



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 10.1.2006  
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**COMMISSION STAFF WORKING DOCUMENT**

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

## EXPLANATORY MEMORANDUM

The OIE Terrestrial Animal Health Standards Commission met at the OIE Headquarters in Paris from 19 to 30 September 2005.

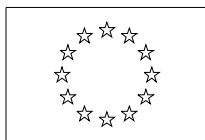
These proposals from the OIE for modifications are for eventual adoption or consideration at the next General Session in May 2006.

The Community comments need to reach the OIE Headquarters by 17 February 2006 in order to be considered at the next meeting of the Commission in March 2006. All texts submitted for comment in this report (Part A) may be proposed for adoption at the 74<sup>th</sup> General Session. Depending on the nature of the comments received on each text, the Terrestrial Code Commission will indicate in its March 2006 meeting report whether a particular text will be proposed for adoption or held over for further work.

The Commission therefore proposes to the Council to authorise the Commission to present to the OIE, as since 1995, the following written comments in the Annex before 17 February prior to the meeting referred to above. This is in order to allow the OIE to take the Community comments into account during their meetings, prior to submission of the final version to the General Session in May 2006. The cover letter to be sent with our response is attached at Annex A (Doc D/(2005) 522619).

In order to facilitate the examination of the comments of the Community, they have been incorporated in boxes into the OIE reports. In this context, the Community thanks the OIE for providing the electronic version of the Report.

## ANNEX



UNION EUROPÉENNE

Bruxelles, le  
D(2005)/522619/HB/vb

**Object: Meetings of the Animal Production Food Safety Working Group, the Scientific Commission on Animal Diseases and the International Terrestrial Animal Health Code commission – Jan/Feb/March 2006**

Dear Bernard,

Please find attached as an annex to this letter the Community comments on the report of the meeting of Code Commission with reference to certain Chapters in the OIE Terrestrial Animal Health Code. In order to facilitate the examination of the comments of the Community, they have been incorporated in boxes into the OIE reports. In this context, the Community thanks the OIE for providing the electronic version of the Report.

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

Jaana Husu-Kallio

*Deputy Director General*

Enclosures: 1

Copy: All CVOs Member States, Bulgaria, Iceland, Norway, Romania and Switzerland

Dr. B. Vallat

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## ANNEX



Original: English

September 2005

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

**Paris, 19-30 September 2005**

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The OIE Terrestrial Animal Health Standards Commission (hereafter referred to as the Terrestrial Code Commission) met at the OIE Headquarters in Paris from 19 to 30 September 2005.

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

The Director General of the OIE, Dr B. Vallat, welcomed the members and thanked them all for their willingness to participate in this important OIE work. He recalled the significant changes to the meeting timetable of the two Code Commissions in that the OIE was reverting to a two-year cycle for the preparation and adoption of standards, except in the case of international crises. He hoped that the changed timetable would further improve coordination in standards work between the Terrestrial Code Commission and the other Commissions.

Dr Vallat recalled the commitments made to Member Countries at the 73<sup>rd</sup> General Session regarding progress on some important texts which had been adopted on the understanding that outstanding Member Countries' comments would be addressed. This included surveillance for

bovine spongiform encephalopathy (BSE) (which would allow the official recognition of BSE status under the new chapter), bluetongue surveillance, the newly adopted standards on animal welfare, the ‘under study’ parts of the avian influenza chapter, and compartmentalisation. Dr Vallat also noted the need to address the recommendations arising from Regional Commission and other OIE meetings, including suggestions for improving the OIE *Terrestrial Animal Health Code* (hereafter referred to as the *Terrestrial Code*) chapters on Veterinary Services (including statutory body responsibilities, rapid response capability and auditing mechanisms).

Dr Vallat encouraged the Terrestrial Code Commission and the Aquatic Animal Health Standards Commission (hereafter referred to as the Aquatic Animals Commission) to continue their collaborative work on harmonisation of the two *Codes*.

The President of the Terrestrial Code Commission considered that the meeting was an appropriate time to examine the ways in which the Terrestrial Code Commission was operating and how procedures could be improved, particularly in relation to the other Commissions and the revised meeting schedule.

The Terrestrial Code Commission examined various *Terrestrial Code* texts in the light of Member Countries’ comments received just prior to and following the 73<sup>rd</sup> General Session. The outcome of the Terrestrial Code Commission’s work is presented as appendices to this report. Amendments made to existing chapters and previously circulated drafts are shown as double underlined text, with deleted text in ~~strikeout~~.

The Terrestrial Code Commission thanked the following Member Countries for providing comments: Argentina, Australia, Botswana, Brazil, Canada, Chile, the European Union (EU), Japan, New Zealand, the Southern Cone countries of South America, Sudan, Switzerland, Taipei China, Thailand and the United States of America (USA).

The Terrestrial Code Commission strongly encouraged Member Countries to participate in the development of the OIE’s international standards by sending comments on this report in sufficient time for them to be considered by the Commission. It would assist the Terrestrial Code Commission if comments were submitted as specific proposed text changes, supported by a scientific rationale.

Comments need to reach the OIE Headquarters by 17 February 2006 in order to be considered at the next meeting of the Commission in March 2006. However, in order to meet the deadlines for meetings of the Animal Production Food Safety Working Group and the Scientific Commission on Animal Diseases (hereafter referred to as the Scientific Commission) comments on Appendices VII, XII, XXIV and XXV should reach the OIE Headquarters by 3 January 2006.

Member Countries should note that, unless stated otherwise, all texts submitted for comment in this report (Part A) may be proposed for adoption at the 74th General Session. Depending on the nature of the comments received on each text, the Terrestrial Code Commission will indicate in its March 2006 meeting report whether a particular text will be proposed for adoption or held over for further work.

## A. TEXTS WHICH ARE SUBMITTED FOR MEMBER COUNTRY COMMENT

### 1. General definitions (Chapter 1.1.1.)

**Community comments:**

**The Community can in general support the proposal at Appendix III but would like the comments noted there taken on board. The Community would like to point out that there are problems with some of the definitions proposed.**

After examining a comment from Australia on the definition of ‘*Case*’, the Terrestrial Code Commission reconfirmed its previous position that limiting the pathogen by referring to ‘listed by the OIE’ would not be wise in order to encourage reporting of diseases not listed by the OIE, notably emerging diseases.

The suggestion by the EU to modify ‘*Outbreak of disease or infection*’ to be serially numbered was not adopted as the Terrestrial Code Commission believes that every Member Country has its own system of numbering and any numbering system OIE suggests may cause confusion.

After considering the comment by Portugal during the 73<sup>rd</sup> General Session, the definition of ‘*Quarantine station*’ was modified to accommodate disease specific conditions.

A set of definitions proposed by the Working Group of Animal Welfare was reviewed and endorsed by the Terrestrial Code Commission with some minor modifications.

Suggested changes are at [Appendix III](#) for the comment of Member Countries.

### 2. Evaluation of Veterinary Services (Chapters 1.3.3. and 1.3.4.)

**Community comments:**

**The Community can support the proposals at Appendices IV, V and VI.**

The Terrestrial Code Commission received from the President of the *ad hoc* Group a draft revised text of Chapters 1.3.3. and 1.3.4. on the evaluation of Veterinary Services. This revision included recommendations on the evaluation of the Veterinary Statutory Body and on a procedure whereby a Member Country can request the OIE to organise an evaluation of its Veterinary Services.

The Terrestrial Code Commission also reviewed the tool (*Performance, Vision, Strategy [PVS] Instrument*) developed by the OIE and the Inter-American Institute for Cooperation on Agriculture (IICA) for the evaluation of Veterinary Services. This evaluation tool has been tested in the Americas and later reviewed and updated on the basis of this experience for a broader application. The *Instrument* was designed to indicate the areas of strength and weakness of a Veterinary Service (with a view to the allocation of resources) rather than to pass or fail it. The Terrestrial Code Commission

was of the opinion that this tool could be used as a guide for self-evaluation by a Member Country of its Veterinary Services and for evaluation by the OIE of a Member Country's Veterinary Services on a voluntary basis.

Suggested changes to the chapters are at Appendices IV and V for the comment of Member Countries. The current version of the *PVS Instrument* is attached for the comment of Member Countries (Appendix VI).

### **3. Zoning and compartmentalisation (Chapter 1.3.5.)**

**Community comments:**

**The Community can support the proposal at Appendix VII but would like the comments noted there taken on board.**

Comments received from Member Countries as well as issues raised during the 73<sup>rd</sup> General Session were examined.

Paragraphs in the articles on 'Introduction' and 'General considerations' were reorganised to address the issues more logically. The Terrestrial Code Commission also clarified the commitment of the Veterinary Administration by modifying the last paragraph of Article 1.3.5.2.

The Terrestrial Code Commission was concerned that the concept of compartmentalisation was not yet well understood. It noted that the application of compartmentalisation was not mandatory and it should be used in a similar manner to zoning, depending on the epidemiology of the disease. While the primary criteria for zoning are related to geography, those for compartments relate to biosecurity management measures; however, the application of zoning includes some biosecurity elements and compartmentalisation will involve a spatial element for some diseases.

The Terrestrial Code Commission also discussed some issues on compartmentalisation with the *ad hoc* Group on Epidemiology which is preparing an explanatory paper on the concept in order to provide guidance to Member Countries.

The revised Chapter 1.3.5. is submitted at Appendix VII for the comment of Member Countries.

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

**Community comments:**

**The Community supports the work of the OIE on this topic.**

The Terrestrial Code Commission was advised that the Scientific Commission will review the work of the *ad hoc* Group on Epidemiology at the Commission's meeting in January 2006 and present a revised appendix for consideration at the Terrestrial Code

Commission's meeting in March 2006. The Terrestrial Code Commission has requested the Scientific Commission to take into account comments received from Member Countries.

The Terrestrial Code Commission has also requested that some guidelines on surveillance for vectors be included in the appendix.

## 5. Criteria for listing diseases (Chapter 2.1.1.)

### **Community comments:**

**The Community can support the proposals at Appendix VIII.**

The Terrestrial Code Commission met with Dr K. Ben Jebara, Head of the OIE Animal Health Information Department, to discuss the comments from Member Countries on the criteria for listing diseases. Minor changes were made to Article 2.1.1.1. and the decision tree in Article 2.1.1.2. was amended accordingly. Member Countries' proposals for the inclusion to or deletion from the OIE list of diseases will be considered by the *ad hoc* Group on Animal Disease Notification. Member Countries are reminded that they need to submit a supporting statement (addressing the relevant criterion) with each proposal.

The revised text at [Appendix VIII](#) is submitted for the comment of Member Countries.

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

### **Community comments:**

**The Community thanks the OIE for taking into account its suggestions and supports the proposals at Appendices IX and X however it is still very concerned about the requirements in Article 2.2.10.20 as it believes the risk of importing bone-in meat from an area which is free of FMD with vaccination is too high. The recent outbreaks in Brazil tend to highlight this problem as there have been about 34 confirmed outbreaks and in addition some suspicions with clinical signs but no virus isolation in an area which is supposed to have a good vaccine status!**

The following modifications, in addition to some minor changes, were made to the chapter on foot and mouth disease (FMD) in response to Member Countries' comments.

After examining a comment from the EU, the Terrestrial Code Commission modified the conditions for "Recovery of free status" in Article 2.2.10.7. to clarify that it also applies to country, not only to zone. After examining a comment from New Zealand, the Terrestrial Code Commission clarified point 5) of Article 2.2.10.8. The Terrestrial Code Commission discussed the comment from the EU regarding the need to certify the vaccination status of an animal and decided to ask the Scientific Commission to further examine the need for such a requirement in Articles 2.2.10.9. and 2.2.10.10.



The Terrestrial Code Commission decided to send the comments from the EU on the milk and milk products for animal feeding in Article 2.2.10.24. and on skins and trophies from wild susceptible animals in Article 2.2.10.29. to the Scientific Commission, for further examination.

The Terrestrial Code Commission noted that the revised Appendix 3.8.7. prepared by the Scientific Commission did not include the concept of compartmentalisation. As a result, the Terrestrial Code Commission did not incorporate the concept into the chapter as requested by some Member Countries.

Some surveillance issues raised by Member Countries were referred to the Scientific Commission for consideration.

The revised chapter and appendix are presented at Appendices IX and X for the comment of Member Countries.

## **7. Bluetongue (Chapter 2.2.13.)**

**Community comments:**

**The Community can support the proposals at Appendices XI and XII but would like the comments noted there taken on board.**

After reviewing comments from New Zealand, the Terrestrial Code Commission modified the southern latitude boundary in Articles 2.2.13.1. and 2.2.13.2.

After examining comments from the EU on the distance from the infection front in which surveillance was required, the Terrestrial Code Commission modified the paragraph to give more flexibility, with a linkage to the proposed surveillance appendix on bluetongue.

The newly developed surveillance appendix was received from the Scientific Commission and is presented unchanged to Member Countries.

The revised chapter and appendix are presented at Appendices XI and XII for the comment of Member Countries.

## **8. Bovine tuberculosis (Chapter 2.3.3.)**

**Community comments:**

**The Community can support the work being done by the OIE on this topic.**

The Terrestrial Code Commission reviewed comments from the EU and New Zealand. The Terrestrial Code Commission decided to forward all comments to the Scientific Commission for examination, including the proposal from some Member Countries to expand the scope of this chapter or develop a new chapter to include bison, deer and wildlife.

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

### Community comments:

**The Community welcomes the work done by the Code Commission but can only support this proposed amendments at Appendices XIII and XIV if the points below are taken on board.**

#### a) Chapter 2.3.13.

The Terrestrial Code Commission recalled the discussion at the 73<sup>rd</sup> General Session where some Member Countries were opposed to inclusion of muscle meat and blood products in the list of commodities which can be traded safely. However, arguments were largely based on studies using laboratory strains of transmissible spongiform encephalopathy (TSE) in laboratory animals, and many scientific papers have confirmed that different TSEs behave differently in various animal models. With respect to BSE, cattle provide the appropriate model to study the distribution of the agent in cattle. A number of studies has failed to demonstrate the presence of BSE in muscle meat or in the blood of experimentally infected cattle not showing clinical signs of BSE.

The Terrestrial Code Commission also took into account information arising from a recent World Health Organization (WHO) Consultation on Tissue Infectivity Distribution in Transmissible Spongiform Encephalopathies, but noted that, in many cases, this was preliminary information requiring further validation. The meeting also referred to an equivocal result for muscle meat (semitendinosus muscle) arising from a clinically affected cow. The Terrestrial Code Commission did not believe that any changes in this regard were required to the current text, but it would continue to monitor the progress in the research.

Comments from New Zealand and the Southern Cone countries of South America, which were endorsed by the *ad hoc* Group on Surveillance for BSE, were taken into account and references to other TSEs was deleted from the BSE chapter, because there is little evidence that surveillance information on other TSEs is necessary to determine the risks presented by the BSE agent. Any risks presented by other TSEs are addressed by the application of measures such as feed bans.

The Terrestrial Code Commission has been concerned for some time that up-to-date recommendations needed to be developed for other commodities, and will ask the Director General to convene an expert group to examine the safety of gelatine and tallow.

It also considered the issue of the specifications in point g) of Article 2.3.13.1 and "...30 months of age or less..." was removed because there is no scientific basis for this age restriction. The reference to "...and were not suspect or confirmed BSE cases..." was also deleted as the ante-mortem and post-mortem inspection specified in the same sentence would automatically exclude such animals. Likewise, in

Article 2.3.13.11, point 1)a) was deleted, as point 1)c) precludes any suspect or confirmed BSE cases.

The Terrestrial Code Commission did not agree with the EU comment that the requirement for annual review of the risk assessment in Article 2.3.13.2. was onerous. It noted that the requirement was that documentation be provided to indicate whether the situation had changed in the previous 12 months.

In revising Articles 2.3.13.3. and 2.3.13.4., the Terrestrial Code Commission took into consideration comments from Canada, the EU, New Zealand and Switzerland, as well as recommendations made by the *ad hoc* Group on Surveillance for BSE. Point 2) of Article 2.3.13.4. was modified to incorporate references to Type B surveillance. In response to a submission from New Zealand and after considering advice from an expert, the reference to progeny was deleted from point 3)b)iii) of Articles 2.3.13.3. and 2.3.13.4. and point 2 a) of Article 2.3.13.8.

The Terrestrial Code Commission is working with an expert to update the existing supporting document on BSE.

The revised chapter is at Appendix XIII for the comment of Member Countries.

**b) Appendix 3.8.4.**

The report of the second meeting of the *ad hoc* Group on Surveillance for BSE is at Appendix XXXIII for the information of Member Countries.

The Terrestrial Code Commission examined the appendix proposed by the experts and endorsed it with minor changes.

The Appendix on surveillance for BSE is at Appendix XIV for the comment of Member Countries.

**c) Appendix 3.8.5.**

The Terrestrial Code Commission recognised that, as a result of changes made in the Appendix 3.8.4., Appendix 3.8.5. needs to be revised. It will work on this and present the draft as a part of the report of its March 2006 meeting.

**10. Classical swine fever (Chapter 2.6.7. and Appendix 3.8.8.)**

**Community comments:**

**The Community can in general support the proposals at Appendices XV and appreciates the improvement to the draft however it could be simplified further and therefore the Community would like the comments noted there taken on board.**

At the request of several Member Countries, the Terrestrial Code Commission worked on the chapter on classical swine fever (CSF) to incorporate the concept of compartmentalisation. The chapter was modified in order to better harmonise various articles, including with equivalent articles in the FMD chapter. However, new science was not introduced.

The chapter now does not make specific reference to countries or zones where there is a different health status of the domestic and wild pig populations, unless compartmentalisation is applied to maintain separation of domestic from wild pigs.

Requests from New Zealand and Japan to refer to surveillance in point 2)b) of Article 2.6.7.4. have been addressed as a result of the revision of the article.

The prescriptive text was deleted from Article 2.6.7.6., as it was considered inappropriate to prescribe such conditions which should be developed on a case-by-case basis.

The Terrestrial Code Commission is submitting the modified chapter for Member Countries' comment (Appendix XV), and will also submit it to the Scientific Commission to allow it to make the necessary changes to the appendix on surveillance. Among the changes required in the appendix, particular emphasis will need to be placed on the type of surveillance necessary to support the establishment and maintenance of a free compartment within infected countries or zones.

The Terrestrial Code Commission is awaiting advice from the Scientific Commission regarding commodities which could be safely traded regardless of the CSF status of the exporting country.

## 11. Avian influenza (Chapter 2.7.12. and Appendix 3.8.9.)

**Community comments:**  
**The Community can only support the proposals at Appendices XVI, XVII and XVIII, if the comments noted there are taken on board.**

### a) Chapter 2.7.12.

During the 73<sup>rd</sup> General Session, a revised *Terrestrial Code* chapter on avian influenza was adopted by the OIE International Committee. This revised chapter and the comments received from Argentina, Australia, Chile, the EU, the International Egg Commission, Japan, New Zealand and an expert were considered by the Terrestrial Code Commission. Among a number of general comments, in particular, comments on compartmentalisation and vaccination were taken into account when addressing specific articles.

New Zealand proposed that a new first article be drafted stating that eggs and poultry meat for human consumption can be freely traded from flocks not free from low

pathogenic avian influenza (LPAI). The Terrestrial Code Commission did not think such an article was possible at this stage; however, it expanded on recommendations within relevant articles.

Japan proposed that the chapter should distinguish between “NAI free with vaccination” and “NAI free without vaccination”. Comments from Argentina and Chile appeared to support the Japanese proposal. The Terrestrial Code Commission noted that Appendix 3.8.9. addressed the issue and inserted reference to this appendix in the text.

New Zealand proposed that Article 2.7.12.6. be deleted. The Terrestrial Code Commission did not accept this proposal because live birds other than poultry pose an avian influenza risk to poultry.

## **b) Appendices**

The Terrestrial Code Commission had a meeting with the *ad hoc* Group on Epidemiology to discuss their recommendations from their May 2005 meeting. The *ad hoc* Group confirmed that comments made by New Zealand had been considered, but had not resulted in changes to the text.

Following a comment submitted by an expert, the fifth paragraph of Article 3.8.9.7. was reorganised to better demonstrate how to distinguish vaccinated from infected poultry.

The Terrestrial Code Commission made some modifications to point 2)a) of Article 3.8.9.2., point 1) of Article 3.8.9.3. and Article 3.8.9.5. for clarification or consistency of terminology.

The Terrestrial Code Commission drafted a new appendix on procedures for the inactivation of highly pathogenic notifiable avian influenza (HPNAI) virus. The information in the appendix was compiled from a published paper and from a manuscript in press, provided by an expert. There are:

- SWAYNE D.E. & BECK J. R. (2004). - Heat inactivation of avian influenza and Newcastle disease viruses in egg products. *Avian Pathology*, **33** (5), 512-518.
- SWAYNE D.E. . - Microassay for Measuring Thermal Inactivation of H5N1 High Pathogenicity Avian Influenza Virus in Naturally-Infected Chicken Meat.

A revised chapter and appendix, and the new appendix on virus inactivation, are presented (Appendices XVI, XVII and XVIII) for the comment of Member Countries.

## **12. Semen and embryo related matters (Appendix 3.2.1)**

**Community comments:**

**The Community can support the proposal at Appendix XIX but would like the comments noted there taken on board.**

The Terrestrial Code Commission accepted the comment from the EU and clarified point 1) of Article 3.2.1.3.

After examining the comment from Australia, the Terrestrial Code Commission modified Articles 3.2.1.5. and 3.2.1.6. to clarify that testing is unnecessary for animals in free countries.

In response to the comments from Australia, the Terrestrial Code Commission agreed to delete caseous lymphadenitis and border disease from point 1) of Article 3.2.1.6., as such diseases are not considered transmissible by semen.

After examining the comment from Australia, point 3) of Article 3.2.1.10. was modified to give further security to semen stored for export.

The revised appendix is at Appendix XIX for the comment of Member Countries.

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

**Community comments:**

**The Community fully supports the work on this Chapter and would ask the OIE to progress it as a matter of urgency in particular as the Community has already submitted a draft proposal last year.**

The Terrestrial Code Commission recalled the request from some Member Countries that a new chapter on this beetle be developed. The Terrestrial Code Commission examined a draft text prepared by the EU and a risk assessment prepared by a New Zealand expert, and decided to ask the Scientific Commission to develop a chapter on the small hive beetle of honey bees for consultation with Member Countries.

**14. Animal welfare (Section 3.7.)**

**Community comments:**

**The Community can support the proposals at Appendices XX, XXI, XXII and XXIII but would like the comments noted there taken into account.**

The Terrestrial Code Commission examined and endorsed the work of the Working Group on Animal Welfare in revising the four adopted chapters on animal welfare, taking into account comments received from Member Countries prior to the 73<sup>rd</sup> General Session, and the discussion at the General Session. The report of the fourth meeting of the Working Group on Animal Welfare is at Appendix XXXV for the information of Member Countries.

The Terrestrial Code Commission noted that some technical issues raised with experts in the *ad hoc* groups had not yet been responded to, but it expected that these should be finalised in time for the next meeting of the Terrestrial Code Commission in March 2006.

The four revised chapters are at Appendices XX, XXI, XXII and XXIII for the comment of Member Countries.

## 15. Animal production food safety

**Community comments:**  
**The Community can support the proposal at appendix XXIV but would like the comments noted there taken into account.**

The Terrestrial Code Commission examined the report of the March 2005 meeting of the Working Group on Animal Production Food Safety and decided to circulate it for the information of Member Countries (Appendix XXXVI).

The Terrestrial Code Commission noted the work of the Food and Agriculture Organization (FAO) on good agricultural practice and recommended that, with regard to the Working Group document 'Guide to good farming practices', the OIE and the FAO coordinate their work with the aim of the information being published by both organisations for the guidance of Member Countries and the public.

Using a detailed discussion paper developed by the Working Group, the Terrestrial Code Commission drafted guidelines for the control of hazards of animal health and public health importance through ante- and post-mortem meat inspection. It is the Commission's intention that this text become a *Code* chapter in a new section on food safety. The draft is at Appendix XXIV for Member Countries' comment.

The Terrestrial Code Commission examined briefly some draft international health certificates, developed under the Working Group's work programme. The Terrestrial Code Commission noted that the Working Group would be examining these draft certificates at its next meeting at the end of January 2006.

## 16. Animal identification and traceability

**Community comments:**  
**The Community can support the proposal at appendix XXV (which it understands is will be further developed) but would like the comments noted there taken on board.**

The Terrestrial Code Commission noted the report of the *ad hoc* Group on Animal Identification and Traceability which is at Appendix XXXIV for the information of Member Countries. The Terrestrial Code Commission supported the recommendation of the *ad hoc* Group that the general principles form a part of a horizontal chapter on animal

identification and traceability, in conjunction with more detailed articles on essential elements. The Terrestrial Code Commission noted the importance of coordination with the Codex Commission during the development of these standards.

The Terrestrial Code Commission made some modifications to the proposed definitions and general principles for animal identification and traceability, and is presenting the modified text at Appendix XXV for Member Countries' comment.

## 17. Carcass disposal

### **Community comments:**

**The Community can support the work of the OIE on this topic.**

The Terrestrial Code Commission received from the Scientific Commission for Animal Diseases a revised text on the disposal of carcasses. The original text had been circulated for Member Countries' comment in 2004. The Terrestrial Code Commission proposed significant changes to the text (including to the title) and decided that the changes should be reviewed by the Scientific Commission before being circulated for further comment by Member Countries.

## 18. Paratuberculosis (Chapter 2.2.6.)

### **Community comments:**

**On the whole, a good start but because epidemiology is complex, and more sensitive/specific tests are not available, herd level assurances need to be clearer/more robust. Hence, the following comments:**

**1. Some guidance/elaboration is required on how to determine that: 'an establishment (is) not known to be, or suspected of being, infected with paratuberculosis'.**

**2. Article 3.1.6.1 - Point 2(a) is ambiguous as one could test 50, and have 30 negative and some (say 20) positive – probably false positive due to cross reacting environmental mycobacteria – results. It can be argued on this basis that Point 2(a) can be certified. But what if the herd is truly infected. Therefore, it may make sense to require compliance with Point 2(b) as well as Point 2(a).**

**Measures aiming effective prevention of the transmission of paratuberculosis by international animal transport imply in all cases a challenge in trade due to the worldwide dissemination of the disease in cattle and sheep. Insofar free trade and control of paratuberculosis exclude each other.**

**The proposed test for trade included in Appendix XXXVII guarantees a minimum safety for the importing country, but is obviously at this moment the most cost-effective and practicable method.**



**However the proposed tests in Articles 3.1.6.1. No 2b and 3.1.6.3. No 3b in animals more than two years of age with negative results don't increase the diagnostic security as many infected animals can't be detected with serology.**

**In each case the status of the herd should be crucial - (no trade with animals from herds in which positive animals have been found with absorbed ELISA respectively in which a specified percentage of positive animals is exceeded. What percentage could be accepted is depending on the test used and has to be agreed in general discussion.). As the lower the rate of serological positive animals in a herd the higher is the likelihood that single animals are really negative."**

The Terrestrial Code Commission recalled the discussion on paratuberculosis at the 68<sup>th</sup> General Session in which Member Countries expressed their concern over possible trade implications of a proposed revised text. The text previously circulated for comment is at [Appendix XXXVII](#) for information.

As the current *Terrestrial Code* chapter is without technical content, the Terrestrial Code Commission is seeking advice from Member Countries on how to proceed in the development of an up-to-date chapter on paratuberculosis, with recommendations which do not unnecessarily disrupt trade.

## **19. Equine diseases (Section 2.5.)**

**Community comments:**

**The Community can support the proposals at appendices XXVI and XXVII, but for XXVIII, XXIX and XXX it can only support these drafts if the comments noted there are taken on board.**

After consultation with OIE Reference Laboratories on some equine disease chapters in need of updating, the Terrestrial Code Commission modified chapters on equine infectious anaemia, equine piroplasmiasis, equine rhinopneumonitis, glanders and equine viral arteritis. The modified texts, at [Appendices XXVI, XXVII, XXVIII, XXIX and XXX](#), are presented for comment by Member Countries.

The Terrestrial Code Commission examined a proposed revised chapter on African horse sickness prepared by a group of experts, and made some appropriate changes. The proposed revision (which is based on the bluetongue chapter), is circulated as clean text at [Appendix XXXI](#) for the comment of Member Countries. It will also be sent to the Scientific Commission for consideration.

## **20. Bovine viral diarrhoea-mucosal disease**

**Community comments:**

**The Community is currently not in the position to confirm its final position how to address to issue. There seem to be for at least two options for OIE – development of a Chapter in the Terrestrial Code or special guidelines for the control of BVD.**

**In some EU Member States control programmes have been initiated mostly on a voluntary basis and some compulsory. The most important element of all control efforts is the identification and removal of persistently infected (PI) animals. It is known that the development of PI animals can be reduced by using vaccination in females.**

**It should be considered if the development of special guidelines for the control of different animal diseases besides the recommendations in the Terrestrial Code are possible.**

**In addition the Community suggests x.x.x.4.1.a)**

**“for non-pregnant animals older than four months of age: if it has been subjected to a diagnostic test for BVD-virus on a blood sample with negative results and for non-pregnant animals younger than four months of age if it has been subjected fo a diagnostic test for BVD-virus and BVD-antibody an a blood sample with negative results.”**

**x.x.x.8.2**

**“if the donor animals were not kept in a BVD-free herd the donor animals should be tested for virus, with negative results.”**

**If they are imported to a BVD-free country, zone or compartment, the donor animals should be tested for virus and antibody with negative results.**

The President of the Commission met some European experts on bovine viral diarrhoea-mucosal disease (BVD-MD) to discuss the BVD-MD situation, control efforts in Europe and possible future steps to make the European experience known internationally. As a result, the Terrestrial Code Commission discussed how guidance on the disease could be provided to Member Countries. It noted that a chapter had not been developed, but that some recommendations were present in the chapter on bovine and small ruminant semen.

The Terrestrial Code Commission recognised that BVD-MD has a worldwide distribution, but that, under certain circumstances, it can cause economic loss. It also recognised that, if certain procedures are followed, the disease could be controlled and eventually eradicated at a herd or regional level. The Terrestrial Code Commission concluded that it would not be appropriate to develop a specific chapter, but that guidance on control could be offered to Member Countries.

The Terrestrial Code Commission is therefore seeking advice from Member Countries as to how the OIE could address diseases such as BVD-MD and listeriosis, using alternative mechanisms to those currently used in the *Terrestrial Code* or *Manual* for such diseases, in order to provide Member Countries with useful guidance on managing such diseases without causing unjustified disruptions to trade.

## **21. International transfer of pathogens (Chapter 1.4.5.)**

**Community comments:**

**The Community can support this work and would suggest that the OIE take contact with IATA before finalising its proposals as the Community is aware of difficulties with the high level of containment required by IATA.**

In consultation with the Terrestrial Code Commission, the Biological Standards Commission (hereafter referred to as the Laboratories Commission) decided to update Chapter 1.4.5. of the *Terrestrial Code* and the relevant sections of the *Terrestrial Manual*. The Terrestrial Code Commission expects to review revised text at its next meeting.

## 22. Future work programme

**Community comments:**

**The Community can support the proposal at appendix XXXII would like the comments noted there taken into account.**

The Terrestrial Code Commission reviewed its work programme, taking into account the outcomes of the 73<sup>rd</sup> General Session, submissions received from Member Countries, and input from the Scientific Commission and the Laboratories Commission. A table summarising planned future activities for the Terrestrial Code Commission is at Appendix XXXII for the comment of Member Countries.

### B. REPORTS OF WORKING GROUPS AND *AD HOC* GROUPS

The following reports are for the information of Member Countries:

- *Ad hoc* Group on Surveillance for Bovine Spongiform Encephalopathy (Appendix XXXIII)
- *Ad hoc* Group on Animal Identification and Traceability (Appendix XXXIV)
- Animal Welfare Working Group (Appendix XXXV)
- Animal Production Food Safety Working Group (Appendix XXXVI)

### C. OTHER DOCUMENT

The following document is for the information of Member Countries: Chapter 2.2.6. on paratuberculosis proposed in 2000 (Appendix XXXVII).

The list of chapters and appendices circulated for the comment of Member Countries is in Section A of this report.

.../Appendices

MEETING OF THE OIE TERRESTRIAL ANIMAL  
HEALTH STANDARDS COMMISSION

Paris, 19-30 September 2005

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**MEETING OF THE OIE TERRESTRIAL ANIMAL  
HEALTH STANDARDS COMMISSION**

**Paris, 19-30 September 2005**

**Agenda**

- Item 1 General definitions (Chapter 1.1.1.)**
- Item 2 Evaluation of Veterinary Services (Chapters 1.3.3. and 1.3.4.)**
- Item 3 Zoning and compartmentalisation (Chapter 1.3.5.)**
- Item 4 General guidelines for animal health surveillance (Appendix 3.8.1.)**
- Item 5 Criteria for listing diseases (Chapter 2.1.1.)**
- Item 6 Foot and mouth disease (Chapter 2.2.10. and Appendix 3.8.7.)**
- Item 7 Bluetongue (Chapter 2.2.13. and surveillance appendix)**
- Item 8 Bovine tuberculosis (Chapter 2.3.3.)**
- Item 9 Bovine spongiform encephalopathy (Chapter 2.3.13. and Appendix 3.8.4.)**
- Item 10 Classical swine fever (Chapter 2.6.7. and Appendix 3.8.8.)**
- Item 11 Avian influenza (Chapter 2.7.12. and Appendix 3.8.9.)**
- Item 12 Semen and embryo related matters (Appendix 3.3.5. and Appendix 3.2.1.)**
- Item 13 Small hive beetle on honey bees (Section 2.9.)**
- Item 14 Animal welfare (Section 3.7)**
- Item 15 Animal production food safety**
- Item 16 Animal identification and traceability**
- Item 17 Carcass disposal**
- Item 18 Paratuberculosis (Chapter 2.2.6.)**
- Item 19 Equine diseases (Section 2.5.)**

**Item 20 Bovine viral diarrhoea-mucosal disease**

**Item 21 International transfer of pathogens (Chapter 1.4.5.)**

**Item 22 Work programme**

**Item 23 Others**

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CHAPTER 1.1.1.

