey bees or bee brood;**

**OR**

- c) **come from an area not subject to any restrictions associated with *Aethina tumida*; and**
- d) **have been subjected to a temperature of -12°C or lower for at least 24 hours or another treatment that ensure the destruction of *Aethina tumida* spp., in conformity with one of the procedures referred to in Appendix XXX (under study);**

**OR**

- e) **in the case of wax, has been refined or rendered;**

**2. all precautions have been taken to prevent infestation/contamination.**

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

1. the products:

EITHER

- a) comes from a country or zone free from *Aethina tumida* infestation; and
- b) contains no live honey bees or bee brood;

OR

- c) contains no live honey bees or bee brood;
- d) has been thoroughly cleaned, and treated to ensure the destruction of *Aethina tumida* spp., in conformity with one of the procedures referred to in Appendix XXX (under study); and

2. all precautions have been taken to prevent infestation/contamination.

Article 2.9.X.10.

*Veterinary Administrations of importing countries* should require:



400

for comb honey

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

1. comes from a country or zone free from *Aethina tumida* infestation; and
2. contains no live honey bees or bee brood.

**Community comments:**

**The Community asks the OIE to provide the Member Countries with a scientific justification for animal health restrictions on the trade of comb honey for human consumption.**