GENERAL DEFINITIONS

**Community comments:**

**The Community can support this proposal but would like the comments below taken into account.**

**Animal handler**

A person with a knowledge of the behaviour and needs of animals which, with appropriate experience and a professional and positive response to an animal's needs, results in effective management and good welfare. Their competence should be demonstrated through independent assessment and certification.

**Container**

A non-self-propelled receptacle or other rigid structure for holding animals during a *journey* by one or several means of transport.

**Death**

Irreversible loss of brain activity demonstrable by the loss of brain stem reflexes.

**Journey**

An animal transport journey commences when the first animal is loaded onto a *vehicle/vessel* or into a *container* and ends when the last animal is unloaded, and includes any stationary resting / holding periods of less than 48 hours. The same animals do not commence a new journey until after a period of over 48 hours for rest and recuperation, with adequate feed and water.

**Killing**

Any procedure which causes the death of an animal.

**Lairage**

Pens, yards and other holding areas used for accommodating animals in order to give them necessary attention (including water, feed, rest) before they are moved on or used for specific purposes including slaughter.

**Loading/Unloading**

**Loading:** the procedure of moving animals onto a *vehicle/vessel* or into a *container* for transport purposes; **unloading:** the procedure of moving animals off a *vehicle/vessel* or out of a *container*.

**Post-journey period**

The period between *unloading* and either recovery from the effects of the *journey* or slaughter (if this occurs before recovery).

**Pre-journey period**

The period during which animals are identified, and often assembled for the purpose of loading them.

**Resting point**

A place where the *journey* is interrupted to rest, feed or water the animals; the animals may remain in



the vehicle/vessel or container, or be unloaded.

### **Restraint**

The application to an animal of any procedure designed to restrict its movements.

### **Slaughter**

Any procedure which causes the death of an animal by bleeding.

**Community** **comment:**  
**The Community wonders whether the wording is correct as slaughter should refer to animals the meat of which is intended to be used for consumption and some animals may be dead prior to bleeding e.g. if they are shot first. Community comments:**

**The following alternative definition of slaughter is suggested**

#### **Slaughter**

**“Any procedure which causes the death of an animal intended for human consumption.”**

**Justification: Animals may be killed without bleeding and since there are a number of methods where death intervenes before bleeding (e.g. gas killing, two-cycle electrical procedures, free-bullet) the definition of slaughter should be replaced by the afore-mentioned text.**

### **Space allowance**

The measure of the floor area and height on a vehicle/vessel or container allocated per individual or body weight of animals transported.

### **Stocking density**

The number or body weight of animals per unit area on a vehicle/vessel or container.

**Community comments:**

**In the next bullet point the words “would allow” should be replaced by “may allow”.**

**Justification**

**There are cases where an animal may not recover full consciousness having been stunned by certain methods (e.g. penetrating captive bolt”).**

### **Stunning**

Any mechanical, electrical, chemical or other procedure which causes immediate loss of consciousness; when used before slaughter, the loss of consciousness lasts until death from the slaughter process; in the absence of slaughter, the procedure would allow the animal to recover consciousness.

### **Transport**

The procedures associated with the carrying of animals for commercial purposes from one location to another by land (road and rail), sea or air.

**Transporter**

The person licensed by the *Competent Authority* to transport animals.

**Travel**

The movement of a *vehicle/vessel* or *container* carrying animals from one location to another.

**Vehicle/vessel**

Any means of conveyance including train, truck, aircraft or ship that is used for carrying animal(s).

**Slaughterhouse/abattoir**

Premises, including facilities for moving or lairaging animals, used for the slaughter of *animals* for human consumption or animal feeding, and approved by the *Veterinary Services* or other *Competent Authority*.

**Quarantine station**

A facility under the control of the *Veterinary Authority* where a group of animals is maintained in isolation with no direct or indirect contact with other animals, to prevent the transmission of specified disease(s), in order to while the animals are undergoing observation for a specified length of time and, if appropriate, testing and treatment.

**Community comments:**

**The Community proposes the following wording: “A facility under control of the Veterinary Authority where an animal or a group of animals....”**

**In addition “...to prevent the transmission of specified disease(s)...” : it would be more relevant to refer to “specific pathogenic agents” (according to the Code, a disease is only clinical and/or pathological manifestation of infection).**

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— text deleted

CHAPTER 1.3.3.

1. EVALUATION OF VETERINARY SERVICES

**Community comments:**

**The Community can support this proposal.**

Article 1.3.3.1.

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

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

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

These fundamental principles are presented in Article 1.3.3.2. ~~The remaining~~ Other factors affecting ~~of~~ quality are described in Part 1. (notification, principles of certification, etc.). ~~and the document entitled Guidelines for the evaluation of Veterinary Services included in Chapter 1.3.4.~~

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

Guidelines for the evaluation of *Veterinary Services* are described in Chapter 1.3.4.

A procedure for evaluating *Veterinary Services* by OIE experts, on a voluntary basis, is described in Article 1.3.3.5.

**Community comments:**

**The Community has a very positive opinion on the PVS document however the PVS refers to self-evaluation ( as well as ) or evaluation by OIE experts.**

## **Fundamental principles of quality**

The *Veterinary Services* shall comply with the following principles to ensure the quality of their activities:

1. Professional judgement

The personnel of *Veterinary Services* should have the relevant qualifications, scientific expertise and experience to give them the competence to make sound professional judgements.

2. Independence

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

3. Impartiality

The *Veterinary Services* should be impartial. In particular, all the parties affected by their activities have a right to expect their services to be delivered under reasonable and non-discriminatory conditions.

4. Integrity

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

5. Objectivity

The *Veterinary Services* should at all times act in an objective, transparent and non-discriminatory manner.

6. General organisation

The *Veterinary Services* must be able to demonstrate by means of appropriate legislation, sufficient financial resources and effective organisation that they are in a position to have control of the establishment and application of animal health measures, and of international veterinary certification activities. Legislation should be suitably flexible to allow for judgements of equivalence and efficient responses to changing situations. In particular, they should define and document the responsibilities and structure of the organisations in charge of the animal identification system, control of animal movements, animal disease control and reporting systems, epidemiological surveillance and communication of epidemiological information.

A similar demonstration should be made by *Veterinary Services* when they are in charge of veterinary public health activities.

The *Veterinary Services* should have at their disposal effective systems for animal disease surveillance and for *notification* of disease problems wherever they occur, in accordance with the provisions of this

*Terrestrial Code*. Adequate coverage of animal populations should also be demonstrated. They should at all times endeavour to improve their performance in terms of animal health information systems and animal disease control.

The *Veterinary Services* should define and document the responsibilities and structure of the organisation (in particular the chain of command) in charge of issuing *international veterinary certificates*.

Each position within the *Veterinary Services* which has an impact on their quality should be described. These job descriptions should include the requirements for education, training, technical knowledge and experience.

#### 7. Quality policy

The *Veterinary Services* should define and document their policy and objectives for, and commitment to, quality, and should ensure that this policy is understood, implemented and maintained at all levels in the organisation. Where conditions allow, they may implement a quality system corresponding to their areas of activity and appropriate for the type, range and volume of work that they have to perform. The guidelines for the quality and evaluation of *Veterinary Services* propose a suitable reference system, which should be used if a Member Country choose to adopt a quality system.

#### 8. Procedures and standards

The *Veterinary Services* should develop and document appropriate procedures and standards for all providers of relevant activities and associated facilities. These procedures and standards may for example relate to:

- a) programming and management of activities, including international veterinary certification activities;
- b) prevention, control and notification of disease *outbreaks*;
- c) risk analysis, epidemiological surveillance and zoning;
- d) inspection and sampling techniques;
- e) diagnostic tests for animal diseases;
- f) preparation, production, registration and control of biological products for use in the diagnosis or prevention of diseases;
- g) border controls and import regulations;
- h) *disinfection* and *disinfestation*;
- i) treatments intended to destroy, if appropriate, pathogens in animal products.

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

9. Information, complaints and appeals

The *Veterinary Administration* should undertake to reply to legitimate requests from *Veterinary Administrations* of other Member Countries or any other authority, in particular ensuring that any requests for information, complaints or appeals that they may present are dealt with in a timely manner.

A record should be maintained of all complaints and appeals and of the relevant action taken by the *Veterinary Services*.

10. Documentation

The *Veterinary Services* should have at their disposal a reliable and up to date documentation system suited to their activities.

11. Self-evaluation

The *Veterinary Services* should undertake periodical self-evaluation especially by documenting achievements against goals, and demonstrating the efficiency of their organisational components and resource adequacy.

~~A Member Country can request the Director General of the OIE to arrange for an expert or experts to assist in the process.~~

A procedure for evaluating *Veterinary Services* by OIE experts, on a voluntary basis, is described in Article 1.3.3.5.

12. Communication

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

13. Human and financial resources

Responsible authorities should ensure that adequate resources are made available to implement effectively the above activities.

Article 1.3.3.3.

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

Any evaluation of *Veterinary Services* should be conducted having regard to the OIE Guidelines for the evaluation of *Veterinary Services* presented in Chapter 1.3.4. of this *Terrestrial Code*.

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

#### Article 1.3.3.4.

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

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

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

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

In the event of a dispute between two Member Countries over the conduct or the conclusions of the evaluation of the *Veterinary Services*, the matter should be dealt with having regard to the procedures set out in Article 1.3.1.3.

#### Article 1.3.3.5.

##### **1.1. Voluntary evaluation by OIE experts**

The OIE maintains a procedure for the evaluation of the *Veterinary Services* of a Member Country, on a voluntary basis.

Under this procedure, on the receipt of a request from a Member Country, the Director General of the OIE recommends an expert(s) from a list of evaluators approved by the OIE International Committee.

The expert(s) evaluates the *Veterinary Services* of the Member Country against the provisions in Chapter 1.3.4 of the *Terrestrial Code*, using the *Performance, Vision, Strategy [PVS] Instrument* as a guide, and produces a report.

The final report is submitted to the Director General and, with the consent of the Member Country, published by the OIE.

**Community comments:**

**This new article and the explicit reference to PVS would imply that PVS is included in the Code. The Community questions the OIE on the future of PVS; an insertion in the Code would at least require some re-wording for standardisation and consistency (glossary, definitions etc...)**

**The Community would like to take the opportunity to raise the broad question of Code/import requirements versus management guidelines for member countries.**

**“Under this procedure.... the Director general of the OIE recommends an expert from a list of evaluators approved by the OIE International Committee” : it is not clear how the conclusions of the experts(s) would bind the OIE (and thereby the member countries) and possibly have official capacity or status.**

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CHAPTER 1.3.4.

1.2. GUIDELINES FOR THE EVALUATION OF  
VETERINARY SERVICES

**Community comments:  
The Community can support this proposal.**

Article 1.3.4.1.

**2. GENERAL CONSIDERATIONS**

1. Evaluation of *Veterinary Services* is an important element in the risk analysis process which countries may legitimately use in their policy formulations directly applying to animal health and sanitary controls of *international trade in animals*, animal-derived products, animal genetic material and animal feedstuffs.

Any evaluation should be carried out with due regard for Chapter 1.3.3. of this *Terrestrial Code*.

2. In order to ensure that objectivity is maximised in the evaluation process, it is essential for some standards of discipline to be applied. The OIE has developed these guidelines which can be practically applied to the evaluation of *Veterinary Services*. These are relevant for evaluation of the *Veterinary Services* of one country by those of another country for the purposes of risk analysis in *international trade*. These guidelines (in conjunction with the *Performance, Vision, Strategy [PVS] Instrument*) will be used by OIE experts when conducting an evaluation on the request of a Member Country. The guidelines are also applicable for evaluation by a country of its own *Veterinary Services* – the process known as self-evaluation ~~or self-assessment~~ – and for periodic re-evaluation.

In carrying out a risk analysis prior to deciding the sanitary/zoosanitary conditions for the importation of a *commodity*, an *importing country* is justified in regarding its evaluation of the *Veterinary Services* of the *exporting country* as critical.

3. The purpose of evaluation may be either to assist a national authority in the decision-making process regarding priorities to be given to its own *Veterinary Services* (self-evaluation) or to assist the process of risk analysis in *international trade in animals* and animal-derived products to which official sanitary and/or zoosanitary controls apply.
4. In both situations, the evaluation should demonstrate that the *Veterinary Services* have the capability for effective control of the sanitary and zoosanitary status of *animals* and animal products. Key elements to be covered in this process include resource adequacy, management capability, legislative

and administrative infrastructures, independence in the exercise of official functions and performance history, including disease reporting.

5. Competence and integrity are qualities on which others base their confidence in individuals or organisations. Mutual confidence between relevant official *Veterinary Services* of trading partner countries contributes fundamentally to stability in *international trade in animals* and animal-related products. In this situation, scrutiny is directed more at the *exporting country* than at the *importing country*.
6. Although quantitative data can be provided on *Veterinary Services*, the ultimate evaluation will be essentially qualitative. While it is appropriate to evaluate resources and infrastructure (organisational, administrative and legislative), it is also appropriate to place emphasis on the evaluation of the quality of outputs and performance of *Veterinary Services*. Evaluation should take into consideration any quality systems used by *Veterinary Services*.
7. An *importing country* has a right of assurance that information on sanitary/zoosanitary situations provided by the *Veterinary Services* of an *exporting country* is objective, meaningful and correct. Furthermore, the *Veterinary Services* of the *importing country* are entitled to expect validity in the veterinary certification of export.
8. An *exporting country* is entitled to expect that its *animals* and animal products will receive reasonable and valid treatment when they are subjected to import inspection in the country of destination. The country should also be able to expect that any evaluation of its standards and performance will be conducted on a non-discriminatory basis. The *importing country* should be prepared and able to defend any position which it takes as a consequence of the evaluation.
9. As the *Veterinary statutory body* is not a part of the *Veterinary Services*, an evaluation of that body should be carried out to ensure that the registration/licensing of *veterinarians* and authorisation of *veterinary para-professionals* is included.

#### Article 1.3.4.2.

### Scope

1. In the evaluation of *Veterinary Services*, the following items may be considered, depending on the purpose of the evaluation:
  - organisation, structure and authority of the *Veterinary Services*;
  - human resources;
  - material (including financial) resources;
  - functional capabilities and legislative support;
  - animal health and veterinary public health controls;
  - formal quality systems including quality policy;

- performance assessment and audit programmes;
  - participation in OIE activities and compliance with OIE Member Countries' obligations.
2. To complement the evaluation of *Veterinary Services*, ~~it is necessary to also consider~~ the organisational structure and functioning of the *Veterinary statutory body* should also be considered.
  3. Article 1.3.4.14. outlines appropriate information requirements for:
    - self-evaluation by national *Veterinary Services* which perceive a need to prepare information for national or international purposes;
    - evaluation by a prospective or actual *importing country* of the *Veterinary Services* of a prospective or actual *exporting country*;
    - verification or re-verification of an evaluation in the course of a visit to the *exporting country* by the *importing country*.
  4. The PVS Instrument should be used as a guide in conducting evaluations and self-evaluations.

#### Article 1.3.4.3.

### **Evaluation criteria for the organisational structure of the Veterinary Services**

1. A key element in the evaluation is the study of the organisation and structure of the official *Veterinary Services*. The *Veterinary Services* should define and set out their policy, objectives and commitment to quality systems and standards. These organisational and policy statements should be described in detail. Organisational charts and details of functional responsibilities of staff should be available for evaluation. The role and responsibility of the Chief Veterinary Officer/Veterinary Director should be clearly defined. Lines of command should also be described.
2. The organisational structure should also clearly set out the interface relationships of government Ministers and departmental Authorities with the Chief Veterinary Officer/Veterinary Director and the *Veterinary Services*. Formal relationships with statutory authorities and with industry organisations and associations should also be described. It is recognised that Services may be subject to changes in structure from time to time. Major changes should be notified to trading partners so that the effects of re-structuring may be assessed.
3. Organisational components of *Veterinary Services* which have responsibility for key functional capabilities should be identified. These capabilities include epidemiological surveillance, disease control, import controls, animal disease reporting systems, animal identification systems, traceability systems, animal movement control systems, communication of epidemiological information, training, inspection and certification. Laboratory and field systems and their organisational relationships should be described.

4. To reinforce the reliability and credibility of their services, the *Veterinary Services* may have set up quality systems that correspond with their fields of activity and to the nature and scale of activities that they carry out. Evaluation of such systems should be as objective as possible.
5. The *Veterinary Administration* alone speaks for the country as far as official international dialogue is concerned. This is also particularly important to cases where zoning and regionalisation are being applied. The responsibilities of the national *Veterinary Administration* and all *Veterinary Authorities* in that country should be made clear in the process of evaluation of *Veterinary Services*.
6. A *Veterinary Authority* is defined in Chapter 1.1.1. of this *Terrestrial Code*. As some countries have some official *Veterinary Authority* roles vested in autonomous sub-national (state/provincial, municipal) government bodies, there is an important need to assess the role and function of these Services. Details of their roles, relationship (legal and administrative) to each other and to the national *Veterinary Services* should be available for evaluation. Annual reports, review findings and access to other information pertinent to the animal health activities of such bodies should also be available.
7. Similarly, where the national *Veterinary Services* have arrangements with other providers of relevant services such as universities, laboratories, information services, etc., these arrangements should also be described. For the purposes of evaluation, it is appropriate to expect that the quality of organisational and functional standards which apply to *Veterinary Services* should also apply to the services of these other providers.

Article 1.3.4.4.

### 3. EVALUATION CRITERIA FOR QUALITY SYSTEMS

1. The *Veterinary Services* should demonstrate a commitment to the quality of the processes and outputs of their services. Where services or components of services are delivered under a formal quality systems programme which is based on OIE recommended standards or, especially in the case of laboratory components of *Veterinary Services* other internationally recognised quality standards, the *Veterinary Services* undergoing evaluation should make available evidence of accreditation, details of the documented quality processes and documented outcomes of all relevant audits undertaken.
2. Where the *Veterinary Services* undergoing evaluation make large use of formal quality systems in the delivery of their services, it is appropriate that greater emphasis be placed on the outcomes of evaluation of these quality systems than on the resource and infrastructural components of the services.

Article 1.3.4.5.

#### Evaluation criteria for human resources

1. The *Veterinary Services* should demonstrate that their human resource component includes an integral core of full-time civil service employees. This core must include *veterinarians*. It should also include administrative officials and *veterinary para-professionals*. The human resources may also include part-time and private sector *veterinarians* and *veterinary para-professionals*. It is essential that all the above categories of personnel be subject to legal disciplinary provisions. Data relating to the resource base of the *Veterinary Services* undergoing evaluation should be available.

2. In addition to raw quantitative data on this resource base, the functions of the various categories of personnel in the *Veterinary Services* should be described in detail. This is necessary for analysis and estimation of the appropriateness of the application of qualified skills to the tasks undertaken by the *Veterinary Services* and may be relevant, for example, to the roles of *veterinarians* and *veterinary para-professionals* in field services. In this case, the evaluation should provide assurances that disease monitoring is being conducted by a sufficient number of qualified, experienced field veterinarians who are directly involved in farm visits; there should not be an over-reliance on *veterinary para-professionals* for this task.
3. Analysis of these data can be used to estimate the potential of the *Veterinary Services* to have reliable knowledge of the state of animal health in the country and to support an optimal level of animal disease control programmes. A large population of private veterinarians would not provide the *Veterinary Services* with an effective epizootiological information base without legislative (e.g. compulsory reporting of notifiable diseases) and administrative (e.g. official animal health surveillance and reporting systems) mechanisms in place.
4. These data should be assessed in close conjunction with the other information described in this Chapter. For example, a large field staff (*veterinarians* and *veterinary para-professionals*) need fixed, mobile and budgetary resources for animal health activities in the livestock farming territory of the country. If deficiencies are evident, there would be reason to challenge the validity of epizootiological information.

#### Article 1.3.4.6.

### Evaluation criteria for material resources

#### 1. Financial

Actual yearly budgetary information regarding the *Veterinary Services* should be available and should include the details set out in the model questionnaire outlined in Article 1.3.4.14. Information is required on conditions of service for veterinary staff (including salaries and incentives) and should provide a comparison with the private sector and perhaps with other professionals. Information should also be available on non-government sources of revenue available to *veterinarians* in their official responsibilities.

#### 2. Administrative

##### a) Accommodation

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

##### b) Communications

The *Veterinary Services* should be able to demonstrate that they have reliable access to effective communications systems, especially for animal health surveillance and control programmes.

Inadequate communications systems within the field services components of these programmes or between outlying offices and headquarters, or between the *Veterinary Services* and other relevant administrative and professional services, signify an inherent weakness in these programmes. Adequate communications systems between laboratories and between field and laboratory components of the *Veterinary Services* should also be demonstrated.

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

c) Transport systems

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

Appropriate means of transport are also vital for the satisfactory receipt of samples to be tested at veterinary laboratories, for inspection of imports and exports, and for the performance of *animals* and animal product inspection in outlying production or processing establishments.

3. Technical

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

a) Cold chain for laboratory samples and veterinary medicines

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

b) Diagnostic laboratories

Analysis of the laboratory service component of *Veterinary Services*, which would include official governmental laboratories and other laboratories accredited by the *Veterinary Services* for specified purposes, is an essential element of the evaluation process. The quality of the veterinary diagnostic laboratories of a country underpins the whole control and certification processes of the zoosanitary/sanitary status of exported *animals* and animal products, and therefore these laboratories should be subject to rigid quality assurance procedures and should

use international quality assurance programmes (wherever available) for standardising test methodologies and testing proficiency. An example is the use of International Standard Sera for standardising reagents.

This emphasis is valid whether one relates it to the actual testing performed on individual export consignments or to the more broad and ongoing testing regimes which are used to determine the animal health and veterinary public health profiles of the country and to support its disease control programmes. For the purposes of evaluation, veterinary diagnostic laboratories include those which are concerned with either animal health or veterinary public health activities. The *Veterinary Services* must approve and designate these laboratories for such purposes and have them audited regularly.

c) Research

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

Article 1.3.4.7.

3.1.1. *Functional capabilities and legislative support*

1. Animal health and veterinary public health

The *Veterinary Services* should be able to demonstrate that they have the capacity, supported by appropriate legislation, to exercise control over all animal health matters. These controls should include, where appropriate, compulsory notification of prescribed animal diseases, inspection, movement controls through systems which provide adequate traceability, registration of facilities, quarantine of infected premises/areas, testing, treatment, destruction of infected *animals* or contaminated materials, controls over the use of veterinary medicines, etc. The scope of the legislative controls should include domestic *animals* and their reproductive material, animal products, wildlife as it relates to the transmission of *diseases* to humans and domestic *animals*, and other products subject to veterinary inspection. Arrangements should exist for co-operation with the *Veterinary Authorities* of the neighbouring countries for the control of animal diseases in border areas and for establishing linkages to recognise and regulate transboundary activities. Information on the veterinary public health legislation covering the production of products of animal origin for national consumption may be also considered in the evaluation.

2. Export/import inspection

National *Veterinary Services* should have appropriate legislation and adequate capabilities to prescribe the methods for control and to exercise systematic control over the import and export processes of *animals* and animal products in so far as this control relates to sanitary and zoonotic matters. The evaluation should also involve the consideration of administrative instructions to ensure the enforcement of *importing country* requirements during the pre-export period.

In the context of production for export of foodstuffs of animal origin, the *Veterinary Services* should demonstrate that comprehensive legislative provisions are available for the oversight by the relevant

authorities of the hygienic process and to support official inspection systems of these *commodities* which function to standards consistent with or equivalent to relevant Codex Alimentarius and OIE standards.

Control systems should be in place which permit the exporting *Veterinary Authorities* to approve export premises. The *Veterinary Services* should also be able to conduct testing and treatment as well as to exercise controls over the movement, handling and storage of exports and to make inspections at any stage of the export process. The product scope of this export legislation should include, *inter alia*, *animals* and animal products (including animal semen, ova and embryos), and animal feedstuffs.

The national *Veterinary Services* should be able to demonstrate that they have adequate capabilities and legislative support for zoosanitary control of imports and transit of *animals*, animal products and other materials which may introduce animal diseases. This could be necessary to support claims by the *Veterinary Services* that the animal health status of the country is suitably stable, and that cross-contamination of exports from imports of unknown or less favourable zoosanitary status is unlikely. The same considerations should apply in respect of veterinary control of public health. The *Veterinary Services* should be able to demonstrate that there is no conflict of interest when certifying veterinarians are performing official duties.

Legislation should also provide the right to deny and/or withdraw official certification. Penalty provisions applying to *malpractice* on the part of certifying officials should be included.

The *Veterinary Services* should demonstrate that they are capable of providing accurate and valid certification for exports of *animals* and animal products, based on Section 1.2. of the *Terrestrial Code*. They should have appropriately organised procedures which ensure that sanitary/animal health certificates are issued by efficient and secure methods. The documentation control system should be able to correlate reliably the certification details with the relevant export consignments and with any inspections to which the consignments were subjected.

Security in the export certification process, including electronic documentation transfer, is important. A system of independent compliance review is desirable, to safeguard against fraud in certification by officials and by private individuals or corporations. The certifying veterinarian should have no conflict of interest in the commercial aspects of the *animals* or animal product being certified and be independent from the commercial parties.

Article 1.3.4.8.

## **Animal health controls**

### 1. Animal health status

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



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

## 2. Animal health control

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

## 3. National animal disease reporting systems

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

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

Article 1.3.4.9.

## **Veterinary public health controls**

### 1. Food hygiene

The national *Veterinary Services* should be able to demonstrate effective responsibility for the veterinary public health programmes relating to the production and processing of animal products. If the national *Veterinary Services* do not exercise responsibility over these programmes, the evaluation should include a comprehensive review of the role and relationship of the organisations (national, state/provincial, and municipal) which are involved. In such a case, the evaluation should consider whether the national *Veterinary Services* can provide guarantees of responsibility for an effective control of the sanitary status of animal products throughout the slaughter, processing, transport and storage periods.

### 2. Zoonoses

Within the structure of *Veterinary Services*, there should be appropriately qualified personnel whose responsibilities *include* the monitoring and control of zoonotic diseases and, where appropriate, liaison with medical authorities.

### 3. Chemical residue testing programmes

Adequacy of controls over chemical residues in exported *animals*, animal products and feedstuffs should be demonstrated. Statistically-based surveillance and monitoring programmes for environmental and other chemical contaminants in *animals*, in animal-derived foodstuffs and in animal feedstuffs should be favourably noted. These programmes should be coordinated nationwide.

Correlated results should be freely available on request to existing and prospective trading partner countries. Analytical methods and result reporting should be consistent with internationally recognised standards. If official responsibility for these programmes does not rest with the *Veterinary Services*, there should be appropriate provision to ensure that the results of such programmes are made available to the *Veterinary Services* for assessment.

### 4. Veterinary medicines

It should be acknowledged that primary control over veterinary medicinal products may not rest with the *Veterinary Authorities* in some countries, owing to differences between governments in the division of legislative responsibilities. However, for the purpose of evaluation, the *Veterinary Services* should be able to demonstrate the existence of effective controls (including nationwide consistency of application) over the manufacture, importation, export, registration, supply, sale and use of veterinary medicines, biologicals and diagnostic reagents, whatever their origin. The control of veterinary medicines has direct relevance to the areas of animal health and public health.

In the animal health sphere, this has particular application to biological products. Inadequate controls on the registration and use of biological products leave the *Veterinary Services* open to challenge over the quality of animal disease control programmes and over safeguards against animal disease introduction in imported veterinary biological products.

It is valid, for evaluation purposes, to seek assurances of effective government controls over veterinary medicines in so far as these relate to the public health risks associated with residues of these chemicals in *animals* and animal-derived foodstuffs. This process should be consistent with the standards set by the Codex Alimentarius or with alternative requirements set by the *importing country* where the latter are scientifically justified.

### 5. Integration between animal health controls and veterinary public health

The existence of any organised programme which incorporates a structured system of information feedback from inspection in establishments producing products of animal origin, in particular meat or dairy products, and applies this in animal health control should be favourably noted. Such programmes should be integrated within a national disease surveillance scheme.

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

## Performance assessment and audit programmes

### 1. Strategic plans

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

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

### 2. Performance assessment

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

### 3. Compliance

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

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

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

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

### 4. Veterinary Services administration

#### a) Annual reports

Official government annual reports should be published, which provide information on the organisation and structure, budget, activities and contemporary performance of the *Veterinary*

*Services*. Current and retrospective copies of such reports should be available to counterpart *Services* in other countries, especially trade partners.

b) Reports of government review bodies

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

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

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

d) In-service training and development programme for staff

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

e) Publications

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

f) Formal linkages with sources of independent scientific expertise

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

g) Trade performance history

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

Article 1.3.4.11.

## Participation in OIE activities

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

Article 1.3.4.12.

## Evaluation of the veterinary statutory body

### 1. Scope

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

- = objectives and functions;
- legislative basis, ~~including~~ autonomy and functional capacity;
- ~~human resources, including~~ the composition and representation of the body's membership;
- ~~institutional arrangements,~~ accountability and transparency of decision-making;
- sources and management of funding;
- ~~functional capabilities, including the ability to enforce its decisions (for example regarding registration requirements, standards of conduct, and disciplinary procedures);~~
- administration of ~~education~~ training programmes and continuing professional development for *veterinarians* and *veterinary para-professionals*.

### 2. Evaluation of objectives and functions

The *veterinary statutory body* should define its policy and objectives, including detailed descriptions of its powers and functions such as:

- = to regulate *veterinarians* and *veterinary para-professionals* through licensing and/or registration of such persons;
- = to determine the minimum standards of training required for degrees, diplomas and certificates entitling the holders thereof to be registered as *veterinarians* and *veterinary para-professionals*;
- = to determine the standards of professional conduct of *veterinarians* and *veterinary para-professionals* and to ensure these standards are met.

### 3. Evaluation of legislative basis, autonomy and functional capacity

The *veterinary statutory body* should be able to demonstrate that it has the capacity, supported by appropriate legislation, to exercise and enforce control over all *veterinarians* and *veterinary para-professionals*. These controls should include, where appropriate, compulsory licensing and registration, minimum standards of training for the recognition of degrees, diplomas and certificates, setting standards of professional conduct and exercising control and the application of disciplinary procedures.

The *veterinary statutory body* should be able to demonstrate autonomy from undue political and commercial interests.

Where applicable, regional agreements for the recognition of degrees, diplomas and certificates for *veterinarians* and *veterinary para-professionals* should be demonstrated.

#### 4. Evaluation of membership representation

Detailed descriptions should be available in respect of the membership of the *veterinary statutory body* and the method and duration of appointment of members. Such information includes:

- = veterinarians designated by the *Veterinary Administration*, such as the Chief Veterinary Officer;
- = veterinarians elected by members registered by the *veterinary statutory body*;
- = veterinarians designated or nominated by the veterinary association(s);
- = representative(s) of veterinary para-professions;
- = representative(s) of veterinary academia;
- = representative(s) of other stakeholders from the private sector;
- = election procedures and duration of appointment;
- = qualification requirements for members.

#### 5. Evaluation of accountability and transparency of decision-making

Detailed information should be available on disciplinary procedures regarding the conducting of enquiries into professional misconduct, transparency of decision-making, publication of findings, sentences and mechanisms for appeal.

Additional information regarding the publication at regular intervals of activity reports, lists of registered or licensed persons including deletions and additions should also be taken into consideration.

#### 6. Evaluation of financial sources and financial management

Information regarding income and expenditure, including fee structure(s) for the licensing/registration of persons should be available.

7. Evaluation of training programmes and programmes for continuing professional development, for veterinarians and veterinary para-professionals

Descriptive summary of continuing professional development, training and education programmes should be provided, including descriptions of content, duration and participants; documented details of quality manuals and standards relating to Good Veterinary Practice should be provided.

Article 1.3.4.13.

1. The *Veterinary Services* of a country may undertake self-evaluation against the above criteria for such purposes as national interest, improvement of internal efficiency or export trade facilitation. The way in which the results of self-evaluation are used or distributed is a matter for the country concerned.
2. A prospective *importing country* may undertake an evaluation of the *Veterinary Services* of an *exporting country* as part of a risk analysis process, which is necessary to determine the sanitary or zoonosanitary measures which the country will use to protect human or animal life or health from disease or pest threats posed by imports. Periodic evaluation reviews are also valid following the commencement of trade.
3. In the case of evaluation for the purposes of *international trade*, the authorities of an *importing country* should use the principles elaborated above as the basis for the evaluation and should attempt to acquire information according to the model questionnaire outlined in Article 1.3.4.14. The *Veterinary Services* of the *importing country* are responsible for the analysis of details and for determining the outcome of the evaluation after taking into account all the relevant information. The relative ranking of importance ascribed, in the evaluation, to the criteria described in this Chapter will necessarily vary according to case-by-case circumstances. This ranking should be established in an objective and justifiable way. Analysis of the information obtained in the course of an evaluation study must be performed in as objective a manner as possible. The validity of the information should be established and reasonableness should be employed in its application. The assessing country must be willing to defend any position taken on the basis of this type of information, if challenged by the other party.

Article 1.3.4.14.

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

1. Organisation and structure of Veterinary Services

a) National Veterinary Services

Organisational chart including numbers, positions and numbers of vacancies.

b) Sub-national Veterinary Services

Organisational charts including numbers, positions and number of vacancies.

c) Other providers of Veterinary Services

Description of any linkage with other providers of *Veterinary Services*.

2. National information on human resources

a) Veterinarians

i) Total numbers of *veterinarians* registered/licensed by the *Veterinary statutory body* of the country:

ii) Numbers of:

- full time government *veterinarians*: national and sub-national;
- part time government *veterinarians*: national and sub-national;
- private *veterinarians* authorised by the *Veterinary Services* to perform official veterinary functions; [*Describe accreditation standards, responsibilities and/or limitations applying to these private veterinarians.*]
- other *veterinarians*.

iii) Animal health:

Numbers associated with farm livestock sector on a majority time basis in a veterinary capacity, by geographical area [*Show categories and numbers to differentiate staff involved in field service, laboratory, administration, import/export and other functions, as applicable.*]:

- full time government *veterinarians*: national and sub-national;
- part time government *veterinarians*: national and sub-national;
- other *veterinarians*.

iv) Veterinary public health:

*Numbers* employed in food inspection on a majority time basis, by commodity [*Show categories and numbers to differentiate staff involved in inspection, laboratory and other functions, as applicable.*]:

- full time government *veterinarians*: national and sub-national;
- part time government *veterinarians*: national and sub-national;



- other *veterinarians*.
- v) Numbers of *veterinarians* relative to certain national indices:
- per total human population;
  - per farm livestock population, by geographical area;
  - per livestock farming unit, by geographical area.
- vi) Veterinary education:
- number of veterinary schools;
  - length of veterinary course (years);
  - international recognition of veterinary degree.
- vii) Veterinary professional associations.
- b) Graduate personnel (non-veterinary)
- Details to be provided by category (including biologists, biometricians, economists, engineers, lawyers, other science graduates and others) on numbers within national *Veterinary Services* and available to national *Veterinary Services*.
- c) Veterinary para-professionals employed by the Veterinary Services
- i) Animal health:
- Categories and numbers involved with farm livestock on a majority time basis:
    - by geographical area;
    - proportional to numbers of field Veterinary Officers in the *Veterinary Services*, by geographical area.
  - Education/training details.
- ii) Veterinary public health:
- Categories and numbers involved in food inspection on a majority time basis:
    - meat inspection: export meat establishments with an export function and domestic meat establishments (no export function);

- dairy inspection;
  - other foods.
  - Numbers in import/export inspection.
  - Education/training details.
- d) Support personnel
- Numbers directly available to *Veterinary Services* per sector (administration, communication, transport).
- e) Descriptive summary of the functions of the various categories of staff mentioned above
- f) Veterinary, *veterinary para-professionals*, livestock owner, farmer and other relevant associations
- g) Additional information and/or comments.

### 3. Financial management information

- a) Total budgetary allocations to the *Veterinary Services* for the current and past two fiscal years:
- i) for the national *Veterinary Services*;
  - ii) for each of any sub-national veterinary authorities;
  - iii) for other relevant government-funded institutions.
- b) Sources of the budgetary allocations and amount:
- i) government budget;
  - ii) sub-national authorities;
  - iii) taxes and fines;
  - iv) grants;
  - v) private services.
- c) Proportional allocations of the amounts in a) above for operational activities and for the programme components of *Veterinary Services*.
- d) Total allocation proportionate of national public sector budget. *[This data may be necessary for comparative assessment with other countries which should take into account the contexts of the importance of the livestock sector to the national economy and of the animal health status of the country.]*

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

#### 4. Administration details

- a) Accommodation

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

- b) Communications

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

- c) Transport

- i) Itemised numbers of types of functional transport available on a full-time basis for the *Veterinary Services*. In addition provide details of transport means available part-time.
- ii) Details of annual funds available for maintenance and replacement of motor vehicles.

#### 5. Laboratory services

- a) Diagnostic laboratories (laboratories engaged primarily in diagnosis)

- i) Descriptive summary of the organisational structure and role of the government veterinary laboratory service in particular its relevance to the field *Veterinary Services*.
- ii) Numbers of veterinary diagnostic laboratories operating in the country:
  - government operated laboratories;
  - private laboratories accredited by government for the purposes of supporting official or officially-endorsed animal health control or public health testing and monitoring programmes and import/export testing.
- iii) Descriptive summary of accreditation procedures and standards for private laboratories.
- iv) Human and financial resources allocated to the government veterinary laboratories, including staff numbers, graduate and post-graduate qualifications and opportunities for further training.
- v) List of diagnostic methodologies available against major diseases of farm livestock (including poultry).

- vi) Details of collaboration with external laboratories including international reference laboratories and details on numbers of samples submitted.
  - vii) Details of quality control and assessment (or validation) programmes operating within the veterinary laboratory service.
  - viii) Recent published reports of the official veterinary laboratory service which should include details of specimens received and foreign animal disease investigations made.
  - ix) Details of procedures for storage and retrieval of information on specimen submission and results.
  - x) Reports of independent reviews of the laboratory service conducted by government or private organisations (if available).
  - xi) Strategic and operational plans for the official veterinary laboratory service (if available).
- b) Research laboratories (laboratories engaged primarily in research)
- i) Numbers of veterinary research laboratories operating in the country:
    - government operated laboratories;
    - private laboratories involved in full time research directly related to animal health and veterinary public health matters involving production animal species.
  - ii) Summary of human and financial resources allocated by government to veterinary research.
  - iii) Published programmes of future government sponsored veterinary research.
  - iv) Annual reports of the government research laboratories.

## 6. Functional capabilities and legislative support

- a) Animal health and veterinary public health
  - i) Assessment of the adequacy and implementation of relevant legislation (national or sub-national) concerning the following:
    - animal and veterinary public health controls at national frontiers;
    - control of endemic animal diseases, including zoonoses;
    - emergency powers for control of exotic disease outbreaks, including zoonoses;

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

7. Animal health and veterinary public health controls

- a) Animal health

- i) Description of and sample reference data from any national animal disease reporting system controlled and operated or coordinated by the *Veterinary Services*.
  - ii) Description of and sample reference data from other national animal disease reporting systems controlled and operated by other organisations which make data and results available to *Veterinary Services*.
  - iii) Description and relevant data of current official control programmes including:
    - epidemiological surveillance or monitoring programmes;
    - officially approved industry administered control or eradication programmes for specific diseases.
  - iv) Description and relevant details of animal disease emergency preparedness and response plans.
  - v) Recent history of animal disease status:
    - animal diseases eradicated nationally or from defined sub-national *zones* in the last ten years;
    - animal diseases of which the prevalence has been controlled to a low level in the last ten years;
    - animal diseases introduced to the country or to previously free sub national regions in the last ten years;
    - emerging diseases in the last ten years;
    - animal diseases of which the prevalence has increased in the last ten years.
- b) Veterinary public health
- i) Food hygiene
    - Annual national slaughter statistics for the past three years according to official data by species of animals (bovine, ovine, porcine, caprine, poultry, farmed game, wild game, equine, other).
    - Estimate of total annual slaughterings which occur but are not recorded under official statistics.
    - Proportion of total national slaughter which occurs in registered export establishments, by category of animal.

- Proportion of total national slaughter which occurs under veterinary control, by category of animal.
  - Numbers of commercial fresh meat establishments in the country which are registered for export by national *Veterinary Services*:
    - slaughterhouses (indicate species of *animals*);
    - cutting/packing plants (indicate meat type);
    - meat processing establishments (indicate meat type);
    - cold stores.
  - Numbers of commercial fresh meat establishments in the country approved by other *importing countries* which operate international assessment inspection programmes associated with approval procedures.
  - Numbers of commercial fresh meat establishments under direct public health control of the *Veterinary Services* (including details of category and numbers of inspection staff *associated* with these premises).
  - Description of the veterinary public health programme related to production and processing of animal products for human consumption (including fresh meat, poultry meat, meat products, game meat, dairy products, fish, fishery products, molluscs and crustaceans and other foods of animal origin) especially including details applying to exports of these *commodities*.
  - Descriptive summary of the roles and relationships of other official organisations in public health programmes for the products listed above if the national *Veterinary Services* do not have responsibility for those programmes which apply to national production destined to domestic consumption and/or exports of the *commodities* concerned.
- ii) Zoonoses
- Descriptive summary of the numbers and functions of staff of the *Veterinary Services* involved primarily with monitoring and control of zoonotic diseases.
  - Descriptive summary of the role and relationships of other official organisations involved in monitoring and control of zoonoses to be provided if the national *Veterinary Services* do not have these responsibilities.
- iii) Chemical residue testing programmes
- Descriptive summary of national surveillance and monitoring programmes for environmental and chemical residues and contaminants applied to animal-derived foodstuffs, *animals* and animal feedstuffs.

- Role and function in these programmes of the national *Veterinary Services* and other *Veterinary Services* to be described in summary form.
- Descriptive summary of the analytical methodologies used and their consistency with internationally recognised standards.

iv) *Veterinary medicines*

- Descriptive summary of the administrative and technical controls involving registration, supply and use of veterinary pharmaceutical products especially including biological products. This summary should include a focus on veterinary public health considerations relating to the use of these products in food-producing *animals*.
- Role and function in these programmes of the national *Veterinary Services* and other *Veterinary Services* to be described in summary form.

8. Quality systems

a) Accreditation

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

b) Quality manuals

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

c) Audit

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

9. Performance assessment and audit programmes

a) Strategic plans and review

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

b) Compliance



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

c) Annual reports of the national *Veterinary Services*

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

d) Other reports

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

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

e) Training

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

ii) Summary descriptions of training courses and duration.

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

f) Publications

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

g) Sources of independent scientific expertise

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

10. Membership of the OIE

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

11. Other assessment criteria

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— text deleted

**Performance, Vision and Strategy (PVS) for**

**VETERINARY SERVICES (VS)<sup>1</sup>**

<p><b>Community comments:</b> <b>The Community supports this draft.</b></p>
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**Introduction**

In this era of globalization, the development and growth in many countries depends on the performance of their agricultural economies, and this, in turn, directly relates to the quality of their national veterinary services (VS). VS play also a major role in Veterinary public health including food-borne diseases and regional and international market access for animals and their products. To be effective, VS should operate based on scientific principles and be technically independent and immune from political pressures of its users'. However, efforts to strengthen official services, requires the active participation and investment on the part of both the public and the private sectors. To assist in this effort, the World Organization for Animal Health (OIE) and the Inter-American Institute for Cooperation on Agriculture (IICA) have joined forces to develop the Performance, Vision and Strategy (PVS) instrument. The PVS instrument can assist VS to establish their current level of performance, form a shared vision with the private sector, establish priorities and facilitate strategic planning in order to take full advantage of the new opportunities and obligations of globalization.

The OIE promotes animal health and public health including food-borne diseases safety in the international trade of animals and their related products by issuing harmonized sanitary guidelines on international certification and disease control methods and working to improve the resources and legal framework of the VS. Likewise, IICA helps to strengthen VS so they can be more efficient and competitive nationally and internationally and can contribute to the improved health of their consumers. Both organizations share a mutual interest to help countries comply with the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) of the World Trade Organization (WTO) and the standards, guidelines and recommendations of the OIE.

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<sup>1</sup> Veterinary services means the Veterinary Administration, all the Veterinary Authorities, and all persons authorized, registered or licensed by the veterinary statutory body of a country. They will be called "VS" in all the document

The traditional mission of VS has been to protect domestic agriculture and, over time, most of its resources were channeled toward the control of diseases<sup>2</sup> that threatened primary production. The focus of the services provided were from the national borders inward and the credibility of these services, in the eyes of its users and other countries, depended in large measure on the effectiveness of its domestic programs, and its response to emergencies arising from the entry of foreign diseases.

In light of the growing international requirements and opportunities facing countries, it behooves VS to adopt a broader mandate and vision, and provide new services that complement the portfolio of existing services. This will entail stronger alliances and closer cooperation with its users, other countries and their national veterinary service counter parts. The WTO/SPS agreement reaffirms the right of the member countries to protect plant, animal and human life or health, but the agreement also requires that countries base their SPS measures on scientific principles and the OIE standards - the fundamental basis of operation to ensure that international trade is free of discrimination and scientifically unjustified restrictions.

Experience has shown that those countries, whose VS are more developed and credible in the eyes of its users, trading partners and other countries, contain four fundamental components: 1) the **technical capability** to address current and new issues based on scientific principles; 2) the **human and financial capital** to attract resources and retain professionals with technical and leadership skills; 3) the **interaction with the private sector** in order to stay on course and carry out relevant joint programs and services; and 4) the ability to **access markets** through the compliance with existing standards and the implementation of new disciplines such as harmonization of standards, equivalence and regionalization. These four components provide the basic structure of the PVS instrument.

### **Applying the PVS Instrument**

To establish the current level of performance, form a shared vision, establish priorities and facilitate strategic planning, a series of five to eight critical competencies have been developed for each of the four fundamental components. For each critical competency, qualitative levels of advancement are described. To help visualize the potential or cumulative level of advancement within each critical competency, a pie chart is shown next to the written explanation for each level. A higher level of advancement assumes that the VS is complying with the preceding (and non zero) levels.

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<sup>2</sup> Clinical and/or pathological manifestation of an infection

In addition to the qualitative levels, additional space has been provided after each critical competency to expand upon or clarify responses, if so desired. The following hypothetical example illustrates the level of advancement determined along with an explanation for the critical competency harmonization, one of the [twenty-eight] critical competencies in the PVS instrument.

### **3. Harmonization**

The capability and authority of the VS to be active in harmonization and ensure that the national regulatory norms covered under its mandate are in conformity with relevant international standards, guidelines and recommendations.

Levels of advancement:

0. The VS has no process to be aware of international standards. National regulatory norms do not take account of international standards, guidelines and recommendations.
1. The VS is aware of relevant standards but has no process to identify gaps, inconsistencies, or non-conformities in national regulatory norms as compared to international standards, guidelines and recommendations.
2. The VS monitors the establishment of new international standards, guidelines and recommendations and periodically reviews national regulatory norms with the aim of harmonizing them as appropriate with international standards, guidelines and recommendations.
3. Same as previous level plus the VS is active in reviewing and commenting on draft standards, guidelines and recommendations.
4. Same as previous level plus the VS actively and regularly participates at the international level in the formulation of international standards, guidelines and recommendations.\*

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

**Using the results**

The PVS instrument is designated for easy understanding and is flexible in its application and use. More than a diagnostic tool, it is a process oriented towards the future which can be used in passive or active mode, depending on the level of interest and commitment by the users and the official service in improving their national services over time.

If it is used in the passive mode, the PVS instrument raises awareness, improves understanding and guides the different sectors participating in the process regarding the basic components and critical competencies the VS must contain in order to function adequately. In this mode the instrument can also be used to develop a shared vision, foster dialogue and adopt a common language for discussion.

The active mode is where the maximum potential is generated and the best results can be obtained, assuming the commitment is present on the part of both the public and private sector. In this mode, performance is assessed, differences are explored and priorities are established. Leadership on the part of the public sector is a critical element for success. This active mode is where actions happen, investments are evaluated and made and commitment is carried out. Continuity of the PVS process is assured when a true partnership between the official and the private sector exists.

As a very important additional reference, Chapter 1.3.3 on the Evaluation of Veterinary Services, in the Terrestrial Animal Health Code of the OIE and Chapter 1.4.3 on the Evaluation of Competent Authorities, in the Aquatic Animal Health Code, expand upon and further clarifies some of the levels of advancement described in some of the critical competencies of the PVS instrument. The instrument can be used to facilitate the dialogue with different users in the public and private sectors that share a common interest in improving the vision and performance of the public services. For example, the interested parties can jointly participate in establishing the current level of performance, identifying priorities and adopting actions that strengthen the national services. In addition, the director of the national VS can use the instrument to monitor progress in each one of the four components.

For the VS, the results of the PVS instrument can help to: 1) indicate the overall performance of each one of the four components; 2) rate the relative performance within each one of the critical competencies; 3) compare the performance of the VS with that of other veterinary services in the region or globally, in order to explore areas for cooperation or negotiation<sup>3</sup>; 4) identify the differences in the responses of the different users in order to arrive at common points of view; 5) foster common understanding in order to achieve greater levels of advancement; 6) help determine the benefits and costs of investing in VS and obtaining

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<sup>3</sup> OIE standards allow importing countries to make audits in exporting countries and in particular check the compliance of exporting countries with OIE standards on quality and evaluation of VS

assistance from financial and technical cooperation agencies, 7) provide a basis for establishing a routine monitoring and follow up mechanism on the overall level of performance of the VS over time; and 8) help identify and present objectives and specific needs when applying for financial support (loans and/or grants). 9) Prepare a process of verification of compliance with OIE standards on quality and evaluation of VS by an external independent body under the auspices of the OIE.

## **FUNDAMENTAL COMPONENTS**

- I. TECHNICAL CAPABILITY
- II. HUMAN AND FINANCIAL CAPITAL
- III. INTERACTION WITH THE PRIVATE SECTOR
- IV. ACCESS TO MARKETS

### **I. TECHNICAL CAPABILITY**

The capability of the VS to establish and apply sanitary measures and science-based procedures.

Critical competencies:

- 1. Diagnostic capability
- 2. Early detection and emergency response capability
- 3. Quarantine
- 4. Epidemiological surveillance
- 5. Quality systems
- 6. Risk analysis
- 7. Technical innovation

#### **1. Diagnostic capability**

The capability and authority of the VS to identify and record those biological, physical and chemical agents including those relevant for public health that can adversely affect animals and their related products.

Levels of advancement:

0. For existing diseases, the VS can carry out the clinical diagnosis, but not the laboratory<sup>4</sup> confirmation.
1. For zoonoses<sup>5</sup> and other diseases with a major economic or public health impact, the VS can collect samples in the country and immediately ship them to the laboratory for confirmation.
2. For zoonoses, and other diseases not present in the country, but known to exist in the region or could enter via trade, the VS has procedures in place to collect samples and immediately ship them to the laboratory for confirmation.
3. In the case of new and emerging diseases in the region or world, the VS has access to a network of national or international reference laboratories and can collect and ship samples to the most qualified laboratory for confirmation.
4. The VS actively promotes the accreditation of its laboratories and audits<sup>6</sup> the quality of its clinical diagnostic, collection and shipment of samples procedures.

## **2. Early detection and emergency response capability**

The capability and authority of the VS to rapidly respond to unexpected disease outbreak<sup>7</sup> or other situations that put at immediate risk the sanitary status<sup>8</sup> of the animal populations covered under its mandate.

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<sup>4</sup> Means a properly equipped institution staffed by technically competent personnel under the control of a specialist in veterinary diagnostic methods, who is responsible for the validity of the results. The Veterinary Administration approves and monitors such laboratories with regard to the diagnostic tests required for international trade.

<sup>5</sup> Zoonoses (Zoonotic diseases): Any disease or infection which is naturally transmissible from animals to humans.

<sup>6</sup> Audits: A systematic and functionally independent examination, the objective of which is to determine if an activity or process and subsequent results meet the prescribed objectives.

<sup>7</sup> Outbreak means an occurrence of one of the diseases listed by the OIE in an establishment, breeding establishment or premises, including all buildings and all adjoining premises, where animals are present. Where it cannot be defined in this way, the outbreak shall be considered as occurring in the part of the territory in which, taking local conditions into account, it cannot be guaranteed that both susceptible and non-susceptible animals have had no direct contact with affected or suspected cases in that area.

<sup>8</sup> The status of a country or compartment within the country with respect to a particular disease, in accordance to the criteria set forward in the Terrestrial Animal Health Code of the OIE.



Levels of advancement:

0. The VS has no field network nor system to determine whether or not a sanitary emergency exists and it does not have the authority to declare such an emergency and take action.
1. The VS has a field network and a system to determine whether or not a sanitary emergency exists but lacks the necessary legal and financial support<sup>9</sup> to take action in response to sanitary emergencies.
2. The VS has a system to make timely decisions on whether or not a sanitary emergency exists. The VS has the legal framework and funding sources to take action in response<sup>10</sup> to sanitary emergencies through an efficient national chain of command.
3. Same as previous level plus the VS has contingency plans or general action plans for diseases of concern that enable it to coordinate actions with other relevant organizations or institutions and the private sector (including veterinary practitioner), in response to sanitary emergencies through an efficient national chain of command.

### 3. Quarantine

The capability and authority of the VS to prevent the entrance and spread of unwanted diseases in the country.

Levels of advancement:

0. The VS does not compile information on the sanitary status in its own country or maintain any type of quarantine procedures with its neighbouring countries or trading partners.
1. The VS has up-to-date information on exporting countries which it incorporates into its quarantine procedures for the commercial trade of primarily farm animals and their related products that come into the country and may threaten its sanitary status.
2. The VS has up-to-date information on exporting countries which it incorporates into quarantine procedures for animals and their related products, even if of no significant

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<sup>9</sup> The phrase, legal and financial support, refers to the VS already having in place the legal framework and financial resources in order to take immediate actions.

<sup>10</sup> Appropriate response to sanitary emergency includes an appropriate early detection system

trade or commercial value (e.g. companion animals) but enter into the country through established trade channels.

3. The VS can or has implemented specialized quarantine programs<sup>11</sup> in the country of origin for specific animals and their related products.
4. The VS carries out quality assurance audits of its own quarantine procedures and, if necessary, those of its trading partners, in compliance with OIE standards on quality and evaluation of VS.

#### **4. Epidemiological surveillance<sup>12</sup>**

The capability and authority of the VS to determine, monitor and verify the sanitary status of the animal populations covered under its mandate.

Levels of advancement:

0. The VS has no program in place for surveillance or monitoring.
1. The VS conducts a surveillance program based on existing information or suspected cases, where samples are collected and sent to the laboratories.
2. The VS conducts active monitoring programs in animal populations on diseases of economic and zoonotic importance.
3. The VS conducts surveillance programs in populations of greatest risk covering zoonoses, and other diseases of economic importance.
4. The VS structures its surveillance programs taking into account the sanitary status of its neighboring countries and trade flows.

#### **5. Quality systems**

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<sup>11</sup> Programs that facilitate the detection of transmissible diseases and make it possible to evaluate the health of the population in question before being transported.

<sup>12</sup> The term, surveillance, refers to the ongoing and systematic process of collecting, analyzing, interpreting and disseminating information on the sanitary status, including early detection of exotic and emerging diseases. The term, monitoring, is more specific in its application and is directed at detecting changes in the prevalence of a pest or disease for a given population and environment.

Surveillance and monitoring procedures take into account as a minimum basis the requirements published in the appendices of the relevant chapters of the OIE *Codes* and *Manuals*.

The authority and capacity of VS to define their veterinary public health policies, formalize their activities, in particular concerning control and certification and making sure that these are well executed.

Levels of advancement:

0. The VS has no system for the control of their activities.
1. The VS has established an administrative structure capable of ensuring the chain of command, defining the required regulations and delegation of authority.
2. The VS has defined the policies and has evaluated the resource needs.
3. The VS has implemented a a general system for registering their procedures and instructions.
4. The VS has a system for the evaluation of the effectiveness of their services (internal audit).
5. The VS is subjected to external audits of its Quality system.

## 6. Risk analysis<sup>13</sup>

The capability of the VS to make decisions and carry out actions based on scientific principles and evidence, including the assessment, communication and management of risk.

Levels of advancement:

0. The VS does not compile data or other kinds of information that could be used to identify potential sanitary hazards and analyze risks. Sanitary decisions are not supported by scientific evidence.

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<sup>13</sup> The term, *risk*, refers to the likelihood of an adverse event and the probable magnitude of the consequences in the importing country during a specified time period. *Risk analysis* refers to the assessment, management and communication of risk, not only for imports but for domestic issues which may also arise.

1. The VS compiles and maintains sources of information or can access the information necessary in order to assess risks. Sanitary decisions may be based on scientific evidence.
2. The VS has a system to actively seek and maintain relevant data and information for risk assessment and dedicated personnel with this responsibility. Scientific principles and evidence provide the basis for options considered by sanitary decision makers in order to manage risks.
3. Same as previous level plus the VS is consistent in conducting scientifically based risk assessments in compliance with relevant OIE standards and communicating the decisions taken to the WTO/SPS, the OIE and its relevant trading partners.
4. Same as previous level plus the VS is consistent in managing and communicating the risks in conformity with the WTO/SPS Agreement and relevant standards of the OIE.

## **7. Technical innovation**

The capability of the VS to update its overall service, in accordance with the latest scientific advances and based on the sanitary norms and measures of the OIE, Codex Alimentarius and the WTO/SPS Agreement.

Levels of advancement:

0. The VS has only informal access to technical innovations through personal contacts or external media sources.<sup>14</sup>
1. The VS maintains information base on technical innovations and international norms through subscriptions to scientific journals and electronic media.
2. The VS carries out a specific program that identifies technical innovations which can improve its operation and procedures.
3. The VS incorporates technical innovations into selected functions and procedures, with specific resources and the collaboration or contributions of its users.<sup>15</sup>
4. The VS has a dedicated budget plus the collaboration and contributions of its users, to continually implement technical innovations throughout the national service.

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<sup>14</sup> External media are those sources of information that may not be available or subscribed to by the VS such as scientific publications and magazines

<sup>15</sup> This includes consulting with the OIE, WTO, Codex websites and books for publications and notices and regular participation in international forum

## II. HUMAN AND FINANCIAL CAPITAL

Institutional and financial sustainability as evidenced by the level of professional talent and financial resources available.

Critical competencies:

1. Human talent
2. Training
3. Funding sources
4. Stability of policies and programs
5. Contingency funds
6. Technical independence
7. Capability to invest and grow

### 1. Human talent (Initial training)

The capability of the VS to efficiently carry out the professional and technical functions; measured in two ways: academic degrees<sup>16</sup> and qualifications of its professional staff.

A veterinary positions:

Levels of advancement:

- 0 In the core of the VS the majority of the veterinary positions are not occupied by personnel holding a university diploma.
- 1 In the core of the VS the veterinary positions are defined in terms of the area of expertise, the placement within the structure, and the level of competence and of initial training (university degree recognized by the State).
- 2 In the core of the VS there is a service in charge of the management of human resources and of the appropriateness of positions and diplomas according to international standards.
- 3 The management of veterinary human resources is subject to internal audits.

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<sup>16</sup> Not all professional positions require a academic degree. Nonetheless, the rate of academic degrees serves as an indicator of the professional excellence within the VS.

A technical and administrative positions:

Levels of advancement:

- 0 . In the core of the VS the majority of technical and administrative positions are not occupied by personnel with professional qualifications<sup>17</sup>.
- 1 . In the core of the VS the majority of technical and administrative positions are occupied by personnel with professional qualifications.
- 2 . In the core of the VS the technical and administrative positions are defined in terms of the area of expertise, the placement within the structure, and the level of competence and of initial training (university degree recognized by the State.
- 3 . In the core of the VS there is a service in charge of the management of human resources and of the appropriateness of positions and diplomas according to international standards.
- 4 . The management of the entire human resources is subject to internal audits.

## **2. Training (Continuing education)**

The capability of the VS to keep its personnel up-to-date in terms of relevant information and knowledge; measured in terms of the implementation of an annual training plan

Levels of advancement:

0. The VS has no training plans. (Continuing education plan)
1. The VS has training plans but they are not updated or funded.
2. The VS has annual training plans that are updated and funded but only partially implemented<sup>18</sup>.
3. The VS has updated and funded training plans largely implemented.
4. The VS has up to date training plans implemented for everyone.

## **3. Funding sources**

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<sup>17</sup> OIE international standards on quality and evaluation of VS make reference to the quality of the professional judgment.

<sup>18</sup> Partially implemented may be only implemented for some personnel or only partially implemented for all personnel.

The ability of the VS to access financial resources for its continued operation and sustainability, independent of any type of political pressure from users.

Levels of advancement:

0. Funding for the VS is neither stable nor clearly defined. The budget for the national veterinary service competes with other State institutions and depends on resources allocated irregularly from the general treasury and/or non national donors.
1. The VS is funded from a continuous specific line item prescribed within the national budget as well as resources coming from non national donors if it is the case.
2. The VS is funded from a continuous specific line item prescribed within the national budget and with user fees generated by providing specific services (e.g. quarantine and certification services).
3. In addition to the previous levels, the VS also receives additional resources from its users<sup>19</sup> to execute specific programs under complete transparency and ensuring full independence<sup>20</sup>.

#### **4. Stability of policies and programs**

The capability of the VS to implement and sustain policies and programs over time; measured by the frequency of which the entire VS is reorganized and by the coordination capability between government institutions.

A. Levels of advancement (VS reorganization):

0. The VS is reorganized frequently<sup>21</sup> at all levels.
1. The VS is reorganized frequently at some levels.
2. The VS is reorganized only at political levels after political changes.

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<sup>19</sup> Users means farmers, livestock traders and/or industry

<sup>20</sup> In compliance with OIE international standards on quality regarding independency and impartiality.

<sup>21</sup> a stable organization maintains its core structure and functions for 5 years or more

3. The VS, is reorganized only occasionally at political levels after political changes.
4. The VS is stable at technical and political levels.

**B. Levels of advancement (coordination capability between government institutions):**

0. The national regulations do not clearly define the obligations and competencies of all the official sector institutions that comprise the VS.
1. There are national regulations that define the obligations and competencies of the official sector institutions at the national and local levels.
2. There are coordinated inter and intra institutional activities in the official sector at least at the national level.
3. There are coordinated inter and intra institutional activities in the official sector at both the national and local levels.

**5. Contingency funds**

The capability of the VS to access extraordinary financial resources in order to respond to emergency situations or emerging issues; measured by the ease of which contingency resources can be made available.

**Levels of advancement:**

0. No contingency fund exists and any extraordinary resources can only be obtained through legislation or presidential decree.
1. A contingency fund with limited resources has been established, but any additional resources must be approved via presidential decree or law.
2. A contingency fund with limited resources has been established, but any additional resources must be approved by the Minister of Agriculture.
3. A contingency fund with substantial resources has been established, but additional resources must be approved by the Minister of Agriculture.



4. A contingency fund with substantial resources has been established and includes additional resources previously made available by its users<sup>22</sup>.

## 6. Technical independence

The capability of the VS to carry out its duties with autonomy and free from political interference that may affect technical and scientific decisions; measured in two ways: political appointments<sup>23</sup> and technical support for decisions.

### A. Levels of advancement (management positions):

0. The Director General of the entire agricultural health and food safety institution (if applicable), the Director of the VS and his/her direct reports are political appointees.
1. The Director General of the entire agricultural health and food safety institution (if applicable) and the Director of the VS are the only political appointees.
2. The selection of the Directors is not made only on political considerations.

### B. Levels of advancement (technical support for decisions):

0. The technical decisions made by the VS are almost always based on political considerations.
1. The technical decisions incorporate scientific principles, but must be modified to conform to any political considerations.
2. The technical decisions are based on scientific principles but are subject to review and possible modification based on political considerations.
3. The technical decisions are based only on scientific principles and are not changed to meet any political considerations<sup>24</sup>.

## 7. Capability to invest and grow

The capability of the VS to secure additional investments over time that leads to a sustained improvement in the entire service. The utilization of such resources is not subject to any type of political pressure from its users.

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<sup>22</sup> “Users” means there all beneficiaries of the activities of VS, such as farmers, traders, consumers and industry.

<sup>23</sup> The phrase, political appointments, refers to appointments made by the party in office, serving at the pleasure of politicians and subject to immediate removal

<sup>24</sup> In accordance with the principles of the OIE *Codes* on quality of VS

Levels of advancement:

0. There are no sustained actions to support the overall structure of the VS.
1. The VS elaborates and presents proposals and secures investment resources for improvements and infrastructures from cooperation or donor agencies.
2. The VS secures over time, significant investment resources for improvements and infrastructure, through extraordinary allocations from the national (general treasury) or local public resources or special line items.
3. In addition to the previous levels, the beneficiaries including farmers and/or industry provide resources to the VS for improvements and infrastructure<sup>25</sup>.

### **III. INTERACTION WITH THE BENEFICIARIES**

The capability of the VS to collaborate with and involve the beneficiaries (including farmers and/or industry) in the implementation of programs and activities.

Critical competencies:

1. Communication
2. Consultation of beneficiaries
3. Official representation
4. Accreditation
5. Statutory body
6. Joint action programs implementation

#### **1. Communication**

The capability of the VS to inform, in a transparent, effective and timely fashion, its users of activities, programs and developments.

Levels of advancement:

0. The VS has no mechanism in place to keep users informed of activities, programs and sanitary developments.
1. The VS maintains an official communication outlet, which users can consult regarding standards, regulations and notifications.
2. The VS routinely<sup>26</sup> publishes the results of its activities, programs and sanitary developments.

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<sup>25</sup> in compliance with OIE standards on independence and impartiality of VS

3. The VS provides up-to-date information, accessible via the internet, on sanitary developments and its programs and activities currently underway, and actively seeks input from the private sector, including farmers.

## **2. Consultation of beneficiaries**

The capability of the VS to maintain fluid channels of consultation with the public and private sectors<sup>27</sup> and users<sup>28</sup>.

Levels of advancement:

0. The VS has no consultation mechanisms in place to facilitate the dialogue between the relevant State institutions and the users.
1. The VS maintains informal channels of consultation with the relevant State institutions and the users.
2. The VS establishes and promotes official dialogue with the different users on its proposed and current regulations.
3. The VS holds forums and meetings with the different users in order to establish or improve its programs and services.
4. The VS actively promotes dialogue with and solicits feedback from the different users regarding national laws and regulations and official representation at the WTO/SPS and OIE
5. The VS actively promotes dialogue with and solicits feedback from the different users regarding national laws and regulations and official representation at the WTO/SPS, OIE and Codex Alimentarius.

## **3. Official representation**

The capability of the VS to regularly and actively participate, coordinate and provide follow up to the meetings of international organizations such as the WTO/SPS, OIE and Codex Alimentarius<sup>29</sup>.

Levels of advancement:

0. The VS does not participate in or follow up on the meetings of the WTO/SPS, OIE and Codex Alimentarius.

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<sup>26</sup> Means every six months

<sup>27</sup> private sector includes farmers, industry, transport and distribution

<sup>28</sup> "users" means all beneficiaries of the VS activities

<sup>29</sup> in compliance with international procedures and practices.

1. The VS participates sporadically or passively<sup>30</sup> in the meetings of the WTO/SPS, OIE and Codex Alimentarius.
2. The VS takes into consideration the opinions of its users and participates regularly and actively<sup>31</sup> in the meetings of the WTO/SPS, OIE and Codex Alimentarius.
3. The VS, in consultation with its different users, identifies strategic topics, provides leadership and coordinates between the national delegations these topics over time as part of the agenda in the meetings of the WTO/SPS, OIE and Codex Alimentarius.

#### **4. Accreditation / Delegation**

The capability and authority of the VS to accredit and delegate<sup>32</sup> with third parties (e.g. private veterinarians, laboratories, etc), the execution of specific official services.

Levels of advancement:

0. The VS has neither the authority nor the capability to accredit and delegate to third parties.
1. The VS has authority to accredit and delegate to third parties but no specific accreditation or delegation activities.
2. The VS has accreditation and delegation programs for third parties and selected services.
3. The VS can develop and implement accreditation and delegation programs for new services.
4. The VS carries out quality assurance audits of its accreditation and delegation programs through an efficient national chain of command in order to maintain the trust of its trading partners.

#### **5. Statutory body**

The veterinary statutory body, in accordance with the OIE's definition, is an independent authority charged with the registration/licensing of veterinarians and authorization of veterinary para-professionals. Among others, it verifies the validity and the level of the veterinary diploma required to exercise the veterinary profession.

Levels of advancement:

0. There is no veterinary statutory body in the country.

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<sup>30</sup> *Passive participation* refers to being present at, but contributing little, to the meetings in question

<sup>31</sup> *Active participation* refers to preparation in advance of, and contributing during the meetings in question, including exploring common solutions and generating proposals and compromises for possible adoption.

<sup>32</sup> In compliance with OIE standards on quality of VS

1. There is a veterinary statutory body, but it does not have the power to discipline or make decisions.
2. The veterinary statutory body can only exercise its authority within the private sector.
3. The veterinary statutory body can also exercise its authority within the public sector.
4. The veterinary statutory body is subjected to auditing and evaluation procedures.

## **6. Joint programmes implementation**

The capability of the VS and the private sector to formulate and implement joint programs on annual and/or pluri-annual bases.

Levels of advancement:

0. The VS has no joint programs.
1. The VS has established annual and/or pluri-annual joint programs but they are not updated or funded.
2. The VS has annual and/or pluri-annual joint programs that are updated and funded but only partially implemented<sup>33</sup>.
3. The veterinary has joint programs that are updated annually and fully implemented.

## **IV. ACCESS TO MARKETS**

The capability and authority of the VS to provide support in order to access, expand and retain regional and international markets for animals and animal products.

Critical competencies:

1. Compliance with regulations
2. Setting of regulations
3. Harmonization
4. Certification
5. Equivalency agreements
6. Traceability
7. Transparency

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<sup>33</sup> Partially implemented may be only implemented for some activities or only partially implemented for all activities.

8. Zoning
9. Compartmentalization

## **1. Compliance with regulations<sup>34</sup>**

The capability and authority of the VS to ensure that users are in compliance with laws and regulations covered under its mandate.

Levels of advancement:

0. The VS has no program to ensure user compliance with laws and regulations.
1. The VS implements a compliance program consisting of inspection and verification of laws and regulations respect for selected animals, animal-products and processes, but only reports instances of non-compliance.
2. The VS implements a compliance program consisting of inspection and verification of laws and regulations respect for selected animals and animal products and processes, and, if necessary, imposes appropriate penalties in instances of non-compliance.
3. The VS implements a compliance program consisting of inspection and verification of laws and regulations respect for all animals, animal-products and processes covered under its mandate, and, if necessary, impose appropriate penalties in instances of non-compliance.
4. The VS carries out audits of its inspection and verification compliance programs through an efficient national chain of command.

## **2. Setting of regulations<sup>35</sup>**

The capability and authority of the VS to propose laws and to formulate and adopt regulations for animals, animal-products and processes covered under its mandate.

Levels of advancement:

0. The VS does not have the authority to prepare national legislation and set regulations.
1. The VS has the technical capability to propose national legislation and formulate regulations.
2. The VS is based on national legislation and has the flexibility and legal framework necessary in order to propose legislation and set regulations s.

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<sup>34</sup> Regulations are sanitary measures that include all pertinent laws, decrees, regulations and technical prescriptions and procedures. Compliance is verified by VS through inspections and performance assessments

<sup>35</sup> Regulations are sanitary measures that include all pertinent laws, decrees, regulations and technical prescriptions and procedures. Compliance is verified by VS through inspections and performance assessments

3. The VS is based on national legislation and proposes legislation and set regulations, applying procedures that take into consideration the opinions of its users.

### 3. International harmonization

The capability and authority of the VS to be active in international harmonization and ensure that the national laws and regulation covered under its mandate are in conformity with relevant international standards, guidelines and recommendations.

Levels of advancement:

0. The VS has no process to be aware of international standards. National laws and regulation do not take account of international standards, guidelines and recommendations.
1. The VS is aware of relevant standards but has no process to identify gaps, inconsistencies, or non-conformities in national laws and regulation as compared to international standards, guidelines and recommendations.
2. The VS monitors the establishment of new international standards, guidelines and recommendations and periodically reviews national laws and regulation with the aim of harmonizing them as appropriate with international standards, guidelines and recommendations.
3. Same as previous level plus the VS is active in reviewing and commenting on draft standards, guidelines and recommendations to relevant intergovernmental organizations.
4. Same as previous level plus the VS actively and regularly participates at the international level in the formulation, negotiation and adoption of international standards, guidelines and recommendations.<sup>36</sup>

### 4. Certification<sup>37</sup>

The capability and authority of the VS to certify products, services and processes covered under its mandate and in accordance with the national laws and regulations and international standards, guidelines and recommendations.

Levels of advancement:

0. The VS has neither the capability nor the authority to certify animal health status, products, services or processes.

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<sup>36</sup> A country could be active in international standard setting without actively pursuing national changes. The importance of this element is to promote national change.

<sup>37</sup> All certification procedures have to take into account the OIE standards on quality of VS and on certification.

In carrying out certification programmes, the VS must always operate free of political interference from the private sector. However some of these programmes can be executed by independent parties, which have been delegated and audited by the Veterinary Services.

1. The VS has the authority to certify selected animals, animal products, services or processes.
2. The VS carries out certification programs for selected animals, animal products, services or processes.
3. The VS can develop and carry out certification programs for all animals, animal products, services or processes.
4. The veterinary service has certification power as necessary for all relevant animals and animal products and carries out audits of its certification programs through an efficient national chain of command in order to maintain confidence in its system.

## **5. Equivalency<sup>38</sup> and other sanitary agreements**

The capability and authority of the VS to negotiate implement and maintain equivalency and other sanitary agreements with other countries on veterinary requirements under its mandate.

Levels of advancement:

0. The VS has neither the authority nor the capability to negotiate and approve equivalency and other sanitary agreements with other countries.
1. The VS has the authority to negotiate and approve equivalency and other sanitary agreements with other countries.
2. Same as previous level plus the VS evaluates and proposes equivalency and other sanitary agreements with other countries on selected animals, animal products and processes.
3. Same as previous level plus the VS actively pursues the development of equivalency and other sanitary agreements with other countries on new products and processes.
4. Same as previous level plus the VS has a program that includes the feedback of its users along with advances in international standards, guidelines and recommendations, and then pursues specific equivalency and other sanitary agreements with other countries.

## **6. Traceability**

The capability and authority of the VS to track the history, location and distribution of animals and their related products covered under its mandate<sup>39</sup>.

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<sup>38</sup> The term, equivalency, refers to the state wherein the sanitary measure(s) proposed by the exporting country as an alternative to those of the importing country, achieve(s) the same level of protection  
Guidelines on equivalency published in the OIE Codes have to be taken into account



Levels of advancement:

0. The VS has no program to track animals and their related products.
1. The VS can document and inspect the sanitary status at specific points across the agro-food chain for selected animals and their related products.
2. The VS has procedures in place and can track and inspect selected animals and their related products across that portion of the agri-food chain covered under its mandate.
3. The VS, along with the other relevant State institutions and its users, has coordinated procedures in place that can track and inspect animals and related animal products across the entire agri-food chain.
4. The VS, in cooperation with the other relevant State institutions and its users, carries out audits of its traceability procedures.
5. The VS manage and/or inspect a national data base on relevant animals and their movements.

## **7. Transparency**

The capability and authority of the VS to notify the WTO/SPS and the OIE of its national regulations, sanitary status and decisions on the control of relevant diseases, in accordance with the obligations, standards and procedures established by these organizations.

Levels of advancement:

0. The VS does not notify the WTO/SPS and the OIE of its national regulations and decisions on control of relevant diseases, and the OIE of its sanitary status.
1. The VS partially notifies the WTO/SPS and the OIE of its national regulations and decisions on control of relevant diseases, and the OIE of its sanitary status.
2. The VS notifies the WTO/SPS and the OIE of its national regulations and decisions on control of relevant diseases, and the OIE of its sanitary status, in full compliance with the criteria established by these organizations.
3. The VS informs users of changes in its regulations and decisions on control of relevant diseases and sanitary status, changes in the regulations and sanitary status of other countries, and raises awareness with its users of the importance of being transparent.
4. The VS, along with the other relevant State institutions, carries out audits of its transparency procedures<sup>40</sup> through an efficient national chain of command.

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<sup>39</sup> In compliance with OIE definitions, guidelines and relevant chapters of the Code on certain diseases.

<sup>40</sup> In compliance with OIE standards on evaluation of VS

## 8. Zoning<sup>41</sup>

The capability and authority of the VS to establish and maintain disease free zones/<sup>42</sup> or zones/ of low disease prevalence<sup>43</sup>, in accordance to the criteria established by the WTO/SPS and the OIE.

Levels of advancement:

0. The VS cannot establish disease free zones or zones of low disease prevalence.
1. The national veterinary service can identify sub-populations to be regionalized, and establish the current sanitary status of selected animals and their related products originating from these prescribed areas.
2. The VS has implemented biosecurity control measures that enable it to establish disease free zones or zones of low disease prevalence for selected animals and their related products.
3. The VS collaborates with its users and relevant State institutions to define responsibilities execute actions and otherwise enable it to maintain disease free zones or zones of low disease prevalence for selected animals and their related products.
4. The VS demonstrates scientifically, the establishment of disease free zones/ or zones of low disease prevalence, and gains the recognition as such by other countries for selected animals and their related products.
5. The VS has a specific program that defines, establishes and demonstrates scientifically, new disease free zones or zones of low disease prevalence

## 9. Compartmentalization<sup>44</sup>

The capability and authority of the VS to establish and maintain disease free compartments<sup>45</sup> / or compartments / of low disease prevalence<sup>46</sup>, in accordance to the criteria established by the WTO/SPS and the OIE.

Levels of advancement:

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<sup>41</sup> For purposes of the Terrestrial Code and the OIE, 'zoning' and 'regionalization' have the same meaning. Implementation of these concepts has to take into account OIE standards included in the Codes

<sup>42</sup> The phrase, disease free zones: refers to animal sub-populations in which the absence of a given disease has been demonstrated to occur in accordance to the provisions outlined in the Terrestrial Animal Health Code of the OIE.

<sup>43</sup> The phrase, zones of low disease prevalence, refers to zones, which can encompass the entire territory of a country, part of a country, or subpopulations within a country, in which a given disease exists only to a limited extent, and is subject to effective surveillance, control or eradication measures

<sup>44</sup> Implementation of this concepts has to take into account OIE standards included in the Codes

<sup>45</sup> The phrase, disease free compartments, refers to animal sub-populations in which the absence of a given disease has been demonstrated to occur in accordance to the provisions outlined in the Terrestrial Animal Health Code of the OIE

<sup>46</sup> The phrase, compartments of low disease prevalence, refers to compartments, which can encompass subpopulation within a compartment, in which a given disease exists only to a limited extent, and is subject to effective surveillance, control or eradication measures.

0. The VS cannot establish disease free compartments or compartments of low disease prevalence.
  1. The national veterinary service can identify sub-populations to be regionalized, and establish the current sanitary status of selected animals and their related products originating from these prescribed areas.
  2. The VS has implemented biosecurity control measures that enable it to establish disease free compartments or compartments of low disease prevalence for selected animals and their related products.
  3. The VS collaborates with its users and relevant State institutions to define responsibilities execute actions and otherwise enable it to maintain disease free compartments or compartments of low disease prevalence for selected animals and their related products.
  4. The VS demonstrates scientifically, the establishment of disease free compartments or compartments of low disease prevalence, and gains the recognition as such by other countries for selected animals and their related products.
  5. The VS has a specific program that defines, establishes and demonstrates scientifically, new disease free compartments or compartments of low disease prevalence.
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## CHAPTER 2.1.1.

## CRITERIA FOR LISTING DISEASES

**Community comments:**  
**The Community supports this proposal.**

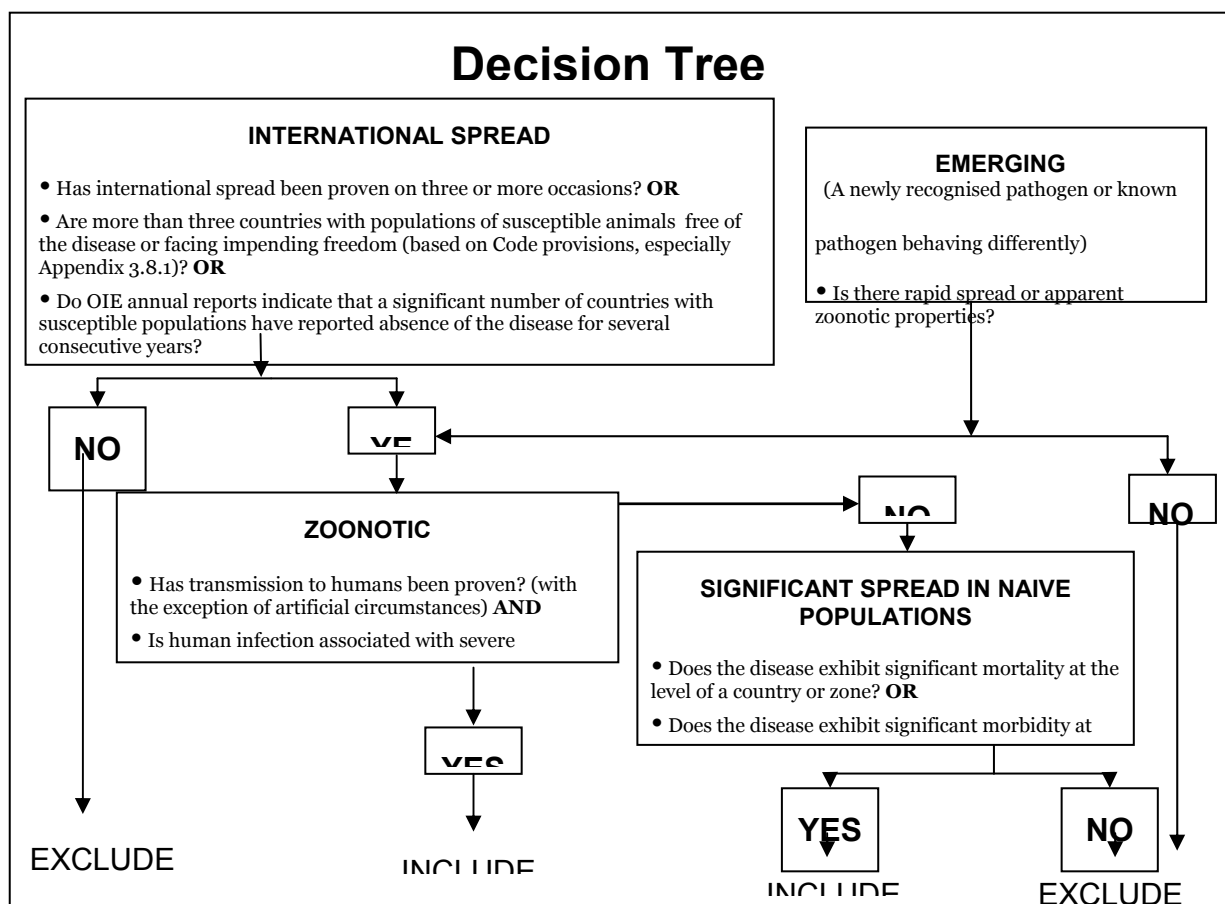
## Article 2.1.1.1.

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

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

## Article 2.1.1.2.

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



Article 2.1.1.3.

The following diseases are included in the OIE List.

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

- Anthrax
- Aujeszky's disease
- Bluetongue
- Brucellosis (*Brucella abortus*)
- Brucellosis (*Brucella melitensis*)
- Brucellosis (*Brucella suis*)
- Crimean Congo haemorrhagic fever

- Echinococcosis/hydatidosis
- Foot and mouth disease
- Heartwater
- Japanese encephalitis
- Leptospirosis
- New world screwworm (*Cochliomyia hominivorax*)
- Old world screwworm (*Chrysomya bezziana*)
- Paratuberculosis
- Q fever
- Rabies
- Rift Valley fever
- Rinderpest
- Trichinellosis
- Tularemia
- Vesicular stomatitis
- West Nile fever.

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

- Bovine anaplasmosis
- Bovine babesiosis
- Bovine genital campylobacteriosis
- Bovine spongiform encephalopathy
- Bovine tuberculosis

- Bovine viral diarrhoea
  - Contagious bovine pleuropneumonia.
  - Enzootic bovine leukosis
  - Haemorrhagic septicaemia
  - Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis
  - Lumpy skin disease
  - Malignant catarrhal fever
  - Theileriosis
  - Trichomonosis
  - Trypanosomosis (tsetse-transmitted).
3. The following diseases are included within the category of sheep and goat diseases:
- Caprine arthritis/encephalitis
  - Contagious agalactia
  - Contagious caprine pleuropneumonia
  - Enzootic abortion of ewes (ovine chlamydiosis)
  - Maedi–visna
  - Nairobi sheep disease
  - Ovine epididymitis (*Brucella ovis*)
  - Peste des petits ruminants
  - Salmonellosis (*S. abortusovis*)
  - Scrapie
  - Sheep pox and goat pox.

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

- African horse sickness
- Contagious equine metritis
- Dourine
- Equine encephalomyelitis (Eastern)
- Equine encephalomyelitis (Western)
- Equine infectious anaemia
- Equine influenza
- Equine piroplasmosis
- Equine rhinopneumonitis
- Equine viral arteritis
- Glanders
- Surra (*Trypanosoma evansi*)
- Venezuelan equine encephalomyelitis.

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

- African swine fever
- Classical swine fever
- Nipah virus encephalitis
- Porcine cysticercosis
- Porcine reproductive and respiratory syndrome
- Swine vesicular disease
- Transmissible gastroenteritis.



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

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

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

- Myxomatosis
- Rabbit haemorrhagic disease.

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

- Acarapisosis of honey bees
- American foulbrood of honey bees
- European foulbrood of honey bees

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

9. The following diseases are included within the category of other diseases:

- Camelpox
- Leishmaniosis.

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## CHAPTER 2.2.10.

## FOOT AND MOUTH DISEASE

**Community comments:**

**The Community can support this proposal but would like the points noted below taken on board. In addition it is still very concerned about the requirements in Article 2.2.10.20 as it believes the risk of importing bone in meat from an area which is free of FMD with vaccination is too high. The recent outbreaks in Brazil tend to highlight this problem as there have been about 34 confirmed outbreaks and in addition some suspicions with clinical signs but no virus isolation in an area which is supposed to have a good vaccine status!**

## Article 2.2.10.1.

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

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

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

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

The following defines the occurrence of FMDV infection:

1. FMDV has been isolated and identified as such from an animal or a product derived from that animal, or
2. viral antigen or viral RNA specific to one or more of the serotypes of FMDV has been identified in samples from one or more animals showing clinical signs consistent with FMD, or epidemiologically linked to a confirmed or suspected *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV, or
3. antibodies to structural or nonstructural proteins of FMDV that are not a consequence of vaccination, have been identified in one or more animals showing clinical signs consistent with FMD, or epidemiologically linked to a confirmed or suspected *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV.

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

## Article 2.2.10.2.

**FMD free country where vaccination is not practised**

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

1. have a record of regular and prompt animal disease reporting;
2. send a declaration to the OIE stating that:
  - a) there has been no *outbreak* of FMD during the past 12 months,
  - b) no evidence of FMDV infection has been found during the past 12 months,
  - c) no vaccination against FMD has been carried out during the past 12 months,

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

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

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

#### Article 2.2.10.3.

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

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

1. have a record of regular and prompt animal disease reporting;
2. send a declaration to the OIE that there has been no *outbreak* of FMD for the past 2 years and no evidence of FMDV circulation for the past 12 months, with documented evidence that:
  - a) surveillance for FMD and FMDV circulation in accordance with Appendix 3.8.7. is in operation, and that regulatory measures for the prevention and control of FMD have been implemented;
  - b) routine vaccination is carried out for the purpose of the prevention of FMD;
  - c) the vaccine used complies with the standards described in the *Terrestrial Manual*.

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

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

#### Article 2.2.10.4.

#### **FMD free zone where vaccination is not practised**

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

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

2. send a declaration to the OIE stating that it wishes to establish an FMD free *zone* where vaccination is not practised, and that within the proposed FMD free zone:
  - a) there has been no *outbreak* of FMD during the past 12 months;
  - b) no evidence of FMDV infection has been found during the past 12 months;
  - c) no vaccination against FMD has been carried out during the past 12 months;
  - d) no vaccinated animal has been introduced into the zone since the cessation of vaccination, except in accordance with Articles 2.2.10.8.;
3. supply documented evidence that surveillance for both FMD and FMDV infection in accordance with Appendix 3.8.7. is in operation in the proposed FMD free *zone* where vaccination is not practised;
4. describe in detail:
  - a) regulatory measures for the prevention and control of both FMD and FMDV infection,
  - b) the boundaries of the FMD free *zone* and, if applicable, the *buffer zone* or physical or geographical barriers,
  - c) the system for preventing the entry of the virus (including the control of the movement of susceptible animals) into the FMDV free *zone* (in particular if the procedure described in Article 2.2.10.8. is implemented),

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

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

#### Article 2.2.10.5.

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

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

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

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

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

3. supply documented evidence that the vaccine used complies with the standards described in the *Terrestrial Manual*;
4. describe in detail:
  - a) regulatory measures for the prevention and control of both FMD and FMDV circulation,
  - b) the boundaries of the FMD free *zone* where vaccination is practised and, if applicable, the *buffer zone* or physical or geographical barriers,
  - c) the system for preventing the entry of the virus into the FMD free *zone* (in particular if the procedure described in Article 2.2.10.8. is implemented),

and supply evidence that these are properly implemented and supervised;

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

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

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

Article 2.2.10.6.

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

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

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

Article 2.2.10.7.

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

1. When an FMD *outbreak* or FMDV infection occurs in an FMD free country or *zone* where vaccination is not practised, one of the following waiting periods is required to regain the status of FMD free country or *zone* where vaccination is not practised:
  - a) 3 months after the last *case* where a *stamping-out policy* and serological surveillance are applied in accordance with Appendix 3.8.7.; or
  - b) 3 months after the slaughter of all vaccinated animals where a *stamping-out policy*, emergency vaccination and serological surveillance are applied in accordance with Appendix 3.8.7.; or
  - c) 6 months after the last *case* or the last vaccination (according to the event that occurs the latest), where a *stamping-out policy*, emergency vaccination not followed by the slaughtering of all vaccinated animals, and serological surveillance are applied in accordance with Appendix 3.8.7.,

provided that a serological survey based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of infection in the remaining vaccinated population.

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

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

Article 2.2.10.8.

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

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

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

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

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

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

Article 2.2.10.9.

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

for FMD susceptible animals

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

1. showed no clinical sign of FMD on the day of shipment;
2. were kept in an FMD free country or *zone* where vaccination is not practised since birth or for at least the past 3 months.

**Community comment:**

**The following wording should be added “and the animals are not vaccinated.” The Community notes that the Scientific Commission has been asked to further examine the need for such a requirement in Articles 2.2.10.9. and 2.2.10.10**

Article 2.2.10.10.

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

for domestic ruminants and pigs

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

1. showed no clinical sign of FMD on the day of shipment;
2. were kept in an FMD free country since birth or for at least the past 3 months; and

**Community comment:**

**The words “or zone” should be added after country.**

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

Article 2.2.10.11.

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

for domestic ruminants and pigs

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

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



2. were kept in the *establishment* of origin since birth, or
  - a) for the past 30 days, if a *stamping-out policy* is in force in the *exporting country*, or
  - b) for the past 3 months, if a *stamping-out policy* is not in force in the *exporting country*,
 and that FMD has not occurred within a 10-kilometre radius of the *establishment* of origin for the relevant period as defined in points a) and b) above; and
3. were isolated in an *establishment* for the 30 days prior to shipment, and all animals in isolation were subjected to diagnostic tests (probang and serology) for evidence of FMDV infection with negative results at the end of that period, and that FMD did not occur within a 10-kilometre radius of the *establishment* during that period; or
4. were kept in a *quarantine station* for the 30 days prior to shipment, all animals in quarantine were subjected to diagnostic tests (probang and serology) for evidence of FMDV infection with negative results at the end of that period, and that FMD did not occur within a 10-kilometre radius of the *quarantine station* during that period;
5. were not exposed to any source of FMD infection during their transportation from the *quarantine station* to the *place of shipment*.

Article 2.2.10.12.

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

for fresh semen of domestic ruminants and pigs

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

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

Article 2.2.10.13.

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

for frozen semen of domestic ruminants and pigs

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

1. the donor animals:
  - a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;

- b) were kept in an FMD free country or *zone* where vaccination is not practised for at least 3 months prior to collection;
2. the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.1. or Appendix 3.2.2., as relevant.

Article 2.2.10.14.

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

for semen of domestic ruminants and pigs

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

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

Article 2.2.10.15.

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

for semen of domestic ruminants and pigs

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

1. the donor animals:
  - a) showed no clinical sign of FMD on the day of collection of the semen;

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

Article 2.2.10.16.

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

Article 2.2.10.17.

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

for *in vitro* produced embryos of cattle

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

1. the donor females:
  - a) showed no clinical sign of FMD at the time of collection of the oocytes;
  - b) were kept in a country or *zone* free from FMD at the time of collection;
2. fertilisation was achieved with semen meeting the conditions referred to in Articles 2.2.10.12., 2.2.10.13., 2.2.10.14. or 2.2.10.15., as relevant;
3. the oocytes were collected, and the embryos were processed and stored in conformity with the provisions of Appendix 3.3.2. or Appendix 3.3.3., as relevant.

Article 2.2.10.18.

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

for *in vitro* produced embryos of cattle

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

1. the donor females:
  - a) showed no clinical sign of FMD at the time of collection of the oocytes;
  - b) were kept in a country or *zone* free from FMD for at least 3 months prior to collection;
  - c) if destined for an FMD free country or *zone* where vaccination is not practised:
    - i) have not been vaccinated and were subjected, with negative results, to tests for antibodies against FMD virus; or
    - ii) had been vaccinated at least twice, with the last vaccination not less than one month and not more than 12 months prior to collection;
2. no other animal present in the *establishment* has been vaccinated within the month prior to collection;
3. fertilization was achieved with semen meeting the conditions referred to in Articles 2.2.10.12., 2.2.10.13., 2.2.10.14. or 2.2.10.15., as relevant;
4. the oocytes were collected, and the embryos were processed and stored in conformity with the provisions of Appendix 3.3.2. or Appendix 3.3.3., as relevant.

Article 2.2.10.19.

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

for *fresh meat* of FMD susceptible animals

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

1. have been kept in the FMD free country or *zone* where vaccination is not practised since birth, or which have been imported in accordance with Article 2.2.10.9., Article 2.2.10.10. or Article 2.2.10.11.;
2. have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results.

Article 2.2.10.20.

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

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

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

1. have been kept in the FMD free country or *zone* where vaccination is practised since birth, or which have been imported in accordance with Article 2.2.10.9., Article 2.2.10.10. or Article 2.2.10.11.;
2. have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results.

Article 2.2.10.21.

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

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

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

1. have been kept in the FMD free country or *zone* where vaccination is practised since birth, or which have been imported in accordance with Article 2.2.10.9., Article 2.2.10.10. or Article 2.2.10.11.;
2. have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results.

Article 2.2.10.22.

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

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

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

1. comes from animals which:
  - a) have remained in the *exporting country* for at least 3 months prior to slaughter;
  - b) have remained, during this period, in a part of the country where cattle are regularly vaccinated against FMD and where official controls are in operation;
  - c) have been vaccinated at least twice with the last vaccination not more than 12 months and not less than one month prior to slaughter;
  - d) were kept for the past 30 days in an *establishment*, and that FMD has not occurred within a 10-kilometre radius of the *establishment* during that period;
  - e) have been transported, in a *vehicle* which was cleansed and disinfected before the cattle were loaded, directly from the *establishment* of origin to the *approved abattoir* without coming into contact with other animals which do not fulfil the required conditions for export;

- f) have been slaughtered in an *approved abattoir*:
    - i) which is officially designated for export;
    - ii) in which no FMD has been detected during the period between the last *disinfection* carried out before slaughter and the shipment for export has been dispatched;
  - g) have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results within 24 hours before and after slaughter;
2. comes from deboned carcasses:
- a) from which the major lymph nodes have been removed;
  - b) which, prior to deboning, have been submitted to maturation at a temperature above + 2°C for a minimum period of 24 hours following slaughter and in which the pH value was below 6.0 when tested in the middle of both the longissimus dorsi.

Article 2.2.10.23.

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

for *meat products* of domestic ruminants and pigs

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

1. the entire consignment of *meat* comes from animals which have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results;
2. the *meat* has been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Article 3.6.2.1.;
3. the necessary precautions were taken after processing to avoid contact of the *meat products* with any potential source of FMD virus.

Article 2.2.10.24.

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

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

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

Article 2.2.10.25.

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

for milk, cream, milk powder and milk products

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

1. these products:
  - a) originate from herds or flocks which were not infected or suspected of being infected with FMD at the time of *milk* collection;
  - b) have been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Article 3.6.2.5. and in Article 3.6.2.6.;
2. the necessary precautions were taken after processing to avoid contact of the products with any potential source of FMD virus.

Article 2.2.10.26.

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

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

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

Article 2.2.10.27.

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

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

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

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

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

Article 2.2.10.28.

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

for straw and forage

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

1. are free of grossly identifiable contamination with material of animal origin;
2. have been subjected to one of the following treatments, which, in the case of material sent in bales, has been shown to penetrate to the centre of the bale:
  - a) either to the action of steam in a closed chamber such that the centre of the bales has reached a

minimum temperature of 80°C for at least 10 minutes,

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

OR

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

Article 2.2.10.29.

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

for skins and trophies derived from FMD susceptible wild animals

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

Article 2.2.10.30.

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

for skins and trophies derived from FMD susceptible wild animals

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

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

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## APPENDIX 3.8.7.

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

**The Community fully supports this proposal as it believes the use of compartmentalisation for FMD is too high a risk to accept at this time.**

## Article 3.8.7.1.

**Introduction**

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

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

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

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

## Article 3.8.7.2.

**General conditions and methods**

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

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

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

#### Article 3.8.7.3.

### Surveillance strategies

#### 1. Introduction

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

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

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

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

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

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

## 2. Clinical surveillance

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

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

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

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

## 3. Virological surveillance

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

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

#### 4. Serological surveillance

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

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

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

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

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

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

Article 3.8.7.4.

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

In addition to the general conditions described in Chapter 2.2.10., a Member Country applying for recognition of FMD freedom for the country or a *zone* ~~or a compartment~~ where vaccination is not practised should provide evidence for the existence of an effective surveillance programme. The strategy and design of the surveillance programme will depend on the prevailing epidemiological circumstances and will be planned and implemented according to general conditions and methods in this Appendix, to demonstrate absence of FMDV infection, during the preceding 12 months in susceptible populations. This requires the support of a national or other laboratory able to undertake identification of FMDV infection through virus/antigen/genome detection and antibody tests described in the *Terrestrial Manual*.

Article 3.8.7.5.

#### **Countries, or zones ~~or compartments~~ applying for freedom from FMD where vaccination is**

## practised

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

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

Article 3.8.7.6.

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

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

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

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

The time periods before which an application can be made for re-instatement of freedom from FMD depends on which of these alternatives is followed. The time periods are prescribed in Article 2.2.10.7.

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

Article 3.8.7.7.

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

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

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

#### 3.1.1.1. 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.

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

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

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

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

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

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

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

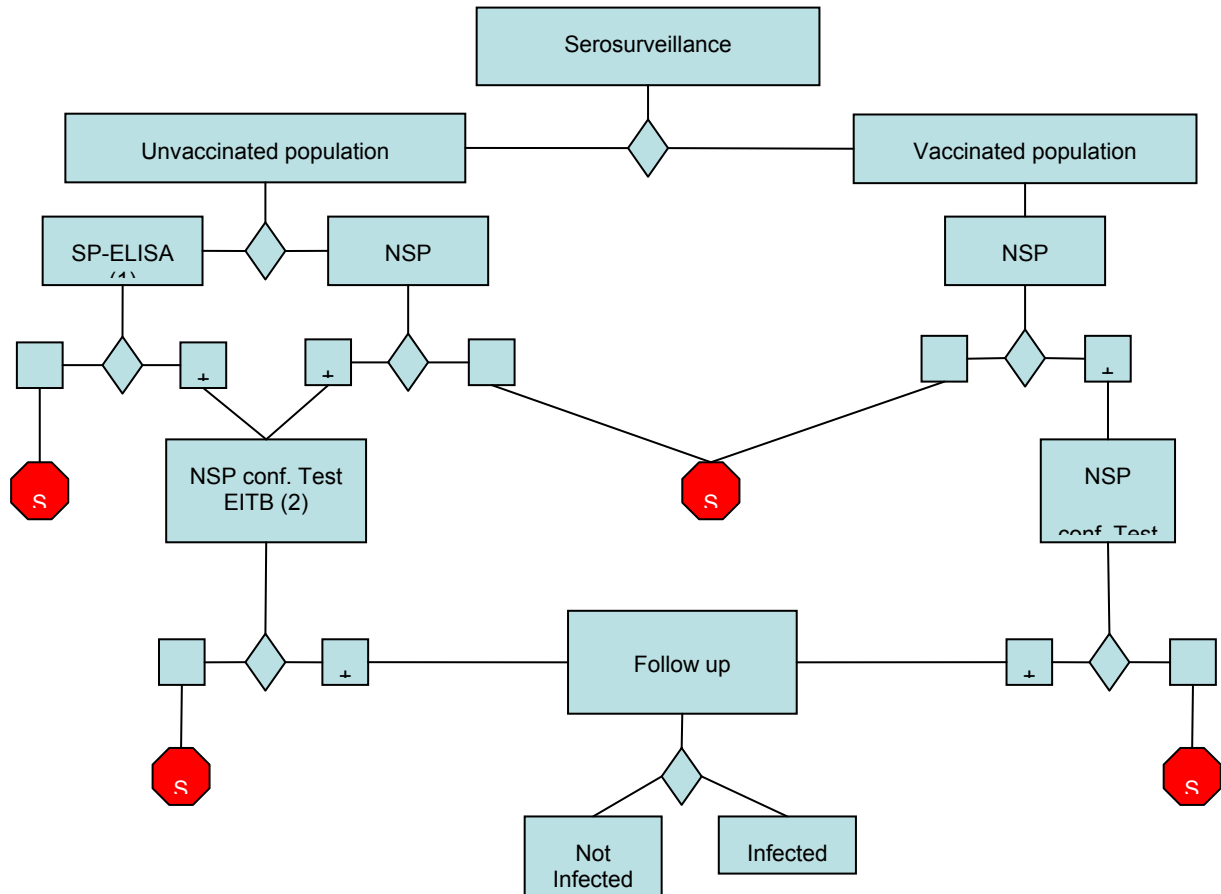
Laboratory results should be examined in the context of the epidemiological situation. Corollary information needed to complement the serological survey and assess the possibility of viral circulation includes but is not limited to:

- characterization of the existing production systems;
- results of clinical surveillance of the suspects and their cohorts;
- quantification of vaccinations performed on the affected sites;
- sanitary protocol and history of the *establishments* with positive reactors;

- control of animal identification and movements;
- other parameters of regional significance in historic FMDV transmission.

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

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



Key:

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



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## CHAPTER 2.2.13.

## BLUETONGUE

**Community comments:**  
**The Community supports this proposal.**

## Article 2.2.13.1.

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

The global BTV distribution is currently between latitudes of approximately 50°N and 34~~5~~°S but is known to be expanding in the northern hemisphere.

In the absence of clinical disease in a country or *zone* within this part of the world, its BTV status should be determined by an ongoing surveillance ~~and monitoring~~ programme (in accordance with Appendix 3.8.X.) ~~designed in accordance with the epidemiology of the disease, i.e. focusing on climatic and geographical factors, the biology and likely competence of *Culicoides* and/or serology of susceptible animals.~~ The programme may need to be adapted to target parts of the country or *zone* at a higher risk due to historical, geographical and climatic factors, ruminant population data and *Culicoides* ecology, or proximity to enzootic or incursional *zones* as described in Appendix 3.8.X.

All countries or *zones* adjacent to a country or *zone* not having free status should be subjected to similar surveillance. 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 BTV, or a bluetongue surveillance programme (in accordance with Appendix 3.8.X.) in the country or *zone* not having free status supports a lesser distance.

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

## Article 2.2.13.2.

**BTV free country or zone**

1. A country or a *zone* may be considered free from BTV when bluetongue is notifiable in the whole country and either:
  - a) the country or *zone* lies wholly north of 50°N or south of 34~~5~~°S, and is not adjacent to a country or *zone* not having a free status; or
  - b) a surveillance and monitoring programme in accordance with Appendix 3.8.X. has demonstrated no evidence of BTV in the country or *zone* during the past 2 years; or
  - c) a surveillance and monitoring programme has demonstrated no evidence of *Culicoides* likely to be competent BTV vectors in the country or *zone*.
2. A BTV free country or *zone* in which surveillance and monitoring has found no evidence that *Culicoides* likely to be competent BTV vectors are present will not lose its free status through the

importation of vaccinated, seropositive or infective animals, or semen or embryos/ova from infected countries or zones.

3. A BTV free country or zone in which surveillance and monitoring has found evidence that *Culicoides* likely to be competent BTV vectors are present will not lose its free status through the importation of vaccinated or seropositive animals from infected countries or zones, provided:
  - a) the animals have been vaccinated in accordance with the *Terrestrial Manual* at least 60 days prior to dispatch with a vaccine which covers all serotypes whose presence in the source population has been demonstrated through a surveillance and monitoring programme in accordance with Appendix 3.8.X., and that the animals are identified in the accompanying certification as having been vaccinated; or
  - b) the animals are not vaccinated, and a surveillance and monitoring programme in accordance with Appendix 3.8.X. has been in place in the source population for a period of 60 days immediately prior to dispatch, and no evidence of BTV transmission has been detected.
4. A BTV free country or zone adjacent to an infected country or zone should include a zone in which surveillance is conducted in accordance with Appendix 3.8.X. Animals within this zone must be subjected to continuing surveillance. The boundaries of this zone must be clearly defined, and must take account of geographical and epidemiological factors that are relevant to BTV transmission.

#### Article 2.2.13.3.

#### **BTV seasonally free zone**

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

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

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

1. at least 28 days before the earliest date that historical data show bluetongue virus activity has recommenced; or
2. immediately if current climatic data or data from a surveillance and monitoring programme indicate an earlier resurgence of activity of adult *Culicoides* likely to be competent BTV vectors.

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

#### Article 2.2.13.4.

#### **BTV infected country or zone**

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

Article 2.2.13.5.

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

1. ruminants and other BTV susceptible herbivores;
2. semen of these species;
3. embryos/ova of these species;
4. *pathological material* and biological products (from these species) (see Chapter 1.4.6. and Section 1.5.).

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

Article 2.2.13.6.

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

for ruminants and other BTV susceptible herbivores

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

1. the animals were kept in a BTV free country or *zone* since birth or for at least 60 days prior to shipment; or
2. the animals were kept in a BTV free country or *zone* for at least 28 days, then were subjected, with negative results, to a serological test to detect antibody to the BTV group according to the *Terrestrial Manual* and remained in the BTV free country or *zone* until shipment; or
3. the animals were kept in a BTV free country or *zone* for at least 7 days, then were subjected, with negative results, to an agent identification test according to the *Terrestrial Manual* and remained in the BTV free country or *zone* until shipment; or
4. the animals:
  - a) were kept in a BTV free country or *zone* for at least 7 days;
  - b) were vaccinated in accordance with the *Terrestrial Manual* 60 days before introduction into the free country or *zone* against all serotypes whose presence in the source population has been demonstrated through a surveillance and monitoring programme as described in Appendix 3.8.1.;
  - c) were identified as having been vaccinated; and
  - d) remained in the BTV free country or *zone* until shipment;

AND

5. if the animals were exported from a free *zone*, either:
  - a) did not transit through an infected *zone* during transportation to the *place of shipment*; or

- b) were protected from attack from *Culicoides* likely to be competent BTV vectors at all times when transiting through an infected *zone*; or
- c) had been vaccinated in accordance with point 4) above.

Article 2.2.13.7.

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

for ruminants and other BTV susceptible herbivores

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

1. were kept during the seasonally free period in a BTV seasonally free *zone* for at least 60 days prior to shipment; or
2. were kept during the BTV seasonally free period in a BTV seasonally free *zone* for at least 28 days prior to shipment, and were subjected during the residence period in the *zone* to a serological test to detect antibody to the BTV group according to the *Terrestrial Manual*, with negative results, carried out at least 28 days after the commencement of the residence period; or
3. were kept during the BTV seasonally free period in a BTV seasonally free *zone* for at least 14 days prior to shipment, and were subjected during the residence period in the *zone* to an agent identification test according to the *Terrestrial Manual*, with negative results, carried out at least 14 days after the commencement of the residence period; or
4. were kept during the seasonally free period in a BTV seasonally free *zone*, and were vaccinated in accordance with the *Terrestrial Manual* 60 days before introduction into the free country or *zone* against all serotypes whose presence in the source population has been demonstrated through a surveillance and monitoring programme in accordance with Appendix 3.8.X., were identified as having been vaccinated and remained in the BTV free country or *zone* until shipment;

AND

5. if the animals were exported from a free *zone*, either:
  - a) did not transit through an infected *zone* during transportation to the *place of shipment*, or
  - b) were protected from attack from *Culicoides* likely to be competent BTV vectors at all times when transiting through an infected *zone*, or
  - c) were vaccinated in accordance with point 4) above.

Article 2.2.13.8.

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

for ruminants and other BTV susceptible herbivores

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

1. were protected from attack from *Culicoides* likely to be competent BTV vectors for at least 60 days prior to shipment; or
2. were protected from attack from *Culicoides* likely to be competent BTV vectors for at least 28 days

prior to shipment, and were subjected during that period to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, with negative results, carried out at least 28 days after introduction into the *quarantine station*; or

3. were protected from attack from *Culicoides* likely to be competent BTV vectors for at least 14 days prior to shipment, and were subjected during that period to an agent identification test according to the *Terrestrial Manual*, with negative results, carried out at least 14 days after introduction into the *quarantine station*; or
4. were vaccinated in accordance with the *Terrestrial Manual* at least 60 days before shipment, against all serotypes whose presence in the source population has been demonstrated through a surveillance and monitoring programme in accordance with Appendix 3.8.1., and were identified in the accompanying certification as having been vaccinated; or
5. are not vaccinated, a surveillance and monitoring programme in accordance with 3.8.1. has been in place in the source population for a period of 60 days immediately prior to shipment, and no evidence of BTV transmission has been detected;

AND

6. were protected from attack from *Culicoides* likely to be competent BTV vectors during transportation to the *place of shipment*; or
7. were vaccinated 60 days before shipment or had antibodies against all serotypes whose presence in the *zones* of transit has been demonstrated through a surveillance and monitoring programme in accordance with Appendix 3.8.1.

Article 2.2.13.9.

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

for semen of ruminants and other BTV susceptible herbivores

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

1. the donor animals:
  - a) were kept in a BTV free country or *zone* for at least 60 days before commencement of, and during, collection of the semen; or
  - b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, between 21 and 60 days after the last collection for this consignment, with negative results; or
  - c) were subjected to an agent identification test according to the *Terrestrial Manual* on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;
2. the semen was collected, processed and stored in conformity with Appendix 3.2.1.

Article 2.2.13.10.

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

for semen of ruminants and other BTV susceptible herbivores

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

1. the donor animals:
  - a) were kept during the BTV seasonally free period in a seasonally free *zone* for at least 60 days before commencement of, and during, collection of the semen; or
  - b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, with negative results, at least every 60 days throughout the collection period and between 21 and 60 days after the final collection for this consignment; or
  - c) were subjected to an agent identification test according to the *Terrestrial Manual* on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;
2. the semen was collected, processed and stored in conformity with Appendix 3.2.1.

Article 2.2.13.11.

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

for semen of ruminants and other BTV susceptible herbivores

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

1. the donor animals:
  - a) were protected from attack from *Culicoides* likely to be competent BTV vectors for at least 60 days before commencement of, and during, collection of the semen; or
  - b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, with negative results, at least every 60 days throughout the collection period and between 21 and 60 days after the final collection for this consignment; or
  - c) were subjected to an agent identification test according to the *Terrestrial Manual* on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;
2. the semen was collected, processed and stored in conformity with Appendix 3.2.1.

Article 2.2.13.12.

Regardless of the bluetongue status of the *exporting country*, *Veterinary Administrations* of *importing countries* should require:

for *in vivo* derived bovine embryos/oocytes

the presentation of an *international veterinary certificate* attesting that the embryos/oocytes were collected, processed and stored in conformity with the provisions of Appendix 3.3.1. or Appendix 3.3.3., as relevant.

Article 2.2.13.13.

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

for *in vivo* derived embryos of ruminants (other than bovines) and other BTV susceptible herbivores

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

1. the donor females:
  - a) were kept in a BTV free country or *zone* for at least the 60 days prior to, and at the time of, collection of the embryos; or
  - b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, between 21 and 60 days after collection, with negative results; or
  - c) were subjected to an agent identification test according to the *Terrestrial Manual* on a blood sample taken on the day of collection, with negative results;
2. the embryos were collected, processed and stored in conformity with Appendix 3.3.1.

Article 2.2.13.14.

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

for *in vivo* derived embryos/oocytes of ruminants (other than bovines) and other BTV susceptible herbivores and for *in vitro* produced bovine embryos

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

1. the donor females:
  - a) were kept during the seasonally free period in a seasonally free *zone* for at least 60 days before commencement of, and during, collection of the embryos/oocytes; or
  - b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, between 21 and 60 days after collection, with negative results; or
  - c) were subjected to an agent identification test according to the *Terrestrial Manual* on a blood sample taken on the day of collection, with negative results;
2. the embryos/oocytes were collected, processed and stored in conformity with Appendix 3.3.1.

Article 2.2.13.15.

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

for *in vivo* derived embryos/oocytes of ruminants (other than bovines) and other BTV susceptible herbivores and for *in vitro* produced bovine embryos

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

1. the donor females:
  - a) were protected from attack from *Culicoides* likely to be competent BTV vectors for at least



60 days before commencement of, and during, collection of the embryos/oocytes; or

- b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, between 21 and 60 days after collection, with negative results; or
  - c) were subjected to an agent identification test according to the *Terrestrial Manual* on a blood sample taken on the day of collection, with negative results;
2. the embryos/oocytes were collected, processed and stored in conformity with Appendix 3.3.1.

Article 2.2.13.16.

### **Protecting animals from *Culicoides* attack**

When transporting animals through BTV infected countries or *zones*, *Veterinary Administrations* should require strategies to protect animals from attack from *Culicoides* likely to be competent BTV vectors during transport, taking into account the local ecology of the vector.

Potential risk management strategies include:

- 1. treating animals with chemical repellents prior to and during transportation;
- 2. loading, transporting and unloading animals at times of low vector activity (i.e. bright sunshine, low temperature);
- 3. ensuring *vehicles* do not stop en route during dawn or dusk, or overnight, unless the animals are held behind insect proof netting;
- 4. darkening the interior of the *vehicle*, for example by covering the roof and/or sides of *vehicles* with shade cloth;
- 5. monitoring for vectors at common stopping and offloading points to gain information on seasonal variations;
- 6. using historical, ongoing and/or BTV modelling information to identify low risk ports and transport routes.

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APPENDIX 3.X.X.

GUIDELINES FOR THE SURVEILLANCE  
OF BLUETONGUE

**Community comments:**

**The Community supports this proposal but would like to suggest that sentinel animals are individually identified (see Article 3.x.x.4 paragraphs 2 and 4).**

Article 3.X.X.1.

**Introduction**

This Appendix defines the principles and provides a guide for the surveillance of bluetongue (BT) in accordance with Appendix 3.8.1., applicable to countries seeking recognition for a declared BT 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 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 only if necessary 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 Member 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, endemic or area of potential spread) to the local conditions. There is considerable latitude available to Member 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.X.X.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 difference 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 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 presence 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 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 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.

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

#### Article 3.X.X.3.

#### General conditions and methods

1. A surveillance system in accordance with Appendix 3.8.1. should be under the responsibility of the *Veterinary Administration*. In particular:
  - a) a formal and ongoing system for detecting and investigating *outbreaks of disease* should be in place;
  - b) a procedure should be in place for the rapid collection and transport of samples from suspect cases of 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) 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 Administration*. 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*.

With regards to BT, compartment refers to establishments where animals are kept in a confirmed vector free environment to prevent BTV infection. Generally, the conditions to prevent exposure of susceptible

animals to BTV infected vectors will be difficult to apply. However, under specific situations like artificial insemination centres or quarantine stations such conditions may be met. The testing requirements for animals kept in these facilities are described in Articles 2.2.13.11 and 2.2.13.15.

#### Article 3.X.X.4.

### Surveillance strategies

The target population for surveillance aimed at identification of *disease* and/or *infection* should cover susceptible domestic ruminants within the country, *zone* or *compartment*. 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 randomised sampling requiring surveillance consistent with demonstrating 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 Country 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 *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 the OIE or international trading partners, or excessively costly and logistically complicated. The design of any surveillance programme, therefore, requires inputs from professionals competent and experienced in this field.

#### 1. Clinical surveillance

Clinical surveillance aims at the detection of clinical signs of 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.

Surveillance may include serological surveys, for example abattoir surveys, , or a combination of methods.

### **Community comments:**

**The Community proposes the following wording “...the use of sentinel animals (which must be individually identifiable)....”**

The objective of serological surveillance is to detect 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*, *zone* or *compartment*. It is, therefore, essential that the survey is thoroughly documented.

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

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 herds

Sentinel herds 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 herd 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 herd programmes allow incidence rates to be determined and the timing of infections to be observed.

A sentinel herd programme should use animals of known source and history of exposure, control management variables such as use of insecticides and be flexible in its design in terms of sampling frequency and choice of tests.

#### **Community comments:**

**The Community proposes the following an additional sentence as follows “Sentinel animals must be individually identifiable.”**

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 herd 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.

The definitive measure of a country or *zone's* BTV infection status is detection 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 vector 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 species present in an area, their seasonal incidence and profile, and their 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 domestic ruminants, or the use of drop traps over ruminant animals.

The number of traps to be used in a vector surveillance system and the frequency of their use will depend on the availability of resources but is also dependent upon the size or ecological characteristics of the area to be surveyed.

The operation of vector surveillance sites at the same locations as sentinel herds 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 herds of domestic ruminants) are preferred to detect virus circulation.

#### Article 3.X.X.5.

#### **Documentation of BTV infection free status**

##### 1. Countries declaring freedom from BTV infection for the country, zone or compartment

In addition to the general conditions described in Chapter 2.2.13. of the Terrestrial Code, a Member Country declaring freedom from BTV infection 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 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, zones or compartments 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, *zone* or *compartment*, it may be that a decision is reached to vaccinate only certain species or other subpopulations.

In countries or *zones* that practice 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.X.X.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

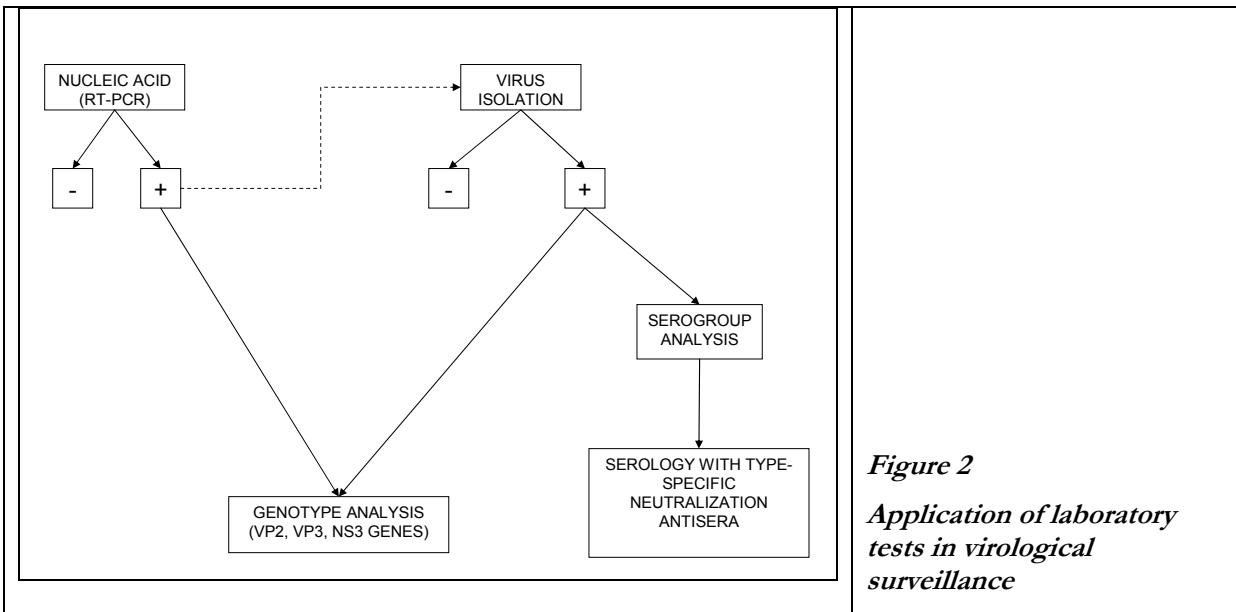
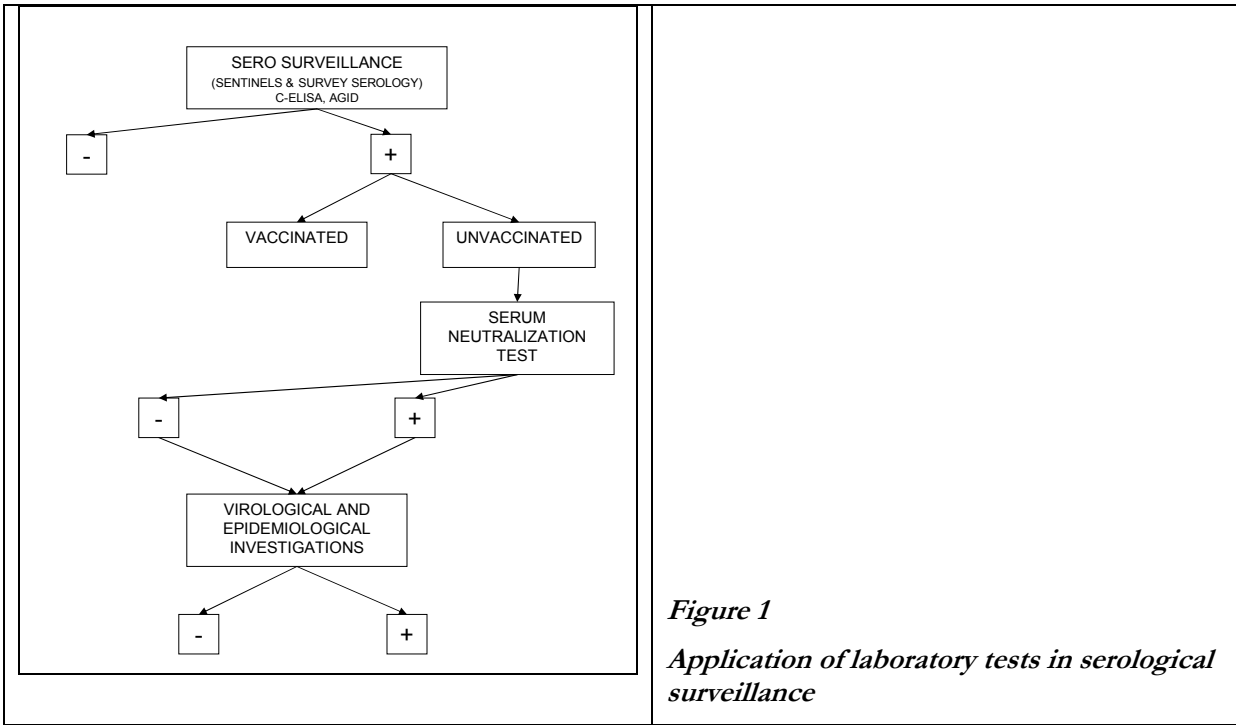
The presence of BTV in ruminant blood and tissues can be detected by virus isolation or polymerase chain reaction (PCR) as described in the *Terrestrial Manual*.

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.





CHAPTER 2.3.13.

BOVINE SPONGIFORM ENCEPHALOPATHY

**Community comment:**

**The Community welcomes the work done by the Code Commission but can only support this proposed amendments if the points below are taken into account.**

Article 2.3.13.1.

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

1. When authorising import or transit of the following *commodities* and any products made from these *commodities* and containing no other tissues from cattle, *Veterinary Administrations* should not require any BSE related conditions, regardless of the BSE risk status of the cattle population of the *exporting country, zone or compartment*:
  - a) *milk and milk products*;
  - b) semen and *in vivo* derived cattle embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society;
  - c) hides and skins;
  - d) gelatin and collagen prepared exclusively from hides and skins;
  - e) protein-free tallow (maximum level of insoluble impurities of 0.15% in weight) and derivatives made from this tallow;

**Community comments**

**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 ~~were subject to passed ante-mortem and post-mortem inspections and were not suspect or confirmed BSE cases~~; and which has been prepared in a manner to avoid contamination with tissues listed in Article 2.3.13.13.;

**Community comment:**

**The Community took note of the proposal to remove the 30 months age limit on trade in deboned skeletal muscle meat between countries, irrespective of BSE status.**

**It may be premature to change the existing controls particularly in view of preliminary data from research by the National Institute of Animal Health regarding PrPsc detection in peripheral nerves ( Iwamura et al 2005, in Prions, Food and Drug Safety), and data from the German research regarding possible low levels of BSE infectivity detected in cranial and peripheral nerves and semitendinosus muscle ( Bushmann & Groschup 2005, in J. Infect.Dis. 192, 934-342). Ongoing pathogenesis studies in UK and DE will provide more information in this respect in the near future.**

**The Community propose to await the results of ongoing research before assessing the modification of the current age criteria for deboned muscle meat of cattle as defined in Article 2.3.13.1, point g).**

- h) blood and blood by-products, from cattle which were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process.
- 2. When authorising import or transit of other *commodities* listed in this chapter, *Veterinary Administrations* should require the conditions prescribed in this Chapter relevant to the BSE risk status of the cattle population of the *exporting country, zone or compartment*.

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

Article 2.3.13.2.

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

## Appendix XIII (contd)

1. the outcome of a *risk assessment* (which is reviewed annually), based on Section 1.3., identifying all potential factors for BSE occurrence and their historic perspective:

### Community comments:

The requirement is that the risk assessment should be annually reviewed. If the intention is that the member countries provided the documentation to indicate whether the situation had changed in the previous 12 months, it should be clearly specified.

### The Community proposes the following:

'1. the outcome of a risk assessment, based on Section 1.3., identifying all potential factors for BSE occurrence and their historic perspective. Countries have to provide the documentation to indicate whether the situation had changed in the previous 12 months. In that case a review of the risk assessment is needed.'

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

- a) Release assessment

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

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

### Community comments

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

- ii) *meat-and-bone meal* or *greaves* from the indigenous ruminant population;
- iii) imported *meat-and-bone meal* or *greaves*;
- iv) imported live ruminants ~~animals~~;
- v) imported animal feed and feed ingredients;

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

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

#### Community comments

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

**On point vi), products from the indigenous ruminant population should also be included under point v), if there is a pre-existing TSE in that population.**

#### b) Exposure assessment

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

- i) recycling and amplification of the BSE agent through consumption by cattle of *meat-and-bone meal* or *greaves* of ruminant origin, or other feed or feed ingredients contaminated with these;
  - ii) the use of ruminant carcasses (including from fallen stock), by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of animal feed manufacture;
  - iii) the feeding or not of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants, including measures to prevent cross-contamination of animal feed;
  - iv) the level of surveillance for BSE conducted on the cattle population to that time and the results of that surveillance;
2. on-going awareness programme for veterinarians, farmers, and workers involved in transportation, marketing and slaughter of cattle to encourage reporting of all *cases* showing clinical signs consistent with BSE in target sub-populations as defined in Appendix 3.8.4.;
  3. the compulsory notification and investigation of all cattle showing clinical signs consistent with BSE;

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

#### Community comments

#### **The Community proposes to replace approved laboratories by approved method.**

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

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

Article 2.3.13.3.

#### **Negligible BSE risk**

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

1. a *risk assessment*, as described in point 1) of Article 2.3.13.2., has been conducted in order to identify the historical and existing risk factors, and the country has demonstrated that appropriate ~~generic~~ specific measures have been taken for the relevant period of time defined below to manage ~~all risks~~ each risk identified;
2. the country has demonstrated that Type B surveillance, in accordance with Appendix 3.8.4, is in place and the relevant points target, in accordance with Table 1, has been met;

#### Community comments

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

3. EITHER:
  - a) there has been no *case* of BSE, or any *case* of BSE has been demonstrated to have been imported and has been completely destroyed, and:
    - i) the criteria in points 2) to 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 *meat-and-bone meal* or *greaves* derived from ruminants has not been fed to ruminants;

#### Community comments

**It is far more relevant to take into account the date of birth rather than the date of reporting. However it seems that there is no rational for the 8 years period. In view of the long incubation period of BSE, it is not possible to precisely assess the impact of any control measure before several years.**

**Simulation studies performed in France to estimate the pattern of the BSE epidemic (not published) indicate that the probability to detect of a BSE case 8 years after taken certain risk management measures is 100 % if 100 animals would have been contaminated just after the measures should have been installed. This probability will be reduced up to 72, 8% if only 10 animals would have been contaminated. This period has to be prolonged up to 11 years to have a probability of 79,8 % to detect a BSE case. Further prolonging the period will not increase the probability due the slaughter and mortality of the animals. The Community proposes to take this into account when evaluating the time period a feed ban has to be in place.**

**Therefore the Community proposes the following:**

**“ii) it has been demonstrated, thorough an appropriate level of control and audit, that for at least 11 years meat-and-bone meal and greaves derived from ruminants has not been fed to ruminants;”**

OR

- b) ~~the last indigenous case of BSE was reported more than 7 years ago~~ any indigenous case of BSE was born more than 8 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, thorough an appropriate level of control and audit, that for at least 8 years *meat-and-bone meal* and *greaves* derived from ruminants has not been fed to ruminants; and

#### **Community comments**

**It is far more relevant to take into account the date of birth rather than the date of reporting. However it seems that there is no rational for the 8 years period. In view of the long incubation period of BSE, it is not possible to precisely assess the impact of any control measure before several years. Simulation studies performed in France to estimate the pattern of the BSE epidemic (not published) indicate that the probability to detect of a BSE case 8 years after taken certain risk management measures is 100 % if 100 animals would have been contaminated just after the measures should have been installed. This probability will be reduced up to 72, 8% if only 10 animals would have been contaminated. This period has to be prolonged up to 11 years to have a probability of 79,8 %. Further prolonging the period will not increase the probability due the slaughter and mortality of the animals. The Community proposes to take this into account when evaluating the time period a feed ban has to be in place.**

**Therefore the Community proposes the following:**

**“b) any indigenous case of BSE was born more than 11 years ago; and**

i) ...

“ii) it has been demonstrated, through an appropriate level of control and audit, that for at least 11 years meat-and-bone meal and greaves derived from ruminants has not been fed to ruminants, and”

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

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

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

Article 2.3.13.4.

### Controlled BSE risk

*Commodities* from the cattle population of a country, *zone* or *compartment* pose a controlled risk of transmitting the BSE agent, should the following conditions be 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, but have not been taken for the relevant period of time to manage all risks identified ~~the country has not demonstrated that appropriate generic measures have been taken for the relevant period of time defined below to manage all risks identified;~~

### Community comments

The Community proposes to reword point 1 of Article 2.3.13.4. which will better reflect the intention.

**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 the risks identified ~~but these measures have not been taken for the relevant period of time to manage all risks identified~~**

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

### Community comments



The level of surveillance needed after reached the target points of type A surveillance is specified but also more clarity on the regime that is required after the points target of type B surveillance is met.

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

3. EITHER

- a) there has been no *case* of BSE or any *case* of BSE has been demonstrated to have been imported and has been completely destroyed, the criteria in points 2) to 4) of Article 2.3.13.2. are complied with, and it can be demonstrated, through an appropriate level of control and audit, that *meat-and-bone meal* and *greaves* derived from ruminants has not been fed to ruminants, but at least one of the following two conditions applies:
  - i) the criteria in points 2) to 4) of Article 2.3.13.2. have not been complied with for 7 years;
  - ii) it cannot be demonstrated that controls over the feeding of *meat-and-bone meal* or *greaves* derived from ruminants to ruminants have been in place for 8 years;

**Community comments**

It is far more relevant to take into account the date of birth rather than the date of reporting. However it seems that there is no rational for the 8 years period. In view of the long incubation period of BSE, it is not possible to precisely assess the impact of any control measure before several years.

Simulation studies performed in France to estimate the pattern of the BSE epidemic (not published) indicate that the probability to detect of a BSE case 8 years after taken certain risk management measures is 100 % if 100 animals would have been contaminated just after the measures should have been installed. This probability will be reduced up to 72,8 % if only 10 animals would have been contaminated. This period has to be prolonged up to 11 years to have a probability of 79,8 %. Further prolonging the period will not increase the probability due the slaughter and mortality of the animals. The Community proposes to take this into account when evaluating the time period a feed ban has to be in place.

Therefore the Community proposes in line with the proposed modification under Article 2.13.3.3. the following:

“ii) it has not been demonstrated, thorough an appropriate level of control and audit, that for at least 11 years *meat-and-bone meal* and *greaves* derived from ruminants has not been fed to ruminants;”

OR

- b) there has been an indigenous *case* of BSE ~~reported~~, the criteria in points 2) to 4) of Article 2.3.13.2. are complied with, and it can be demonstrated, through an appropriate level of control and audit that *meat-and-bone meal* and *greaves* derived from ruminants have not been fed to ruminants, but at least one of the following two conditions applies:

- i) the criteria in points 2) to 4) of Article 2.3.13.2. have not been complied with for 7 years;
- ii) it cannot be demonstrated that controls over the feeding of *meat-and-bone meal* and *greaves* derived from ruminants to ruminants have been in place for 8 years;

#### Community comments

**It is far more relevant to take into account the date of birth rather than the date of reporting. However it seems that there is no rationale for the 8 years period. In view of the long incubation period of BSE, it is not possible to precisely assess the impact of any control measure before several years.**

**Simulation studies performed in France to estimate the pattern of the BSE epidemic (not published) indicate that the probability to detect of a BSE case 8 years after taken certain risk management measures is 100 % if 100 animals would have been contaminated just after the measures should have been installed. This probability will be reduced up to 72, 8% if only 10 animals would have been contaminated. This period has to be prolonged up to 11 years to have a probability of 79,8 %. Further prolonging the period will not increase the probability due the slaughter and mortality of the animals. The Community proposes to take this into account when evaluating the time period a feed ban has to be in place.**

**Therefore the Community proposes in line with the proposed modification under Article 2.13.3.3. the following:**

**“ b) there has been an indigenous case of BSE less than 11 years ago, ....**

**ii) it has not been demonstrated, thorough an appropriate level of control and audit, that for at least 11 years meat-and-bone meal and greaves derived from ruminants has not been fed to ruminants;”**

AND

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

- ~~all the progeny of female *cases*, born within 2 years prior to or after clinical onset of the disease, and~~
- all cattle which, during their first year of life, were reared with the BSE *cases* during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or
- if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE *cases*,  
if alive in the country, *zone* or *compartment*, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed.

Article 2.3.13.5.

#### 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.

**Community comments**

**It should be specified that pending the final categorisation in one of the other categories, the country should be regarded as a country with an undetermined BSE risk.**

Article 2.3.13.6.

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

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

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

**Community comments**

**Taking into account that within the cattle population of a country with a negligible risk status with indigenous cases in the past, potential infected animals may be present in the age cohorts born before the risk management measures were taken for the appropriate period of time, assurances should be given to exclude those animals and products derived from trade. In practice, those animals and products derived should be excluded from trade from countries with a negligible BSE risk status.**

**In addition in line with Article 2.3.13.7., this Article should deal with trade from cattle originating from a country with negligible BSE risk status.**

**Therefore the Community proposes the following:**

**“for cattle**

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

- 1. the country, zone or compartment complies with the conditions in Article 2.3.13.3.;**
- 2. cattle selected for export are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin, and are not exposed cattle as described in point 3) b) iii) of Article 2.3.13.3. point 3,b,iii);**
- 3. cattle selected for export were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants had been enforced.”**

Article 2.3.13.7.

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

for cattle

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

1. the country, *zone* or *compartment* complies with the conditions in Article 2.3.13.4.;
2. cattle selected for export are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin, and are not exposed cattle as described in point 3) b) iii) of Article 2.3.13.4.;
3. in the case of a country, *zone* or *compartment* with an indigenous *case*, cattle selected for export were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants had been effectively enforced.

**Community comments**

**The current wording in point 3) referring to indigenous cases could be misinterpreted that only countries with indigenous cases should comply with point 3). The Community proposes to clarify as follows:**

**'3) Cattle selected for export were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants had been effectively enforced.'**

Article 2.3.13.8.

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

for cattle

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

1. the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced;
2. all BSE *cases*, as well as:
  - a) ~~all the progeny of female *cases*, born within 2 years prior to or after clinical onset of the disease,~~  
~~and~~
  - b) all cattle which, during their first year of life, were reared with the BSE *cases* during their first year of life, and, which investigation showed consumed the same potentially contaminated feed during that period, or
  - c) if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE *cases*,  
if alive in the country, *zone* or *compartment*, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed;
3. cattle selected for export:
  - a) are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin and are not the progeny of BSE suspect or confirmed females;
  - b) were born at least 2 years after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants was effectively enforced.

Article 2.3.13.9.

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

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

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

1. the country, *zone* or *compartment* complies with the conditions in Article 2.3.13.3.;
2. the cattle from which the fresh meat and meat products were derived passed ante-mortem and post-mortem inspections ~~ante-mortem and post-mortem inspections were carried out on all cattle from which the fresh meat or meat products originate.~~

**The Community proposes to amend Article 13, point 1) as follows:**

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

**Note to the reader (delete before submission to OIE)**

***With the proposed wording in Article 2.3.13.3, the feed ban has to be in place for 11 years. For countries with indigenous cases, the country can comply with the criteria if the last indigenous case was born before the feed ban has been in place. If an indigenous case is detected born less than 11 years ago the country will lose his status. The wording proposed under this Article will compartmentalize the country and will only allow meat without SRM removal from animals born after the feed ban. It should be discussed if an additional safety margin after the implementation of the feed ban is needed.***

**The Community proposes:**

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

Article 2.3.13.10.

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

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

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

1. the country, *zone* or *compartment* complies with the conditions in Article 2.3.13.4.;
2. the cattle from which the *fresh meat* and *meat products* were derived passed ante-mortem and post-mortem inspections ~~ante-mortem and post-mortem inspections were carried out on all cattle from which the *fresh meat* and *meat products* originate;~~
3. cattle from which the *fresh meat* and *meat products* destined for export originate were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process;
4. the *fresh meat* and *meat products* ~~do not contain~~ were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:
  - a) the tissues listed in Article 2.3.13.13.,
  - b) mechanically separated meat from the skull and vertebral column from cattle over 30 months of age,

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

#### Community comments

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

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

**‘4) b) mechanically separated meat from all bones from cattle of all ages,’**

Article 2.3.13.11.

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

#### Community comments

**Taking into account that the risk of these countries is unknown these countries should only trade the commodities listed in Article 1. 1).**

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) ~~are not suspect or confirmed BSE cases;~~
  - b) have not been fed *meat-and-bone meal* or *greaves* derived from ruminants;
  - c) ~~were subjected to~~ passed ante-mortem and post-mortem inspections;
  - d) were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process;
  
2. the *fresh meat* and *meat products* ~~do not contain~~ were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:
  - a) the tissues listed in Article 2.3.13.13.,
  - b) nervous and lymphatic tissues exposed during the deboning process,
  - c) mechanically separated meat from the skull and vertebral column from cattle over 12 months of age,

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

Article 2.3.13.12.

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

**Community comments**

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

**Therefore the Community proposes the following:**

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

Article 2.3.13.13.

1. From cattle of any age originating from a country, *zone* or *compartment* defined in Articles 2.3.13.4. and 2.3.13.5., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: tonsils and distal ileum, and protein products derived thereof. Food, feed,

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

#### **Community comments**

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

**The Community proposes to amend Article 13, point 1) as follows:**

**“From cattle of any age originating from a country, zone or compartment defined in Articles 4 and 5, the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: tonsils and intestines, and protein products derived thereof. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.”**

2. From cattle that were at the time of slaughter over 30 months of age originating from a country, *zone* or *compartment* defined in Article 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, vertebral column and derived protein products. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

#### **Community comments**

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

**The recent conclusions from the recent EFSA opinion on SRM, published in May 2005, stated that following a cautious approach and taking into account the appearance of infectivity in central nervous system (CNS) at  $\frac{3}{4}$  of the incubation period and the age of BSE cases in young animals (less than 35 months old, 0.06 % of total of BSE cases), a cut-off at 21 months would give the highest safety margin. If the rare BSE cases found in very young animals (4 cases in 40 Million tested since 2001) are not taken into account, a cut-off at 30 months would represent a “considerable but not an absolute safety margin with respect to detectable infectivity”. There is no scientific basis to raise the age limit for removal of tonsils and intestines. In addition EFSA recommends further work on the epidemiological data to evaluate the likelihood of infectivity in SRM derived from young animals.**

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



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

Article 2.3.13.14.

*Veterinary Administrations of importing countries* should require:

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

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

1. a country, *zone* or *compartment* posing a negligible BSE risk; or
2. a country, *zone* or *compartment* posing a controlled BSE risk; and
  - a) skulls and vertebrae (except tail vertebrae) have been excluded;
  - b) the bones have been subjected to a process which includes all the following steps:
    - i) pressure washing (degreasing),
    - ii) acid demineralisation,
    - iii) prolonged alkaline treatment,
    - iv) filtration,
    - v) sterilisation at  $\geq 138^{\circ}\text{C}$  for a minimum of 4 seconds,or to an equivalent process in terms of infectivity reduction.

Article 2.3.13.15.

*Veterinary Administrations of importing countries* should require:

for tallow and dicalcium phosphate (other than protein-free tallow as defined in Article 2.3.13.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

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

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

Article 2.3.13.16.

*Veterinary Administrations of importing countries* should require:

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

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

1. they originate from a country, *zone* or *compartment* posing a negligible BSE risk; or
2. they have been produced by hydrolysis, saponification or transesterification using high temperature and pressure.

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## APPENDIX 3.8.4.

SURVEILLANCE FOR BOVINE SPONGIFORM  
ENCEPHALOPATHY**Community comments**

At the General Session in May 2005 it was agreed that countries were allowed to use the full BSurVE model on the countries own data as an alternative to the Terrestrial Code Appendix 3.8.4, but this has not been reflected in the appendix and this is not reflected in chapter 2.3.13 either. The country should of course be able to defend scientifically the parameters selected.

## 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 on farm, during transport or at an abattoir (fallen stock);
  - d) cattle over 36 months of age at routine slaughter.
5. A gradient is used to describe the relative value of surveillance applied to each subpopulation. Surveillance should focus on the first subpopulation, but investigation of other subpopulations will help to provide an accurate assessment of the BSE situation in the country, *zone* or *compartment*. ~~All countries should sample at least three of the four subpopulations.~~ This approach is consistent with Appendix 3.8.1. on general guidelines for animal health surveillance.

#### Community comments

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

**However the Community strongly opposes to the proposal to limit the surveillance activity in a country with a negligible BSE risk without mitigation measures to the examination of animals showing clinical signs compatible with BSE (type B - passive surveillance).**

**Any surveillance activity should at least include the different risk animals i.e. clinical suspects, fallen stock and emergency slaughtered animals or animals with observations at the ante mortem inspection. Since often many of these animals show clinical signs not recognised as being compatible with BSE this target group should be included in any surveillance.**

**In addition, the assessment of the surveillance programme should also take into account the number of clinical suspects identified in the country during previous years. The clinical suspects should be documented.**

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.

## Description of cattle subpopulations

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

Cattle affected by illnesses that are refractory to treatment, and displaying progressive behavioural changes such as excitability, persistent kicking when milked, changes in herd hierarchical status, hesitation at doors, gates and barriers, as well as those displaying progressive neurological signs without signs of infectious illness are candidates for examination. These behavioural changes, being very subtle, are best identified by those who handle animals on a daily basis. Since BSE causes no pathognomonic clinical signs, all countries with cattle populations will observe individual animals displaying clinical signs consistent with BSE. It should be recognised that cases may display only some of these signs, which may also vary in severity, and such animals should still be investigated as potential BSE affected animals. The rate at which such suspicious cases are likely to occur will differ among epidemiological situations and cannot therefore be predicted reliably.

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

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

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

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

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

4. Cattle over 36 months of age at routine slaughter

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

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

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

Article 3.8.4.3.

4) ~~Implementation of Type A surveillance~~

In order to implement efficiently a surveillance strategy for BSE, a country must use ~~good quality data (or reliable estimates)~~ documented records or reliable estimates of ~~concerning~~ the age distribution of ~~it's~~ the adult cattle population and the number of cattle tested for BSE stratified by age and by subpopulation within the country, zone or compartment. ~~The application of the following procedure will allow the detection of BSE at a prevalence of at least one case per 100,000 in the adult cattle population, at a confidence level of 95% in the country, zone or compartment of concern.~~

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

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

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

- a) ~~a~~ the design prevalence for Type A or Type B surveillance of one case per 100,000 of the adult cattle population;
- b) a confidence level of 95%;
- c) the pathogenesis, and pathological and clinical expression of BSE:
  - i) sensitivity of diagnostic methods used;
  - ii) relative frequency of expression by age;
  - iii) relative frequency of expression within each subpopulation;
  - iv) interval between clinical pathological change and clinical expression;
- d) demographics of the cattle population, including age distribution;

- e) influence of BSE on culling or attrition of animals from the cattle population via the four subpopulations;
- f) percentage of infected animals in the cattle population which are not detected.

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

- a) cattle population numbers stratified by age;
- b) the number of cattle tested for BSE stratified by age and by subpopulation.

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

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

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

#### 1. Type A surveillance

The application of Type A surveillance will allow the detection of BSE around a design prevalence<sup>47</sup> of at least one case per 100,000 in the adult cattle population in the country, *zone* or *compartment* of concern, at a confidence level of 95%.

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

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

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

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

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<sup>47</sup> DP (design prevalence) is used to determine the size of a testing survey expressed in terms of target points. If the actual prevalence is greater than the selected design prevalence, the survey is highly likely to detect disease.

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

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

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

Article 3.8.4.4.

1. Selecting the points target

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

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

<b>Points targets for country, zone or compartment with 0 cases, 95% confidence</b>		
<b>Adult cattle population size (24 months and older)</b>	<b>Type A surveillance</b>	<b>Type B surveillance</b>
≥ 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
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DP is the maximum possible prevalence or “design prevalence”.

**Community comments**

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

2. Determining the point values of samples collected

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

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

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

**Community comments**

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

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

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

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

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

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

<sup>1</sup> See point 4) of Article 3.8.4.2.

<sup>2</sup> See point 3) of Article 3.8.4.2.

<sup>3</sup> See point 2) of Article 3.8.4.2.

<sup>4</sup> See point 1) of Article 3.8.4.2.

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

**Community comments**

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

~~Article 3.8.4.5.~~

~~To monitor the evolution of BSE in a country, zone or compartment once it is detected~~

~~To monitor the evolution of BSE in a country, *zone* or *compartment* once it is detected, a more intensive sampling method needs to be used to determine disease prevalence. For countries that have determined that BSE exists within their cattle population, the goal of surveillance shifts from one of detection to one of monitoring the extent and evolution of the disease, and monitoring the effectiveness of control measures such as feed bans and policies for the removal of specified risk materials.~~

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— text deleted

## CHAPTER 2.6.7.

## CLASSICAL SWINE FEVER

**Community comments:**

**The Community appreciates the improvements of the draft that has become clearer and better structured. Further simplifications of the text however are proposed.**

**Some clarifications need however to be provided where appropriate and proposals are made below.**

**The Community supports the introduction of the concept of compartmentalisation into the Chapter. The text could be significantly improved by deleting articles 2.6.7.5 and 2.6.7.7. The relevant contents of article 2.6.7.7 can be added to article 2.6.7.4 where appropriate and article 2.6.7.5 seems even more redundant in this case.**

**The Community supports also the proposal on article 2.6.7.6. on the recovery of free status but points out the inconsistency that the status may be restored after 30 days but according article 2.6.7.8. (2) and other following articles, animals must have been kept since birth or for at least 3 months in a free country, zone of compartment.**

**The Community acknowledges the efforts to take into account the possible use of vaccination against CSF with marker vaccine. Although the Community's policy of stamping-out CSF only foresees the use of emergency vaccination in domestic and wild pigs as an additional tool to eradicate the disease, the Community does not reject the principle that a country, zone or compartment may be considered as free from CSF if vaccination with a marker vaccine is carried out. The conditions to be considered free from CSF in these circumstances have however to be clearly defined. For this reason, Appendix 3.8.8 on surveillance and the Diagnostic Manual need to be reviewed and expanded and to clarify what in practice is meant by "where there are validated means of distinguishing between vaccinated and infected pigs" in this Chapter. For the sake of clarity the Community considers that the text should mention clearly the term "marker vaccination" where appropriate.**

## Article 2.6.7.1.

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

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

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

#### Article 2.6.7.2.

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

1. a *risk assessment* has been conducted, identifying all potential factors for CSF occurrence and their historic perspective;
2. CSF should be notifiable in the whole country, and all clinical signs suggestive of CSF should be subjected to field and/or laboratory investigations;
3. an on-going awareness programme should be in place to encourage reporting of all *cases* suggestive of CSF;
4. the *Veterinary Administration* should have current knowledge of, and authority over, all domestic establishments ~~containing~~ pigs in the ~~whole~~ country, *zone or compartment*;
5. the *Veterinary Administration* should have current knowledge about the population and habitat of wild pigs in the ~~whole~~ country or *zone*.

#### Article 2.6.7.3.

~~For the purposes of the *Terrestrial Code*:~~

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

~~‘Country, zone or compartment with CSF infection in domestic pigs’ means a country, zone or compartment containing a CSF infected establishment.~~

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

#### Article 2.6.7.4.

~~Country or zone~~ **Country, zone or compartment free of CSF in domestic and wild pigs**

1. Historically free status

A ~~country or zone~~ country, zone or compartment may be considered free from the disease ~~in domestic and wild pigs~~ after conducting a *risk assessment* as referred to in Article 2.6.7.2. but without formally

applying a specific surveillance programme (~~historical freedom~~) if the country or ~~zone~~ complies with if the provisions of Appendix 3.8.48 are complied with.

2. Free status as a result of an eradication a specific surveillance programme

A ~~country or zone~~ country, zone or compartment which does not meet the conditions of point 1) above may be considered free from CSF ~~in domestic and wild pigs~~ after ~~the conducting of a risk assessment~~ as referred to in Article 2.6.7.2. and surveillance in accordance with Appendix 3.8.8. is in place, and when:

a) ~~if~~ CSF is a notifiable disease;

AND EITHER

b) no outbreak has been observed in domestic pigs for at least 12 months; or

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

c) where a *stamping-out policy* with vaccination is practised, either

i) no outbreak has been observed in domestic pigs for at least 6 months after the last vaccinated pig was slaughtered; or

ii) where there are validated means of distinguishing between vaccinated and infected pigs, no outbreak has been observed in domestic pigs for at least 6 months;

c)bis where a vaccination strategy is practised ~~has been adopted~~, ~~with or~~ without a *stamping-out policy*,

i) vaccination ~~against CSF~~ has been banned in all domestic pigs in the ~~country or zone~~ country, zone or compartment for at least 12 months ~~one year~~, unless there are validated means of distinguishing between vaccinated and infected pigs;

ii) if vaccination has been practised within ~~occurred in~~ the past 5 years, surveillance in accordance with Appendix 3.8.8. has been in place for at least 6 months to demonstrate the absence of infection within the population of domestic pigs 6 months to one year old; and

iii) no outbreak has been observed in domestic pigs for at least 12 months;

AND

d) based on surveillance in accordance with Appendix 3.8.8, CSF infection is not known to occur in the any wild pig population in the country, zone or compartment and surveillance of wild pigs indicates that there is no residual infection.

**Community comments:**

**The Community proposes to simplify the text by deleting overlapping articles. Furthermore the period of no evidence of CSF in wild pigs should be defined.**

**It is proposed to delete article 2.6.7.7. and to replace article 2.6.7.4. (2)(d) with the text of article 2.6.7.7. point 2 to 4. The Community proposes to modify d) as follows:**

**“d) 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, zone or compartment and:**

- i) there has been no clinical, nor virological evidence of CSF in wild pigs during the past 12 months;**
- ii) no seropositive wild pigs have been detected in the age class 6-12 months during the past 12 months;**
- iii) there has been no vaccination in wild pigs for the past 12 months;**
- iv) the feeding of swill to wild pigs is forbidden, unless the swill has been treated to destroy any CSF virus that may be present, in conformity with one of the procedures referred to in Article 3.6.4.1.;**

Article 2.6.7.5.

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

**Community comments:**

**The Community proposes to delete this article because the possibility is covered by the proposed modified article 2.6.7.4.**

Requirements in point 2) ~~a) to c)bis~~ of Article 2.6.7.4. as relevant, are complied with. ~~As but~~ CSF infection ~~is known to occur~~ may be present in the wild pigs population, the following additional conditions are complied with for the free status ~~are that in the country or zone~~:

1. a programme for the management of CSF in wild pigs is in place, ~~and CSF wild pig control areas are delineated around every CSF case reported in wild pigs~~, taking into account the measures in place to manage the disease in the wild pig population, the presence of natural boundaries, the ecology of the wild pig population, and an assessment of the risk of disease spread;
2. ~~biosecurity measures are~~ zoning or compartmentalisation is applied to prevent transmission of CSF from wild pigs to domestic pigs;
3. ~~surveillance in accordance with Appendix 3.8.8. is carried out in the domestic pig population, with negative results.~~

Article 2.6.7.6.

**Recovery of free status**

Should a CSF *outbreak* occur in ~~an establishment of a free country or zone~~ country, zone or compartment (~~free in domestic and wild pigs, or free in domestic pigs only~~), the status of the country, ~~or zone or compartment~~ may be restored ~~at least~~ not less than 30 days after completion of a *stamping-out policy* where surveillance in

~~accordance with Appendix 3.8.8. has been carried out with negative results, which should include the following measures:~~

- ~~1. a CSF domestic pig control area (including an inner protection area of at least 3 kilometre radius and an outer surveillance area of at least 10 kilometre radius) should be delineated around the outbreak, taking into account the control measures applied, the presence of natural and administrative boundaries, and an assessment of the risk of disease spread;~~
- ~~2. all the pigs have been killed and their carcasses destroyed, and disinfection has been applied within the establishment;~~
- ~~3. in the protection area around a CSF outbreak:
  - ~~a) a risk assessment should be carried out to determine the likelihood of CSF infection in neighbouring establishments; when a significant risk is indicated, a stamping-out policy of all domestic pigs within a radius of at least 0.5 kilometre may be applied;~~
  - ~~b) an immediate clinical examination of all pigs in all pig establishments situated within the protection area has been carried out;~~~~
- ~~4. in the surveillance area around a CSF outbreak, all sick pigs should be subjected to laboratory tests for CSF;~~
- ~~5. surveillance in accordance with Appendix 3.8.8. has been carried out in all pig establishments that have been directly or indirectly in contact with the infected establishment and in all pig establishments located within the CSF domestic pig control area, demonstrating that these establishments are not infected;~~
- ~~6. measures aimed at preventing any virus spread by live pigs, pig semen and pig embryos, contaminated material, vehicles, etc. have been implemented.~~

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

Article 2.6.7.7.

#### Country or zone free of CSF in wild pigs

##### **Community comments:**

**The Community proposes to simplify the text by deleting overlapping articles. It is proposed to delete article 2.6.7.7. and to replace article 2.6.7.4. (2) (d) with the text of article 2.6.7.7. point 2 to 4.**

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

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



2. surveillance in accordance with Appendix 3.8.8. has been in place to determine the CSF status of the wild pig population in the country, and in the country or *zone*:
  - a) there has been no clinical, nor virological evidence of CSF in wild pigs during the past 12 months;
  - b) no seropositive wild pigs have been detected in the age class 6-12 months during the past 12 months;
3. there has been no vaccination in wild pigs for the past 12 months;
4. the feeding of swill to wild pigs is forbidden, unless the swill has been treated to destroy any CSF virus that may be present, in conformity with one of the procedures referred to in Article 3.6.4.1.;
5. imported wild pigs comply with the relevant requirements set forth in the present chapter.

A zoning compartmentalisation approach within the country or zone can only be adopted if there is a wild pig sub-population that is isolated through a biosecurity management system from other wild pigs.

#### Article 2.6.7.8.

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

##### for domestic pigs

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

1. showed no clinical sign of CSF on the day of shipment;
2. were kept in a ~~country or zone~~ country, zone or compartment free of CSF ~~in domestic and wild pigs~~ since birth or for at least the past 3 months;
3. have not been vaccinated against CSF, nor are they the progeny of vaccinated sows, unless there are validated means of distinguishing between vaccinated and infected pigs.

#### Article 2.6.7.9.

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

##### for domestic pigs

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

1. were kept in a country or *zone* free of CSF in domestic pigs since birth or for at least the past 3 months;
2. have not been vaccinated against CSF, nor are they the progeny of vaccinated sows, unless there are validated means of distinguishing between vaccinated and infected pigs;
3. come from ~~an *establishment* a *free zone* or *compartment* which is not located in a CSF wild pig control area as defined in Article 2.6.7.5., and has undergone surveillance to verify absence of CSF in accordance with Appendix 3.8.8.;~~
4. ~~have had no contact with pigs introduced into the *establishment* during the past 40 days;~~
5. showed no clinical sign of CSF on the day of shipment.

Article 2.6.7.10.

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

for domestic pigs

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

1. have not been vaccinated against CSF nor are they the progeny of vaccinated sows, unless there are validated means of distinguishing between vaccinated and infected pigs;
2. were kept since birth or for the past 3 months, in ~~an *establishment* a *free compartment* not situated in a CSF domestic or wild pig control area as defined in Article 2.6.7.5. and in Article 2.6.7.6.;~~
3. ~~were isolated in a *quarantine station* for at least 40 days;~~
4. ~~were subjected during that period of quarantine to a virological test, and a serological test performed at least 21 days after entry into the *quarantine station*, with negative results;~~
5. showed no clinical sign of CSF on the day of shipment.

Article 2.6.7.11.

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

for wild pigs

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

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

2. have been captured in a country or *zone* free from CSF ~~in domestic and wild pigs~~;
3. have not been vaccinated against CSF, unless there are validated means of distinguishing between vaccinated and infected pigs;

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

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

Article 2.6.7.12.

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

for semen of domestic pigs

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

1. the donor animals:
  - a) were kept in a ~~country or zone~~ country, zone or compartment free of CSF ~~in domestic and wild pigs~~ since birth or for at least ~~the past 3 months~~ prior to collection;
  - b) showed no clinical sign of CSF on the day of collection of the semen;
2. the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.2.

Article 2.6.7.13.

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

for semen of domestic pigs

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

1. the donor animals:
  - a) were kept in a country, zone or compartment free of CSF in domestic pigs since birth or for at least 3 months prior to collection have been kept in an *artificial insemination centre* which is not located in a CSF wild pig control area and is regularly monitored to verify absence of CSF in accordance with Appendix 3.8.8.;
  - b) were isolated in the *artificial insemination centre* for at least 40 days prior to collection;

- e) showed no clinical sign of CSF on the day of collection of the semen and for the following 40 days;
2. the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.2.

Article 2.6.7.14.

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

for semen of domestic pigs

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

1. the donor animals:
  - a) were kept in a compartment free of CSF in domestic pigs since birth or for at least 3 months prior to collection;
  - a)bis showed no clinical sign of CSF on the day of collection of the semen and for the following 40 days ~~3 months~~;
  - b) have not been vaccinated against CSF, and were subjected to a serological test performed at least 21 days after collection, with negative results;
2. the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.2.

Article 2.6.7.15.

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

for *in vivo* derived embryos of pigs

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

1. the donor females showed no clinical sign of CSF on the day of collection of the embryos;
2. the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.1.

Article 2.6.7.16.

When importing from countries ~~or zones~~ free of CSF in domestic pigs but with ~~infection in the~~ 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~~ were kept for at least 40 days prior to collection in an *establishment* which is not located in a CSF domestic or wild pig control area and is regularly monitored to verify absence of CSF in accordance with Appendix 3.8.8.;
  - b) showed no clinical sign of CSF on the day of collection of the embryos;
2. the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.1.

Article 2.6.7.17.

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

for *in vivo* derived embryos of pigs

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

1. the donor females:
  - a) ~~were kept in a *compartment* free of CSF in domestic pigs since birth or for at least 3 months prior to collection~~; were kept for at least 40 days prior to collection in an *establishment* which is not located in a CSF domestic or wild pig control area and is regularly monitored to verify absence of CSF in accordance with Appendix 3.8.8.;
  - b) showed no clinical sign of CSF on the day of collection of the embryos and for the following ~~24~~ 40 days;
  - c) have not been vaccinated against CSF and were subjected, with negative results, to a serological test performed at least 21 days after collection;
2. the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.1.

Article 2.6.7.18.

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

for *fresh meat* of domestic pigs

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

1. have been kept in a country, ~~or zone or compartment~~ free of CSF ~~in domestic and wild pigs~~ since birth or for at least the past 3 months;
2. have been slaughtered in an *approved abattoir*, have been subjected to ante-mortem and post-mortem inspections and have been found free of any sign suggestive of CSF.

Article 2.6.7.19.

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

for fresh meat of domestic pigs

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

1. were kept in a country, ~~or zone or compartment~~ free of CSF in domestic pigs since birth or for at least the past 3 months;
2. ~~were kept in an establishment which was not located in a CSF wild pig control area and had undergone surveillance to verify absence of CSF in accordance with Appendix 3.8.8.;~~
3. have been slaughtered in an *approved abattoir* ~~not located in a CSF control area~~, have been subjected to ante-mortem and post-mortem inspections and have been found free of any sign suggestive of CSF.

Article 2.6.7.20.

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

for fresh meat of wild pigs

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

1. the entire consignment of meat comes from animals which:
  - a) have been killed in a country or *zone* free of CSF ~~in domestic and wild pigs~~;
  - b) have been subjected to post-mortem inspection in an approved examination centre, and have been found free of any sign suggestive of CSF;

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

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

Article 2.6.7.21.

*Veterinary Administrations of importing countries* should require:

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

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

1. have been prepared:
  - a) exclusively from *fresh meat* meeting the conditions laid down in Articles 2.6.7.18., 2.6.7.19. or 2.6.7.20., as relevant;
  - b) in a processing establishment:
    - i) approved by the *Veterinary Administration* for export purposes;
    - ii) ~~regularly inspected by the *Veterinary Authority*;~~
    - iii) ~~not situated in a CSF control area;~~
    - iv) processing only meat meeting the conditions laid down in Articles 2.6.7.18., 2.6.7.19. or 2.6.7.20., as relevant;

OR

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

Article 2.6.7.22.

*Veterinary Administrations of importing countries* should require:

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

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

1. have been prepared:

- a) exclusively from products meeting the conditions laid down for *fresh meat* in Articles 2.6.7.18., 2.6.7.19. or 2.6.7.20., as relevant;
- b) in a processing establishment:
  - i) approved by the *Veterinary Administration* for export purposes;
  - ii) ~~regularly inspected by the *Veterinary Authority*;~~
  - iii) ~~not situated in a CSF control area;~~
  - iv) processing only products meeting the conditions laid down in point a) above;

OR

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

Article 2.6.7.23.

*Veterinary Administrations of importing countries* should require:

for bristles (from pigs)

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

- 1. come from a country, ~~or zone or compartment~~ free of CSF ~~in domestic and wild pigs~~; or
- 2. have been processed in an establishment approved by the *Veterinary Administration* for export purposes ~~and regularly inspected by the *Veterinary Authority*~~ so as to ensure the destruction of the CSF virus.

Article 2.6.7.24.

*Veterinary Administrations of importing countries* should require:

for litter and manure (from pigs)

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

- 1. come from a country, ~~or zone or compartment~~ free of CSF ~~in domestic and wild pigs~~; or
- 2. ~~come from establishments situated in a country or zone free of CSF in domestic pigs but with infection in wild pigs, but not located in a CSF control area;~~ or



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

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CHAPTER 2.7.12.

AVIAN INFLUENZA

**Community comments:**

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

Article 2.7.12.1.

1. For the purposes of this *Terrestrial Code*, avian influenza in its notifiable form (NAI) is defined as an infection of poultry caused by any influenza A virus of the H5 or H7 subtypes or by any AI virus with an intravenous pathogenicity index (IVPI) greater than 1.2 (or as an alternative at least 75% mortality) as described below. NAI viruses can be divided into highly pathogenic notifiable avian influenza (HPNAI) and low pathogenicity notifiable avian influenza (LPNAI):
  - a) HPNAI viruses have an IVPI in 6-week-old chickens greater than 1.2 or, as an alternative, cause at least 75% mortality in 4-to 8-week-old chickens infected intravenously. H5 and H7 viruses which do not have an IVPI of greater than 1.2 or cause less than 75% mortality in an intravenous lethality test should be sequenced to determine whether multiple basic amino acids are present at the cleavage site of the haemagglutinin molecule (HA0); if the amino acid motif is similar to that observed for other HPNAI isolates, the isolate being tested should be considered as HPNAI.
  - b) LPNAI are all influenza A viruses of H5 and H7 subtype that are not HPNAI viruses.
2. Poultry is defined as ‘all birds reared or kept in captivity for the production of meat or eggs for consumption, for the production of other commercial products, for restocking supplies of game, or for breeding these categories of birds’.
3. For the purposes of *international trade*, this chapter deals not only with the occurrence of clinical signs caused by NAI virus, but also with the presence of infection with NAI virus in the absence of clinical signs.
4. The following defines the occurrence of infection with NAI virus:
  - a) HPNAI virus has been isolated and identified as such or viral RNA specific for HPNAI has been detected in poultry or a product derived from poultry; or
  - b) LPNAI virus has been isolated and identified as such or viral RNA specific for LPNAI has been detected in poultry or a product derived from poultry; or
  - c) antibodies to H5 or H7 subtype of NAI virus that are not a consequence of vaccination have

been detected in poultry. In the case of isolated serological positive results, NAI infection may be ruled out on the basis of a thorough epidemiological investigation that does not demonstrate further evidence of NAI infection.

For the purposes of the *Terrestrial Code*, 'NAI free establishment' means an *establishment* in which the poultry have shown no evidence of NAI infection, based on surveillance in accordance with Appendix 3.8.9.

For the purposes of the *Terrestrial Code*, the *incubation period* for NAI shall be 21 days.

Standards for diagnostic tests, including pathogenicity testing, are described in the *Terrestrial Manual*. Any vaccine used should comply with the standards described in the *Terrestrial Manual*.

#### Article 2.7.12.2.

The NAI status of a country, a *zone* or a *compartment* can be determined on the basis of the following criteria:

1. the outcome of a *risk assessment* identifying all potential factors for NAI occurrence and their historic perspective;
2. NAI is notifiable in the whole country, an on-going NAI awareness programme is in place, and all notified suspect occurrences of NAI are subjected to field and, where applicable, laboratory investigations;
3. appropriate surveillance is in place to demonstrate the presence of infection in the absence of clinical signs in poultry, and the risk posed by birds other than poultry; this may be achieved through an NAI surveillance programme in accordance with Appendix 3.8.9.

#### Article 2.7.12.3.

### **NAI free country, zone or compartment**

A country, *zone* or *compartment* may be considered free from NAI when it has been shown that neither HPNAI nor LPNAI infection has been present in the country, *zone* or *compartment* for the past 12 months, based on surveillance in accordance with Appendix 3.8.9. The surveillance may need to be adapted to parts of the country or existing *zones* or *compartments* depending on historical or geographical factors, industry structure, population data, or proximity to recent *outbreaks*.

If infection has occurred in a previously free country, *zone* or *compartment*, free status can be regained:

1. In the case of HPNAI infections, 3 months after a *stamping-out policy* (including *disinfection* of all affected *establishments*) is applied, providing that surveillance in accordance with Appendix 3.8.9. has been carried out during that three-month period.
2. In the case of LPNAI infections, poultry may be kept for slaughter for human consumption subject to specified conditions specified in Article 2.7.12.19 or 2.7.12.20 or a *stamping-out policy* may be applied; in either case, 3 months after the disinfection of all affected establishments, providing that surveillance in accordance with Appendix 3.8.9. has been carried out during that three-month period.

#### Article 2.7.12.4.

### **HPNAI free country, zone or compartment**

A country, *zone* or *compartment* may be considered free from HPNAI when it has been shown that HPNAI infection has not been present in the country, *zone* or *compartment* for the past 12 months, although its LPNAI status may be unknown, when, based on surveillance in accordance with Appendix 3.8.9., it does not meet the criteria for freedom from NAI but any NAI virus detected has not been identified as HPNAI virus. The surveillance may need to be adapted to parts of the country or *zones* or *compartments* depending on historical or geographical factors, industry structure, population data, or proximity to recent *outbreaks*.

If infection has occurred in a previously free country, *zone* or *compartment*, free status can be regained 3 months after a *stamping-out policy* (including *disinfection* of all affected *establishments*) is applied, providing that surveillance in accordance with Appendix 3.8.9. has been carried out during that three-month period.

Article 2.7.12.5.

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

for live poultry (other than day-old poultry)

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

1. the poultry showed no clinical sign of NAI on the day of shipment;
2. the poultry were kept in an NAI free country, *zone* or *compartment* since they were hatched or for the past 21 days;
3. the required surveillance has been carried out on the *establishment* within the past 21 days;
4. if vaccinated, the poultry have been vaccinated in accordance with Appendix 3.8.9., and the relevant information is attached.

~~Information concerning the vaccination status of the poultry (including the dates of vaccination, and the vaccine used should be included in the veterinary certificate.~~

Article 2.7.12.6.

Regardless of the NAI status of the country, *zone* or *compartment* of origin, *Veterinary Administrations* should require:

for live birds other than poultry

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

1. showed no clinical sign of infection with a virus which would be considered NAI in poultry on the day of shipment;
2. were kept in isolation approved by the *Veterinary Services* since they were hatched or for 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. 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. are transported in new containers.

Article 2.7.12.7.

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

for day-old live poultry

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

1. the poultry were kept in an NAI free country, *zone* or *compartment* since they were hatched;
2. the poultry were derived from parent flocks which had been kept in an NAI free country, *zone* or *compartment* for at least 21 days prior to and at the time of the collection of the eggs;
3. if the poultry or the parent flocks were vaccinated, vaccination was carried out in accordance with Appendix 3.8.9., and the relevant information is attached.

~~Information concerning the vaccination status of the poultry and the parent flocks (including the dates of vaccination, and the vaccine used) should be included in the veterinary certificate.~~

Article 2.7.12.8.

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

for day-old live poultry

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

1. the poultry were kept in an HPNAI free country, *zone* or *compartment* since they were hatched;
2. the poultry were derived from parent flocks which had been kept in an NAI free *establishment* for at least 21 days prior to and at the time of the collection of the eggs;
3. the poultry are transported in new containers.
4. if the poultry or the parent flocks were vaccinated, vaccination was carried out in accordance with Appendix 3.8.9., and the relevant information is attached.

~~Information concerning the vaccination status of the poultry and the parent flocks (including the dates of vaccination, and the vaccine used) should be included in the veterinary certificate.~~

Article 2.7.12.9.

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

for hatching eggs

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

1. the eggs came from an NAI free country, *zone* or *compartment*;
2. the eggs were derived from parent flocks which had been kept in an NAI free country, *zone* or *compartment* for at least 21 days prior to and at the time of the collection of the eggs.
3. if the parent flocks were vaccinated, vaccination was carried out in accordance with Appendix 3.8.9., and the relevant information is attached.

~~Information concerning the vaccination status of the parent flocks (including the dates of vaccination, and the vaccine used) should be included in the veterinary certificate.~~

Article 2.7.12.10.

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

for hatching eggs

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

1. the eggs came from an HPNAI free country, *zone* or *compartment*;
2. the eggs were derived from parent flocks which had been kept in an NAI free *establishment* for at least 21 days prior to and at the time of the collection of the eggs;
3. the eggs have had their surfaces sanitised (in accordance with Article 3.4.1.7) and are transported in new packing material;
4. if the parent flocks were vaccinated, vaccination was carried out in accordance with Appendix 3.8.9., and the relevant information is attached.

~~Information concerning the vaccination status of the parent flocks (including the dates of vaccination, and the vaccine used) should be included in the veterinary certificate.~~

Article 2.7.12.11.

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

for eggs for human consumption

the presentation of an *international veterinary certificate* attesting that the eggs come from an NAI free country, *zone* or *compartment*.

Article 2.7.12.12.

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

for eggs for human consumption

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

1. come from a HPNAI free country, *zone* or *compartment*;
2. come from *establishments* in which there has been no evidence of NAI in the past 21 days;
3. have had their surfaces sanitised (in accordance with Article 3.4.1.7) and are transported in new packing material.

**Community comments:**

**The Community points out that EFSA Scientific Report on “Animal health and welfare aspects of Avian Influenza” of September 2005 indicates that there has been no report of a natural infection of laying birds with LPAI viruses that has resulted in eggs containing virus internally. However, LPAI viruses are excreted in large amounts in the faeces of infected birds and faecal material frequently contaminates the outside of eggs shells. It would seem a wise precaution that the outside of table eggs are treated in some way to reduce the likelihood of faecal and/or virus contamination, either as a routine measure or when the parent flock is known to be or suspected of being infected with LPAI virus. Respecting this opinion No 2 above should be deleted.**

Article 2.7.12.13.

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

for egg products

the presentation of an *international veterinary certificate* attesting that the egg products come from, and were processed in, an NAI free country, *zone* or *compartment*.

Article 2.7.12.14.

Regardless of the NAI status of the country, *zone* or *compartment* of origin, *Veterinary Administrations* should require:

for egg products

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

1. 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. were processed to ensure the destruction of NAI virus (under study), and the necessary precautions were taken after processing to avoid contact of the *commodity* with any source of NAI virus.

Article 2.7.12.15.

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

for poultry semen

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

1. showed no clinical sign of NAI on the day of semen collection;
2. were kept in an NAI free country, *zone* or *compartment* for at least the 21 days prior to and at the time of semen collection.

~~Information concerning the vaccination status of the donor poultry (including the dates of vaccination, and the vaccine used) should be included in the veterinary certificate.~~

Article 2.7.12.16.

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

for poultry semen

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

- ~~1) came from an HPNAI free country, *zone* or *compartment*;~~
- ~~2) were kept in an NAI free *establishment* for at least 21 days prior to and at the time of semen collection.~~
1. showed no clinical sign of HPNAI on the day of semen collection;
2. were kept in an HPNAI free country, *zone* or *compartment* for at least the 21 days prior to and at the time of semen collection.

~~Information concerning the vaccination status of the donor flocks (including the dates of vaccination and the vaccine used) should be included in the veterinary certificate.~~

Article 2.7.12.17.

Regardless of the NAI status of the country, *zone* or *compartment* of origin, *Veterinary Administrations* should require:

for semen of birds other than poultry

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

1. were kept in isolation approved by the *Veterinary Services* for at least the 21 days prior to semen collection;
2. showed no clinical sign of infection with a virus which would be considered NAI in poultry during the isolation period;
3. were tested between 7 and 14 days prior to semen collection and shown to be free of NAI infection.

Article 2.7.12.18.

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

for fresh meat of poultry

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

1. which have been kept in an NAI free country, *zone* or *compartment* since they were hatched or for at least the past 21 days;
2. which have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for NAI with favourable results.



Article 2.7.12.19.

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

for fresh meat of poultry

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

1. ~~which have been kept in an HPNAI free country, *zone* or *compartment* since they were hatched or for at least the past 21 days~~ which have been kept in an *establishment* since they were hatched or for at least the past 21 days and in which there has been no evidence of NAI in the past 21 days;
2. which have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for NAI with favourable results.

Article 2.7.12.20.

Regardless of the NAI status of the country, *zone* or *compartment* of origin, *Veterinary Administrations* should require:

for meat products of poultry

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

1. the *commodity* is derived from *fresh meat* which meet the requirements of Articles 2.7.12.18. or 2.7.12.19.; or
2. the *commodity* has been processed to a core temperature of 70°C for one second (or to an equivalent process), to ensure the destruction of NAI virus (~~under study~~);

**Community**

**comment:**

**The Community proposes the following wording: “2. the commodity:**

**a) is derived from birds which have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for NAI with favourable results and**

**b) has been processed to ensure the destruction of NAI virus in accordance with Appendix 3.6.X.”**

**Without the addition of a) it is not ensured the meat used in the meat product has undergone meat inspection and our proposed new wording of b) is self explanatory.**

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Article 2.7.12.21.

Regardless of the NAI status of the country, *zone* or *compartment* of origin, *Veterinary Administrations* should

require:

for products of poultry origin intended for use in animal feeding, or for agricultural or industrial use  
the presentation of an *international veterinary certificate* attesting that:

1. these *commodities* come from ~~birds~~ poultry which have been kept in an NAI free country, *zone* or *compartment* since they were hatched or for at least the past 21 days; or
2. these *commodities* have been processed to ensure the destruction of NAI virus (~~under study in accordance with Appendix 3.6.X.~~);
3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Article 2.7.12.22.

Regardless of the NAI status of the country, *zone* or *compartment* of origin, *Veterinary Administrations* should require:

for feathers and down (from poultry)

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

1. these *commodities* come from ~~birds~~ poultry which have been kept in an NAI free country, *zone* or *compartment* since they were hatched or for at least the past 21 days; or
2. these *commodities* have been processed to ensure the destruction of NAI virus (under study);
3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Article 2.7.12.23.

Regardless of the NAI status of the country, *zone* or *compartment*, *Veterinary Administrations* should require for the importation of:

meat or other products from birds other than poultry

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

1. the *commodity* has been processed to ensure the destruction of NAI virus (under study);
2. the necessary precautions were taken after processing to avoid contact of the *commodity* with any source of NAI virus.

— text deleted

## APPENDIX 3.8.9.

GUIDELINES FOR THE SURVEILLANCE  
OF AVIAN INFLUENZA**Community comments:**

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

## Article 3.8.9.1.

**Introduction**

This Appendix defines the principles and provides a guide for the surveillance of notifiable avian influenza (NAI) in accordance with Appendix 3.8.1., applicable to countries seeking recognition for a declared NAI status, with or without the use of vaccination. This may be for the entire country, *zone* or *compartment*. Guidance for countries seeking free status following an *outbreak* and for the maintenance of NAI status are provided. This Appendix complements Chapter 2.7.12.

The presence of avian influenza viruses in wild birds creates a particular problem. In essence, no country can declare itself free from avian influenza (AI) in wild birds. However, the definition of NAI in Chapter 2.7.12. refers to the infection in poultry only and this Appendix was developed under this definition.

The impact and epidemiology of NAI differ widely in different regions of the world and therefore it is impossible to provide specific guidelines for all situations. It is axiomatic that the surveillance strategies employed for demonstrating freedom from NAI at an acceptable level of confidence will need to be adapted to the local situation. Variables such as the frequency of contacts of poultry with wild birds, different biosecurity levels and production systems and the commingling of different susceptible species including domestic waterfowl require specific surveillance strategies to address each specific situation. It is incumbent upon the country to provide scientific data that explains the epidemiology of NAI in the region concerned and also demonstrates how all the risk factors are managed. There is therefore considerable latitude available to Member Countries to provide a well-reasoned argument to prove that absence of NAI virus (NAIV) infection is assured at an acceptable level of confidence.

Surveillance for NAI should be in the form of a continuing programme designed to establish that the country, *zone* or *compartment*, for which application is made, is free from NAIV infection.

## Article 3.8.9.2.

**General conditions and methods**

1. A surveillance system in accordance with Appendix 3.8.1. should be under the responsibility of the *Veterinary Administration*. In particular:
  - a) a formal and ongoing system for detecting and investigating *outbreaks of disease* or infection with NAIV should be in place;

- b) a procedure should be in place for the rapid collection and transport of samples from suspect cases of NAI to a laboratory for NAI diagnosis as described in the *Terrestrial Manual*;
  - c) a system for recording, managing and analysing diagnostic and surveillance data should be in place.
2. The NAI surveillance programme should:
- a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers, who have day-to-day contact with poultry, as well as diagnosticians, should report promptly any suspicion of NAI to the *Veterinary Authority*. They should be supported directly or indirectly (e.g. through private veterinarians or *veterinary para-professionals*) by government information programmes and the *Veterinary Administration*. All suspected cases of NAI should be investigated immediately. ~~Where As suspicion cannot be resolved by epidemiological and clinical investigation alone, as is frequently the case with low pathogenicity notifiable avian influenza (LPNAI) virus infections,~~ samples should be taken and submitted to an *approved laboratory*. This requires that sampling kits and other equipment are available for those responsible for surveillance. Personnel responsible for surveillance should be able to call for assistance from a team with expertise in NAI diagnosis and control. In cases where potential public health implications are suspected, notification to the appropriate public health authorities is essential;
  - b) implement, when relevant, regular and frequent clinical inspection, serological and virological testing of high-risk groups of animals, such as those adjacent to an NAI infected country, *zone* or *compartment*, places where birds and poultry of different origins are mixed, such as live bird markets, poultry in close proximity to waterfowl or other sources of 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 stand-still orders, etc.).

#### Article 3.8.9.3.

### Surveillance strategies

#### 1. Introduction

The target population for surveillance aimed at identification of *disease* and *infection* should cover all the susceptible poultry species within the country, *zone* or *compartment*. Active and passive surveillance for NAI should be ongoing. The frequency of active surveillance should be at least every 6 months. Surveillance should be composed of random and targeted approaches using virological, serological and clinical methods.

The strategy employed may be based on randomised sampling requiring surveillance consistent with demonstrating the absence of 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. It may, for example, be appropriate to target clinical surveillance at particular species likely to exhibit clear clinical signs (e.g. chickens). Similarly, virological and serological testing could be targeted to species that may not show clinical signs (e.g. ducks).

If a Member Country wishes to declare freedom from 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 ~~to be accepted by the OIE or international trading partners~~, or excessively costly and logistically complicated. The design of any surveillance programme, therefore, requires inputs from professionals competent and experienced in this field.

## 2. Clinical surveillance

Clinical surveillance aims at the detection of clinical signs of NAI at the flock level. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, surveillance based on clinical inspection should not be underrated. Monitoring of production parameters, such as increased mortality, reduced feed and water consumption, presence of clinical signs of a respiratory disease or a drop in egg production, is important for the early detection of 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) 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 3.8.9.7.

Article 3.8.9.4.

### **Documentation of NAI or HPNAI free status**

#### 1. Countries declaring freedom from NAI or HPNAI for the country, zone or compartment

In addition to the general conditions described in Chapter 2.7.12. of the *Terrestrial Code*, a Member Country declaring freedom from NAI or highly pathogenic notifiable avian influenza (HPNAI) for the entire country, or a *zone* or a *compartment* should provide evidence for the existence of an effective surveillance programme. The strategy and design of the surveillance programme will depend on the prevailing epidemiological circumstances and should be planned and implemented according to general conditions and methods described in this Appendix, to demonstrate absence of NAIV or HPNAIV infection, during the preceding 12 months in susceptible poultry populations (vaccinated and non-vaccinated). This requires the support of a laboratory able to undertake identification of NAIV or HPNAIV infection through virus detection and antibody tests described in the *Terrestrial Manual*. This surveillance may be targeted to poultry population at specific risks linked to the types of production, possible direct or indirect contact with wild birds, multi-age flocks, local trade patterns including live bird markets, use of possibly contaminated surface water, and the presence of more than one species on the holding and poor biosecurity measures in place.

#### 2. Additional requirements for countries, zones or compartments that practise vaccination

Vaccination to prevent the transmission of HPNAI virus may be part of a disease control programme. The level of flock immunity required to prevent transmission will depend on the flock size, composition (e.g. species) and density of the susceptible poultry population. It is therefore impossible to be prescriptive. The vaccine must also comply with the provisions stipulated for NAI vaccines in the *Terrestrial Manual*. Based on the epidemiology of NAI in the country, *zone* or *compartment*, it may be that a decision is reached to vaccinate only certain species or other poultry subpopulations.

In all vaccinated flocks there is a need to perform virological and serological tests to ensure the absence of virus circulation. The use of sentinel poultry may provide further confidence of the absence of virus circulation. The tests have to be repeated at least every 6 months or at shorter intervals according to the risk in the country, *zone* or *compartment*.

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

Article 3.8.9.5.

### **Countries, zones or compartments ~~re-declaring~~ regaining freedom from NAI or HPNAI following an outbreak**

In addition to the general conditions described in Chapter 2.7.12., a country ~~re-declaring for~~ regaining country, *zone* or *compartment* freedom from NAI or HPNAI virus infection should show evidence of an active surveillance programme depending on the epidemiological circumstances of the *outbreak* to



demonstrate the absence of the *infection*. This will require surveillance incorporating virus detection and antibody tests described in the *Terrestrial Manual*. The use of sentinel birds may facilitate the interpretation of surveillance results.

**Community comment:**

**The first sentence should read “....a country ~~re-declaring for~~ regaining freedom for country, zone or compartment from NAI or HPNAI virus infection....”**

A Member Country declaring freedom of country, *zone* or *compartment* after an *outbreak* of NAI or HPNAI (with or without vaccination) should report the results of an active surveillance programme in which the NAI or HPNAI susceptible poultry population undergoes regular clinical examination and active surveillance planned and implemented according to the general conditions and methods described in these guidelines. The surveillance should at least give the confidence that can be given by a randomized representative sample of the populations at risk.

Article 3.8.9.6.

**NAI free establishments within HPNAI free compartments**

The declaration of NAI free *establishments* requires the demonstration of absence of 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.

**Community comment:**

**The heading should read” NAI free establishments within a HPNAI free compartment” and in addition the text needs to be clarified as its unclear what is the purpose of free establishments in a free compartment either the whole compartment is free or it isn’t. So the Community suggests to add “In this compartment all the establishments must have the same NAI free status” as in this case the status is NAI free in all the establishments in a defined compartment.**

Article 3.8.9.7.

**The use and interpretation of serological and virus detection tests**

Poultry infected with NAI virus produce antibodies to haemagglutinin (HA), neuraminidase (NA), nonstructural proteins (NSPs), nucleoprotein/matrix (NP/M) and the polymerase complex proteins. Detection of antibodies against the polymerase complex proteins will not be covered in this Appendix. Tests for NP/M antibodies include direct and blocking ELISA, and agar gel immunodiffusion (AGID) tests. Tests for antibodies against NA include the neuraminidase inhibition (NI), indirect fluorescent antibody and direct ELISA tests. For the HA, antibodies are detected in haemagglutination inhibition (HI) and neutralization (SN) tests. The HI test is reliable in avian species but not in mammals. The SN test can be used to detect subtype specific antibodies to the haemagglutinin and is the preferred test for mammals and some avian species. The AGID test is reliable for detection of NP/M antibodies in chickens and turkeys, but not in other avian species. As an alternative, blocking ELISA tests have been developed to detect NP/M antibodies in all avian species.

The HI and NI tests can be used to subtype AI viruses into 16~~5~~ haemagglutinin and 9 neuraminidase subtypes. Such information is helpful for epidemiological investigations and in categorization of AI viruses.

Poultry can be vaccinated with a variety of AI vaccines including inactivated whole AI virus vaccines, and haemagglutinin expression-based vaccines. Antibodies to the haemagglutinin confer subtype specific protection. Various strategies can be used to differentiate vaccinated from infected birds including serosurveillance in unvaccinated sentinel birds or specific serological tests in the vaccinated birds.

AI virus infection of unvaccinated birds including sentinels is detected by antibodies to the NP/M, subtype specific HA or NA proteins, or NSP. Poultry vaccinated with inactivated whole AI vaccines containing an influenza virus of the same H sub-type but with a different neuraminidase may be tested for field exposure by applying serological tests directed to the detection of antibodies to the NA of the field virus. For example, birds vaccinated with H7N3 in the face of a H7N1 epidemic may be differentiated from infected birds (DIVA) by detection of subtype specific NA antibodies of the N1 protein of the field virus. Alternatively, in the absence of DIVA, inactivated vaccines may induce low titres of antibodies to NSP and the titre in infected birds would be markedly higher. Encouraging results have been obtained experimentally with this system, but it has not yet been validated in the field. In poultry vaccinated with haemagglutinin expression-based vaccines, antibodies are detected to the specific HA, but not any of the other AI viral proteins. Infection is evident by antibodies to the NP/M or NSP, or the specific NA protein of the field virus. ~~Poultry vaccinated with inactivated whole AI vaccines may develop low titres of antibodies to NSP, but the titre in infected birds will be markedly higher. Alternatively, usage of a vaccine strain with a different NA subtype than the field virus can allow differentiation of vaccinated from infected birds (DIVA) by detection of subtype specific NA antibodies of the field virus.~~ Vaccines used should comply with the standards of the *Terrestrial Manual*.

All flocks with seropositive results should be investigated. Epidemiological and supplementary laboratory investigation results should document the status of NAI infection/circulation for each positive flock.

A confirmatory test should have a higher specificity than the screening test and sensitivity at least equivalent than that of the screening test.

Information should be provided on the performance characteristics and validation of tests used.

### 3.1.1.3. 1. The follow up procedure in case of positive test results if vaccination is used

In case of vaccinated populations, one has to exclude the likelihood that positive test results are indicative of virus circulation. To this end, the following procedure should be followed in the investigation of positive serological test results derived from surveillance conducted on NAI-vaccinated poultry. The investigation should examine all evidence that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were not due to virus circulation. All the epidemiological information should be substantiated and the results should be collated in the final report.

Knowledge of the type of vaccine used is crucial in developing a serological based strategy to differentiate infected from vaccinated animals.

- a) Inactivated whole AI virus vaccines can use either homologous or heterologous neuraminidase subtypes between the vaccine and field strains. If poultry in the population have antibodies to NP/M and were vaccinated with inactivated whole AI virus vaccine, the following strategies should be applied:
  - i) sentinel birds should remain NP/M antibody negative. If positive for NP/M antibodies, indicating AI virus infection, specific HI tests should be performed to identify H5 or H7 AI virus infection;
  - ii) if vaccinated with inactivated whole AI virus vaccine containing homologous NA to field virus, the presence of antibodies to NSP could be indicative of infection. Sampling should be initiated to exclude the presence of NAIV by either virus isolation or detection of virus specific genomic material or proteins;

- iii) if vaccinated with inactivated whole AI virus vaccine containing heterologous NA to field virus, presence of antibodies to the field virus NA or NSP would be indicative of infection. Sampling should be initiated to exclude the presence of 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.

#### 3.1.1.4. 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 NAIIV transmission.

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

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

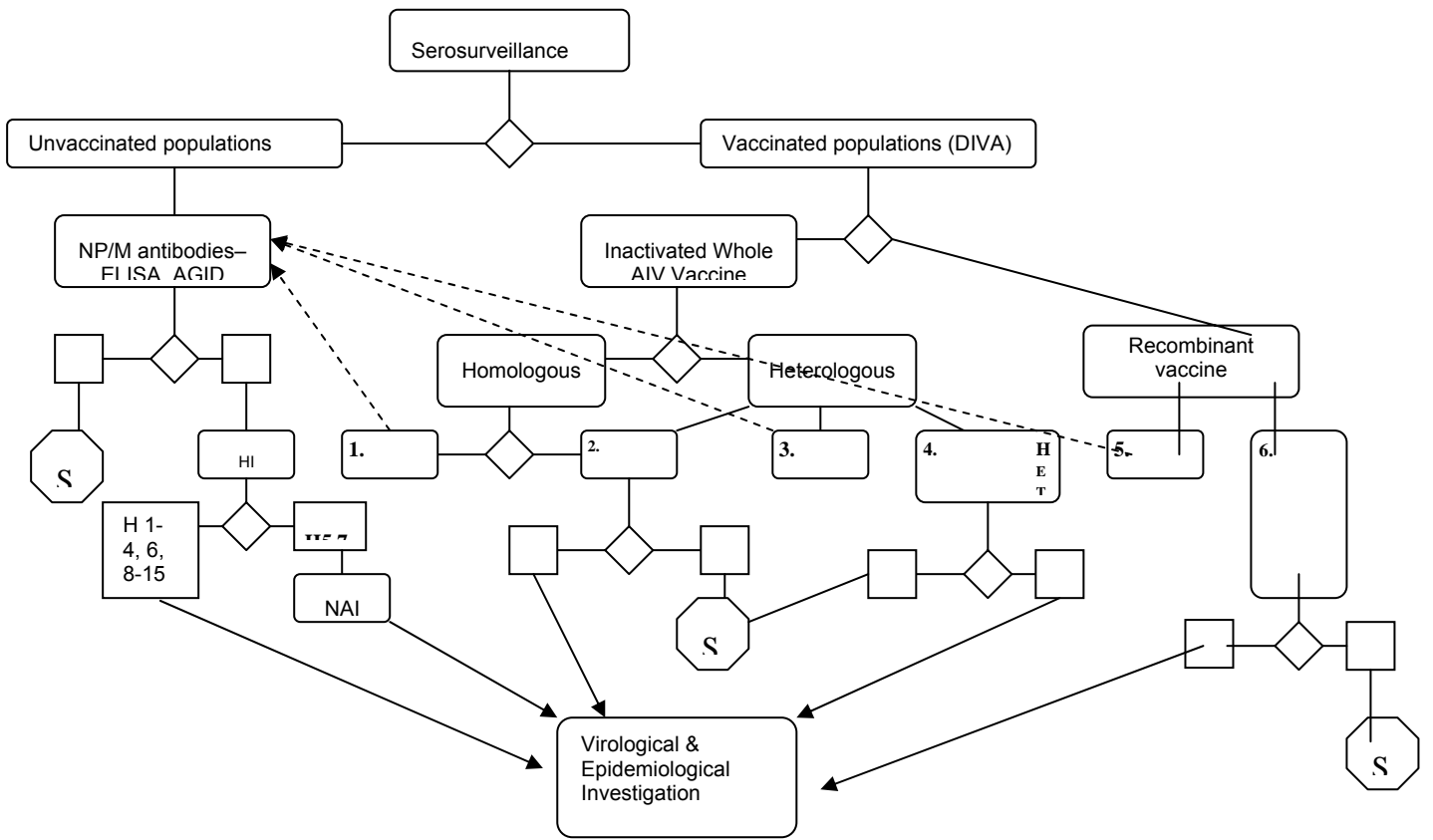
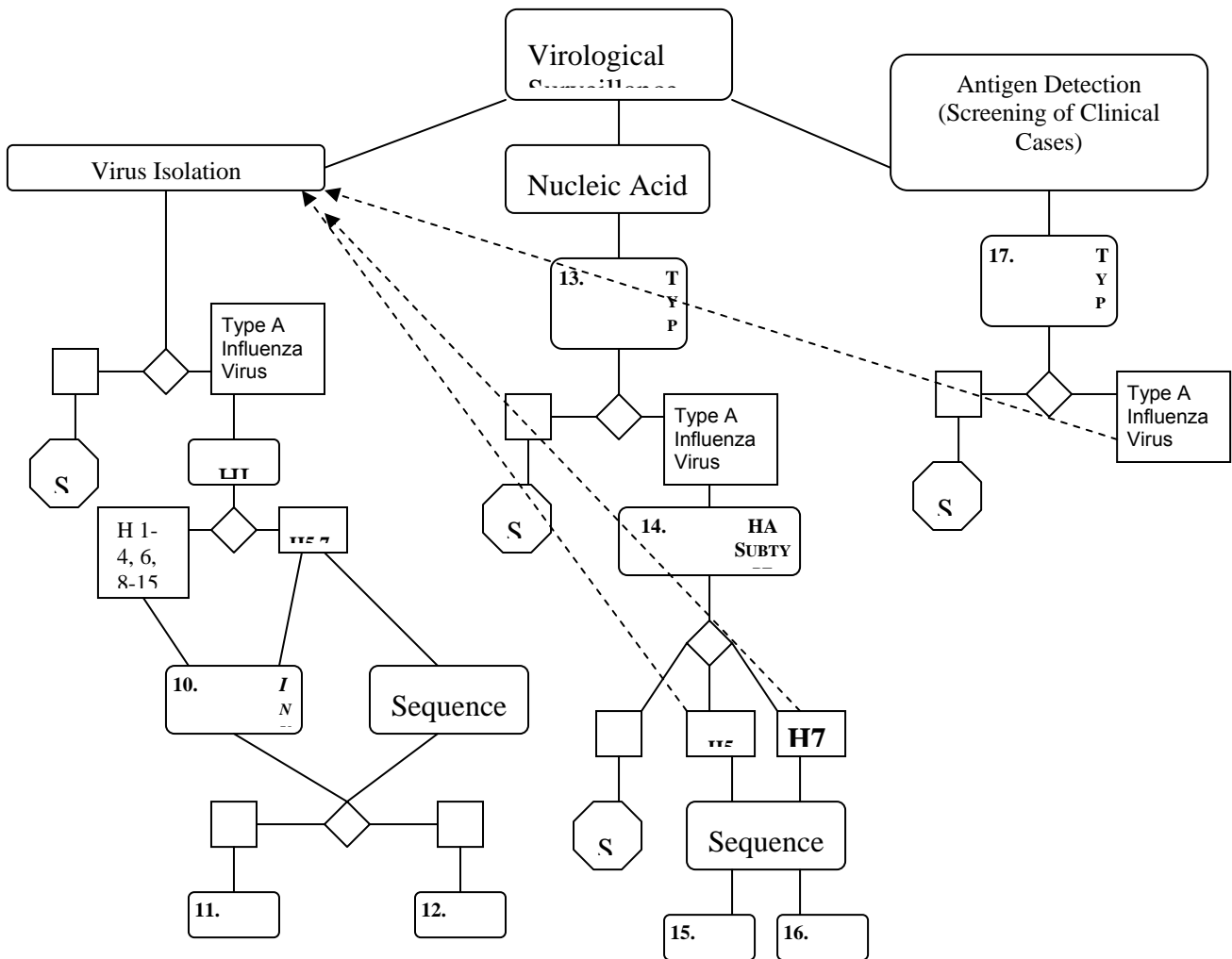


Figure 2. - Schematic representation of laboratory tests for determining evidence of NAI infection using virological methods



The above diagram indicates the tests which are recommended for use in the investigation of poultry flocks.

Key:

AGID	Agar gel immunodiffusion
DIVA	Differentiating infected from vaccinated animals
ELISA	Enzyme-linked immunosorbant assay
HA	Haemagglutinin
HI	Haemagglutination inhibition
NA	Neuraminidase
NP/M	Nucleoprotein and matrix protein
NSP	Nonstructural protein
S	No evidence of NAI

— text deleted

## APPENDIX 3.8.X.

GUIDELINES FOR THE INACTIVATION  
OF THE AVIAN INFLUENZA VIRUS

**Community comments:**  
**The Community supports this Chapter**

Article 3.8.X.1.

**Egg and egg products**

The following industry standard procedures are suitable for the inactivation of highly pathogenic notifiable avian influenza (HPNAI) virus present in egg and egg products:

	Temperature (°C)	Time
Whole egg	60	210 seconds
Whole egg blends	60	372 seconds
Whole egg blends	61.1	210 seconds
Liquid egg white	55.6	372 seconds
Liquid egg white	56.7	210 seconds
10% salted yolk	62.2	372 seconds
10% salted yolk	63.3	210 seconds
Dried egg white	67	15 days

Article 3.8.X.2.

**Meat**

A procedure which produces a core temperature of 70°C for one second is suitable for the inactivation of HPNAI virus present in meat.

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APPENDIX 3.2.1.

BOVINE AND SMALL RUMINANT SEMEN

**Community comments:**  
**The Community can support this proposal but would like the comments below taken into account.**

Article 3.2.1.1.

**General considerations**

The purposes of official sanitary control of semen production are to:

1. maintain the health of animals on an *artificial insemination centre* at a level which permits the international distribution of semen with a negligible risk of infecting other animals or humans with pathogens transmissible by semen;
2. ensure that semen is hygienically collected, processed and stored.

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

Article 3.2.1.2.

**Conditions applicable to artificial insemination centres**

1. The *artificial insemination centre* is comprised of:
  - a) animal accommodation areas (including one isolation facility for sick animals) and a semen collection room, these two premises hereon designated as semen collection facilities; accommodation areas should be species specific where relevant;
  - b) a semen laboratory and semen storage areas;
  - c) administration offices.

A *quarantine station* may also be attached to the centre, provided that it is on a different location from that of those two first parts.

2. The centre should be officially approved by the *Veterinary Administration*.
3. The centre should be under the supervision and control of the *Veterinary Authority* which will be responsible for regular audits, at an interval of no more than 6 months, of

protocols, procedures and prescribed records on the health and welfare of the animals in the centre and on the hygienic production, storage and dispatch of semen.

4. The centre should be under the direct supervision and control of a veterinarian designated by the *artificial insemination centre* and accredited by the *Veterinary Administration* for relevant official tasks.

#### Article 3.2.1.3.

#### **Conditions applicable to semen collection facilities**

1. The semen collection facilities should include separate and distinct areas for accommodating resident animals, for semen collection, for feed storage, for manure storage, and for the isolation of ~~suspect~~ animals suspected of being infected.
2. Only animals associated with semen production should be permitted to enter the semen collection facilities. Other species of animals may be resident at the centre, if necessary for the movement or handling of the donors and teasers or for security, but contact with the donors and teasers should be minimised. All animals resident at the semen collection facilities must meet the minimum health requirements for donors.
3. The donors and teasers should be adequately isolated to prevent the transmission of diseases from farm livestock and other animals. Measures should be in place to prevent the entry of wild animals susceptible to OIE-listed ruminant diseases transmissible via semen.
4. Personnel at the centre should be technically competent and observe high standards of personal hygiene to preclude the introduction of pathogenic organisms. Special protective clothing and footwear for use only at the semen collection facilities should be provided and worn at all times inside.
5. Visitors to the semen collection facilities should be kept to a minimum, and visits should be subject to formal authorisation and control. Equipment for use with the livestock should be dedicated to the semen collection facilities or disinfected prior to entry. All equipment and tools brought on to the premises must be examined and treated if necessary to ensure that they cannot introduce disease.
6. *Vehicles* used for transport of animals to and from the semen collection facilities should not be allowed to enter the facilities.
7. The semen collection area should be cleaned daily after collection. The animals' accommodation and semen collection areas should be cleaned and disinfected at least once a year.
8. Fodder introduction and manure removal should be done in a manner which poses no significant animal health risk.

#### Article 3.2.1.4.

##### **Conditions applicable to semen laboratories**

1. The semen laboratory should be physically separated from the semen collection facilities, and include separate areas for artificial vagina cleaning and preparation, semen evaluation and processing, semen pre-storage and storage. Entry to the laboratory should be prohibited to unauthorised personnel.
2. The laboratory personnel should be technically competent and observe high standards of personal hygiene to preclude the introduction of pathogenic organisms during semen evaluation, processing and storage.
3. Visitors to the laboratory should be kept to a minimum, and visits should be subject to formal authorisation and control.
4. The laboratory should be constructed with materials that permit effective cleaning and *disinfection*.
5. The laboratory should be regularly cleaned. Work surfaces for semen evaluation and processing should be cleaned and disinfected at the end of each workday.
6. The laboratory should be treated against rodents and insects on a regular basis as needed to control these pests.
7. The storage rooms and individual semen containers should be easy to clean and disinfect.
8. Only semen collected from donors having a health status equivalent to or better than the donors at the semen collection facilities should be processed in the laboratory.

#### Article 3.2.1.5.

##### **Conditions applicable to testing of bulls and teaser animals**

Bulls and teaser animals ~~can~~ should enter an *artificial insemination centre* only if they fulfil the following requirements ~~laid down by the Veterinary Administration~~.

##### 1. Pre-quarantine

The animals should comply with the following requirements prior to entry into isolation at the *quarantine station*.

- a) Bovine brucellosis

The animals should comply with point 3 or 4 of Article 2.3.1.5. of the *Terrestrial Code*.

b) Bovine tuberculosis

The animals should comply with point 2, 3 or 4 of Article 2.3.3.4. of the *Terrestrial Code*.

c) Bovine viral diarrhoea-mucosal disease (BVD-MD)

The animals should be subjected to the following tests:

- i) a virus isolation test or a test for virus antigen, with negative results;
  - ii) a serological test to determine the serological status of every animal.
- d) Infectious bovine rhinotracheitis-infectious pustular vulvovaginitis (IBR/IPV) If the *artificial insemination centre* is to be considered as IBR/IPV free, the animals should either:
- i) come from an IBR/IPV free herd as defined in Article 2.3.5.3.; or
  - ii) be subjected, with negative results, to a serological test for IBR/IPV on a blood sample.

e) Bluetongue

The animals should comply with Article 2.2.13.6., 2.2.13.7. or 2.2.13.8., depending on the bluetongue status of the country of origin of the animals.

2. Testing in the quarantine station prior to entering the semen collection facilities

Prior to entering the semen collection facilities of the *artificial insemination centre*, bulls and teaser animals should be kept in a *quarantine station* for at least 28 days. The animals should be subjected to diagnostic tests as described below a minimum of 21 days after entering the *quarantine station*, except for *Campylobacter fetus* subsp. *venerealis* and *Trichomonas foetus*, for which testing may commence after 7 days in quarantine. All the results should be negative except in the case of BVD-MD antibody serological testing (see point 2b)i) below).

a) Bovine brucellosis

If the country is not free from brucellosis, the animals should be subjected to a serological test with negative results.

**Community comment:**

**The Community cannot support the proposed amendment for the following reason:**

**The Community believes that an AI centre is a special entity where only higher standards should be accepted. The economic consequences of a spread of brucellosis are enormous compared to the costs of testing.**

b) BVD-MD

- i) All animals should be tested for viraemia as described in point 1c) above.

Only when all the animals in quarantine test negative for viraemia may the animals enter the semen collection facilities upon completion of the 28-day quarantine period.

- ii) After 21 days in quarantine, all animals should be subjected to a serological test to determine the presence or absence of BVD-MD antibodies.
- iii) Only if no sero-conversion occurs in the animals which tested seronegative before entry into the *quarantine station*, may any animal (seronegative or seropositive) be allowed entry into the semen collection facilities.
- iv) If sero-conversion occurs, all the animals that remain seronegative should be kept in quarantine over a prolonged time until there is no more seroconversion in the group for a period of 3 weeks. Serologically positive animals may be allowed entry into the semen collection facilities.

c) *Campylobacter fetus* subsp. *venerealis*

- i) Animals less than 6 months old or kept since that age only in a single sex group prior to quarantine should be tested once on a preputial specimen, with a negative result.
- ii) Animals aged 6 months or older that could have had contact with females prior to quarantine should be tested three times at weekly intervals on a preputial specimen, with a negative result in each case.

d) *Trichomonas foetus*

- i) Animals less than 6 months old or kept since that age only in a single sex group prior to quarantine, should be tested once on a preputial specimen, with a negative result.
- ii) Animals aged 6 months or older that could have had contact with females prior to quarantine should be tested three times at weekly intervals on a preputial specimen, with a negative result in each case.

e) IBR/IPV

If the *artificial insemination centre* is to be considered as IBR/IPV free, the animals should be subjected, with negative results, to a diagnostic test for IBR/IPV on a blood sample. If any animal tests positive, the animal should be removed immediately from the *quarantine station* and the other animals of the same group should remain in quarantine and be retested, with negative results, not less than 21 days after removal of the positive animal.

f) Bluetongue

The animals should comply with Article 2.2.13.9., 2.2.13.10. or 2.2.13.11., depending on the bluetongue status of the country of origin of the animals.

3. Testing for BVD-MD prior to the initial dispatch of semen from each serologically positive bull

Prior to the initial dispatch of semen from BVD-MD serologically positive bulls, a semen sample from each animal should be subjected to a virus isolation or virus antigen ELISA test for BVD-MD. In the event of a positive result, the bull should be removed from the centre and all of its semen destroyed.

**Community comment:**

**The Community proposes that the sentence “...subjected to a virus isolation or virus antigen ELISA test for BVD-MD” is changed to “...subjected to a relevant test for BVD-MD virus” for the following reason:**

**It should be noted that antigen ELISAs (at current) are not used to detect BVDV in semen. It is not a method of choice for this specimen. The suitable method is RT-PCR. Virus isolation can be used, but raw semen is cytotoxic and must be diluted in culture medium. Extended semen can usually be inoculated directly on to cell monolayers, but may occasionally cause cytotoxicity. Also, note that the target population for this test, seropositive bulls with localized persistent infection, are likely to have low levels of virus in semen and this is an additional reason to use RT-PCR for this purpose.**

**If the OIE wishes to refer to what is recommended in the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, the alternative wording above may be used. Note, however, that the Manual (chapter 2.10.6) is not exhaustive on this particular matter (detection of virus in semen) and we therefore recommend a revision where this aspect is included.**

4. Testing of frozen semen for IBR/IPV in artificial insemination centres not considered as IBR/IPV free

Each aliquot of frozen semen should be tested as per Article 2.3.5.7.

5. Testing programme for bulls and teasers resident in the semen collection facilities

All bulls and teasers resident in the semen collection facilities should be tested at least annually for the following diseases, with negative results, where the country of origin is not free:

- a) Bovine brucellosis
- b) Bovine tuberculosis
- c) BVD-MD

Animals negative to previous serological tests should be retested to confirm absence of antibodies.

Should an animal become serologically positive, every ejaculate of that animal collected since the last negative test should be either discarded or tested for virus with negative results.

- d) *Campylobacter fetus* subsp. *venerealis*
  - i) A preputial specimen should be cultured.
  - ii) Only bulls on semen production or having contact with bulls on semen production need to be tested. Bulls returning to collection after a lay off of more than 6 months should be tested not more than 30 days prior to resuming production.

- e) Bluetongue

The animals should comply with the provisions referred to in Article 2.2.13.9., 2.2.13.10. or 2.2.13.11., depending on the bluetongue status of the country of origin of the animals.

- f) *Trichomonas foetus*
  - i) A preputial specimen should be cultured.
  - ii) Only bulls on semen production or having contact with bulls on semen production need to be tested. Bulls returning to collection after a lay off of more than 6 months should be tested not more than 30 days prior to resuming production.

- g) IBR/IPV

If the *artificial insemination centre* is to be considered as IBR/IPV free, the animals should comply with the provisions in point 2)c) of Article 2.3.5.3.

#### Article 3.2.1.6.

### Conditions applicable to testing of rams/bucks and teaser animals

Rams/bucks and teaser animals can enter an *artificial insemination centre* only if they fulfil the following requirements ~~laid down by the Veterinary Administration.~~

#### 1. Pre-quarantine

The animals should comply with the following requirements prior to entry into isolation at the *quarantine station*.

##### a) Caprine and ovine brucellosis

The animals should comply with Article 2.4.2.6.

##### b) Ovine epididymitis

The animals should comply with Article 2.4.1.3.

##### c) Contagious agalactia

The animals should comply with points 1 and 2 of Article 2.4.3.1.

##### d) Peste des petits ruminants

The animals should comply with points 1, 2, and 4 ~~and~~ 5 of Article 2.4.9.7.

##### e) Contagious caprine pleuropneumonia

The animals should comply with Article 2.4.6.5. or Article 2.4.6.7., depending on the CCPP status of the country of origin of the animals.

##### ~~f) Caseous lymphadenitis~~

~~The animals should be free from clinical signs for the past 12 months.~~

##### g) Paratuberculosis

The animals should be free from clinical signs for the past 2 years.



h) Scrapie

If the animals do not originate from a scrapie free country or *zone* as defined in Article 2.4.8.3., the animals should comply with points 1 and 2 of Article 2.4.8.8.

i) Maedi-visna

The animals should comply with Article 2.4.5.2.

j) Caprine arthritis/encephalitis

The animals should comply with Article 2.4.4.2.

k) Bluetongue

The animals should comply with Article 2.2.13.6., 2.2.13.7. or 2.2.13.8., depending on the bluetongue status of the country of origin of the animals.

l) Tuberculosis

In the case of goats, the animals should be subject to a single or comparative tuberculin test, with negative results.

m) ~~Border disease~~

~~The animals should be subject to a viral agent isolation test with negative results.~~

**Community comment:**

**The Community cannot support the proposed amendment for the following reasons:**

**The virus is present in semen of persistently infected (PI) and apparently healthy animals; PI animals can spread infection horizontally, and there is evidence that infected ewes can infect the fetus (vertical transmission). Unlike BVD, Border Disease has not been thoroughly or extensively researched. According to EU laboratory experts, the probability of infected semen causing disease in recipients is lower than in the case of BVD and cattle. Nevertheless, it cannot be discounted. Border disease is in IETS category IV, hence the risk of producing infected embryos cannot be discounted either.**

2. Testing in the quarantine station prior to entering the semen collection facilities

Prior to entering the semen collection facilities of the *artificial insemination centre*, rams/bucks and teasers should be kept in a *quarantine station* for at least 28 days. The

animals should be subjected to diagnostic tests as described below a minimum of 21 days after entering the *quarantine station*, with negative results:

a) Caprine and ovine brucellosis

The animals should be subject to testing as described in point 1 b) or c) of Article 2.4.2.8.

b) Ovine epididymitis

The animals and semen should be subject to testing as described in points 1 d) and 2 of Article 2.4.1.4.

c) Maedi-visna and caprine arthritis/encephalitis ~~or CAE~~

The animals should be subjected to a serological test.

d) Bluetongue

The animals should comply with the provisions referred to in Article 2.2.13.9., 2.2.13.10. or 2.2.13.11., depending on the bluetongue status of the country of origin of the animals.

3. Testing programme for rams/bucks and teasers resident in the semen collection facilities

All rams/bucks and teasers resident in the semen collection facilities should be tested at least annually for the following diseases, with negative results, where the country of origin is not free:

- a) caprine and ovine brucellosis;
- b) ovine epididymitis;
- c) Maedi-visna and caprine arthritis/encephalitis ~~or CAE~~;
- d) tuberculosis (for goats only);
- e) bluetongue.

Article 3.2.1.7.

**General considerations for hygienic collection and handling of semen**

Observation of the recommendations described in the Articles below will very significantly reduce the likelihood of the semen being contaminated with common bacteria which are potentially pathogenic.

Article 3.2.1.8.

**Conditions applicable to the management of bulls, rams and bucks**

The objective is to keep the animals in a satisfactory state of cleanliness, particularly of the lower thorax and abdomen.

1. Whether on pasture or housed, the animal should be kept under hygienic conditions. If housed, the litter must be kept clean and renewed as often as necessary.
2. The coat of the animal should be kept clean.
3. For bulls, the length of the tuft of hairs at the preputial orifice, which is invariably soiled, should be cut to about 2 cm. The hair should not be removed altogether, because of its protective role. If cut too short, irritation of the preputial mucosa may result because these hairs aid the drainage of urine.
4. The animal should be brushed regularly, and where necessary on the day before semen collection, paying special attention to the underside of the abdomen.
5. In the event of obvious soiling, there should be careful cleaning, with soap or a detergent, of the preputial orifice and the adjoining areas, followed by thorough rinsing and drying.
6. When the animal is brought into the collection area, the technician must make sure that it is clean, and that it is not carrying any excessive litter or particles of feed on its body or its hooves, for such materials are always heavily contaminated.

Measures similar to the above should be adapted to rams and bucks.

#### Article 3.2.1.9.

#### **Conditions applicable to the collection of semen**

1. The floor of the mounting area should be easy to clean and to disinfect. A dusty floor should be avoided.
2. The hindquarters of the teaser, whether a dummy or a live teaser animal, must be kept clean. A dummy must be cleaned completely after each period of collection. A teaser animal must have its hindquarters cleaned carefully before each collecting session. The dummy or hindquarters of the teaser animal should be sanitized after the collection of each ejaculate. Disposable plastic covers may be used.
3. The hand of the person collecting the semen must not come into contact with the animal's penis. Disposable gloves should be worn by the collector and changed for each collection.
4. The artificial vagina must be cleaned completely after each collection. It should be dismantled, its various parts washed, rinsed and dried, and kept protected from dust. The inside of the body of the device and the cone should be disinfected before re-assembly using approved *disinfection* techniques such as those involving the use of 70° ethyl or 98-

99° isopropyl alcohol, ethylene oxide or steam. Once re-assembled, it should be kept in a cupboard which is regularly cleaned and disinfected.

5. The lubricant used should be clean. The rod used to spread the lubricant must be clean and should not be exposed to dust between successive collections.
6. The artificial vagina should not be shaken after ejaculation, otherwise lubricant and debris may pass down the cone to join the contents of the collecting tube.
7. When successive ejaculates are being collected, a new artificial vagina should be used for each mounting. The vagina should also be changed when the animal has inserted its penis without ejaculating.
8. The collecting tubes should be sterile, and either disposable or sterilised by autoclaving or heating in an oven at 180°C for at least 30 minutes. They should be kept sealed to prevent exposure to the environment while awaiting use.
9. After semen collection, the tube should be left attached to the cone and within its sleeve until it has been removed from the collection room for transfer to the laboratory.

#### Article 3.2.1.10.

### **Conditions applicable to the handling of semen and preparation of semen samples in the laboratory**

#### 1. Diluents

- a) All receptacles used should have been sterilised.
- b) Buffer solutions employed in diluents prepared on the premises should be sterilized by filtration (0.22 µm) or by autoclaving (121°C for 30 minutes) or be prepared using sterile water before adding egg yolk (if applicable) or equivalent additive and antibiotics.
- c) If the constituents of a diluent are supplied in commercially available powder form, the water used must have been distilled or demineralised, sterilized (121°C for 30 minutes or equivalent), stored correctly and allowed to cool before use.
- d) When egg yolk is used, it should be separated from eggs using aseptic techniques. Alternatively, commercial egg yolk prepared for human consumption or egg yolk treated by, for example, pasteurisation or irradiation to reduce bacterial contamination, may be used. Other additives must also be sterilized before use.

- e) Diluent should not be stored for more than 72 hours at +5°C before use. A longer storage period is permissible for storage at -20°C. Storage vessels should be stoppered.
- f) A mixture of antibiotics should be included with a bactericidal activity at least equivalent to that of the following mixtures in each ml of frozen semen: either gentamicin (250 µg), tylosin (50 µg), lincomycin-spectinomycin (150/300 µg) or penicillin (500 IU), streptomycin (500 µg), lincomycin-spectinomycin (150/300 µg).

The names of the antibiotics added and their concentration should be stated in the *international veterinary certificate*.

## 2. Procedure for dilution and packing

- a) The tube containing freshly collected semen should be sealed as soon as possible after collection, and kept sealed until processed.
- b) After dilution and during refrigeration, the semen should also be kept in a stoppered container.
- c) During the course of filling receptacles for dispatch (such as insemination straws), the receptacles and other disposable items should be used immediately after being unpacked. Materials for repeated use should be sterilised with alcohol, ethylene oxide, steam or other approved sterilisation techniques.
- d) If sealing powder is used, care should be taken to avoid its being contaminated.

## 3. Conditions applicable to the storage of semen

Semen for export should be stored separately from other genetic material not meeting these guidelines in fresh liquid nitrogen in sterilised/sanitised flasks before being exported.

Semen straws should be sealed and code marked in line with the international standards of the International Committee for Animal Recording (ICAR)\*.

Prior to export, semen straws or pellets should be identified and placed into new liquid nitrogen in a new or sterilised flask or container under the supervision of an Official Veterinarian. The contents of the container or flask should be verified by the Official Veterinarian prior to sealing. Containers should be sealed with an official numbered seal under the responsibility of the Veterinary Administration before export and accompanied by an international veterinary certificate listing the contents and the number of the official seal.

<b>Community comment:</b>
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The Community believes the requirement for an official veterinarian to supervise these procedures is too onerous as a designated veterinarian to carry out official duties is required according to Article 3.2.1.2 point 4 and it suggests the following wording:

**“Prior to export, semen straws or pellets should be identified and placed into new liquid nitrogen in a new or sterilised flask or container under the supervision of the designated centre veterinarian. The contents of the container or flask should be verified by the centre veterinarian prior to sealing according to the instructions from the *Official Veterinarian*.”**

- \* The ICAR international standards on straws are contained in *Recording Guidelines* - Appendices to the international agreement of recording practices. Section 9, Appendix B relating to semen straw identification.

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APPENDIX X.X.X.

GUIDELINES FOR THE CONTROL OF HAZARDS OF ANIMAL  
HEALTH AND PUBLIC HEALTH IMPORTANCE THROUGH  
ANTE- AND POST-MORTEM MEAT INSPECTION

**Community comments:**

**The Community can support this proposal but would like the points below taken into account to improve the text.**

**Introduction**

Foodborne disease and zoonoses are important public health problems and important causes of decreased economic productivity in developed and developing countries. Similarly, transmission of hazards of animal health importance via the food chain and associated by-products can result in significant economic loss in livestock. Inspection of animals at slaughter can provide a valuable contribution to surveillance for certain diseases of animal and public health importance. Control and/or reduction of hazards of animal and public health importance by ante- and post-mortem meat inspection are a core responsibility of *Veterinary Services*.

**Community comments:**

**The first sentence should read as follows:**

**“Foodborne disease and zoonoses are important public health problems and causes of.....”**

**3.2. Design and management of inspection programmes**

At the end of this chapter the following two sentences should be added:

A priority should be the collation and analysis of the information gained from the surveillance of primary production, ante and post mortem inspections in a transparent way. These results should be made available in a timely way.

## Purpose

These guidelines provide a basis for future development of OIE standards for animal production food safety.

### **Community comments:**

**The sentence should read as follows:**

**“These guidelines provide a basis for future development of OIE standards for animal production food safety having regard to the food chain or farm to fork concept.”**

## Hygienic practice throughout the food chain

The Codex Alimentarius Code of Hygienic Practice for Meat<sup>48</sup> (CHPM) constitutes the primary international standard for meat hygiene and incorporates a risk-based approach to application of sanitary measures throughout the food chain. Ante-mortem inspection is described as a primary component of meat hygiene pre-slaughter, and post-mortem inspection is described as a primary component of process control in post-slaughter meat hygiene. The CHPM specifically recognises the dual objectives that slaughterhouse inspection activities deliver in terms of animal and public health.

The CHPM does not provide inspection measures for specific hazards or organoleptically detected abnormalities, which remain the responsibility of national competent authorities. The animal and public health risks associated with livestock populations vary across regions and animal husbandry systems, and ante- and post-mortem inspection needs to be tailored to the individual country situation and its animal and public health objectives.

The CHPM provides a platform for development of meat hygiene systems that are based on risk assessment. There are few risk assessment models or relevant scientific information available on public health hazards, making difficult the development of risk-based standards for food-borne zoonoses. While this scientific information is being accumulated, ante- and post-mortem inspection systems will remain dependent on traditional approaches.

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<sup>48</sup> Code of Hygienic Practice for Meat, CAC/RCP 58-2005



### 3.2.1.1.

**Community comments:**

**The last sentence should read:**

**“It is foreseen that by linking up surveillance data, epidemiologic knowledge with risk assessments major advances can be made in the years to come to develop evidence based risk management policies”.**

### **Veterinary Services and meat inspection programmes**

*Veterinary Services* are primarily responsible for the development of ante- and post-mortem meat inspection programmes. Wherever possible, inspection procedures should be risk-based and management systems should reflect international norms. In respect of ante- and post-mortem inspection as a component of meat hygiene, responsibilities of *Veterinary Services* include:

- Risk assessment
- Establishment of policies and standards
- Design and management of inspection programmes
- Assurance and certification of appropriate delivery of inspection and compliance activities
- Dissemination of information throughout the food chain

**Community comments:**

**The Community proposes to add the following 2 bullets:**

**“Design and management of monitoring and surveillance program  
Risk management.”**

### **Risk assessment**

*Veterinary Services* should utilise risk assessment to the greatest extent possible in the development of sanitary measures. *Veterinary Services* should give priority to addressing microbiological contamination, rather than gross abnormalities detected at ante and post-mortem inspection, as this has been found to be the most important source of hazards.

**Community comment:**

**The second sentence should read as follows:**

**“*Veterinary Services* should in general give priority to addressing microbiological contamination, rather than gross abnormalities detected at ante and post-mortem inspection, as this has been found to be the most important source of hazards.”**

**A third sentence should be added as follows:**

**“However, the animal health importance of detecting diseased animals at ante and post mortem inspection should be kept in mind”.**

Microbiological, serological or other testing at single-animal and herd level as part of ante- and post-mortem inspection should be used to support surveillance, as well as risk assessment of prioritised foodborne hazards. The information gathered should be linked to human disease data to allow an assessment of the effectiveness of various management options, as well as a general evaluation of food sources of foodborne disease.

Application of a generic framework should provide a systematic and consistent process for managing all biosecurity risks, while accommodating the different risk assessment methodologies used in animal and public health.

### **Establishment of policies and standards**

The national competent authority(s) should provide an appropriate institutional environment to allow *Veterinary Services* to develop the necessary policies and standards.

As well as meeting public health objectives, policies and standards relating to ante- and post-mortem inspection should aim to detect and remove hazards of animal health significance from the food chain. This may be achieved by the removal of live animals at ante-mortem inspection or by the removal of specific tissues at post-mortem inspection.

*Veterinary Services* should integrate their activities to the maximum extent possible and practicable so as to increase the efficacy of policies to prevent duplication of effort and unnecessary costs e.g. within the process of international certification.

### **Design and management of inspection programmes**

In meeting animal and public health objectives prescribed in national legislation or required by *importing countries*, *Veterinary Services* contribute through the direct performance of some veterinary tasks or through the auditing of animal and public health activities conducted by other agencies or the private sector. To this end, *Veterinary Services* provide assurances domestically and to trading partners that safety and suitability standards have been met.

*Veterinary Services* should allow flexibility in meat inspection service delivery through an officially recognised competent body operating under its supervision and control. In recognition of the contribution of industry to food safety, quality assurance systems may be extended in the case of ante- and post-mortem inspection to systems that integrate industry and *Veterinary Services* activities. Nevertheless, *Veterinary Services* should take into account the factors identified in Chapter 1.3.3 on the Evaluation of *Veterinary Services*. For example, if personnel from the private sector are used to carry out ante- and post-mortem inspection activities under the overall supervision and responsibility of the *Veterinary Services*, the *Veterinary Services* should specify the competency requirements for all such persons and verify their performance.

### **Assurance and certification**

Assurance and certification of appropriate delivery of inspection and compliance activities is a vital function of *Veterinary Services*. International health certificates providing official assurances for trading of meat must engender full confidence to the country of importation.

### **Dissemination of information**

Organisation and dissemination of information throughout the food chain involves multidisciplinary inputs. To ensure the effective implementation of ante- and post-mortem inspection procedures, *Veterinary Services* should have in place systems for the monitoring of these procedures and the exchange of information gained. Animal identification and traceability systems should be integrated in order to be able to trace slaughtered animals back to their place of origin, and products derived from them forward to processors.

CHAPTER 1.3.7.

ANIMAL IDENTIFICATION AND TRACEABILITY

**Community comments:**

**The Community can support this proposal but would like the comments below taken into account. The Community welcomes this first draft but understands that this work will be further elaborated by the working group being set up on this subject.**

**Proposed definitions** (to be located in Chapter 1.1.1)

*Animal identification* means the identification and registration of an animal individually or collectively by its *epidemiological unit* or group. Methods of animal identification include tag, brand, tattoo, transponder (microchip), collar, ring and mark.

**Community comment:**

**Animals are identified individually by individual identification (individual number) or group identification (collective marks). The construction of the above definition may be misleading (“by its *epidemiological unit* or group” goes with “collectively” only, not with “individually”). The insertion of a comma after “*individually or...*” could help in clarifying this.**

**A possible alternative would be to modify the definition as follows:**

**“*Animal identification* is the identification and registration of an animal individually, with a unique identifier; or collectively by its *epidemiological unit* or group, with a unique group identifier.”**

*Animal identification system* means the inclusion and linking of components such as *identification of establishments/owners*, the person(s) responsible for the animal(s) and records with *animal identification*.

*Animal identification system*

- “*Animal identification system* includes and links components such as *identification of establishments/owners*, the person(s) responsible for the animal(s) and records with animal identification.”

**Community comments:**

The Community believes that this is not clear enough and needs to be clarified e.g.

(1) **“records”** ... of what? (movements? changes of individual identification?).

The Community proposes the following wording:

**“Movements”** have to feature in any discussion on and definition relating to identification. If you do not have track of movements, how can you ensure traceability. It is also the key consideration in relation to animal health problems with some third countries. They are frequently unable to account for the origins of animals as they do not have record of movements which in turn is because they do not have proper identification systems. In practice, it is difficult to ensure traceability of movements without individual identification.

(2) **links** “... components such as *identification of establishments/owners*, ... with *animal identification*.”

One possible solution would be to add a specific sentence specifying what kind of records is addressed here (i.e. records of movements, including in particular herd of origin and date of entry into the “new” herd).

*Animal traceability* means the ability to follow an animal during specified stage(s) of its life.

**Community comments:**

The Community proposes the following wording “*Animal traceability* means the ability to trace an animal during all stages of its life”.

*Individual identification* means the identification of each animal using a unique identifier.

*Group identification* means the identification of a group of animals using a unique group identifier.

*Register* means the system by which animal identification and traceability information is securely stored and appropriately accessed by the *Competent Authority*.

Article 1.3.7.1.

**General principles**

1. There is a critical relationship between *animal identification* and the traceability of animals and *products of animal origin*.
2. *Animal traceability* and traceability of *products of animal origin* should have the capability to be linked to food product traceability in order to maintain traceability throughout the food chain.

**Community comments:**

Bearing in mind ongoing discussions in the Codex framework (CCFICS - Proposed draft Principles for the Application of Traceability/Product Tracing in the context of Food Import and Export Inspection and Certification Systems), a stronger link should be established in the “General Principles for Animal Identification and Animal Traceability” between “animal traceability” and “product tracing”. Such a link could follow the “one step back” / “one step forward “ approach as mentioned under paragraph 12 (Design) of the Codex “Proposed draft Principles for the Application of Traceability/Product Tracing in the context of Food Import and Export Inspection and Certification Systems”: “12. *The traceability/product tracing tool should be able to identify at any specified stage of the food chain (from production to distribution) from where the food came (one step back) and to where the food went (one step forward), as appropriate to the objectives of the food inspection and certification system.*”

The Community proposes the following wording:

**“2. *Animal traceability and food product traceability should have the capacity to be linked in order to maintain traceability throughout the food chain continuum. Animal traceability should be able to identify at any specified stage of the food chain (from production to distribution) from where the food came (one step back) and to where the food went (one step forward), as appropriate to the objectives of the food inspection and certification system.*”**

It may also be appropriate to cover the feed chain (a link should also be possible between the animal and the feed it has eaten).

3. *Animal identification and animal traceability* are important tools for addressing animal health (including zoonoses) and food safety, and may significantly improve the effectiveness of the management of disease outbreaks and food safety incidents, vaccination programmes, herd/flock husbandry, *zoning/compartmentalisation*, surveillance, early response and notification systems, animal movement controls and assurances of safety in trade.

**Community comments:**

Bearing in mind ongoing discussions at the WTO/SPS committee on regionalisation, direct reference to “regionalisation” could also appear here as this is still used in CODEX:

The Community proposes the following wording:

**“3. *Animal identification and animal traceability* are key tools for animal health, including zoonoses, and food safety, and may significantly improve the effectiveness of the management of disease outbreaks and food safety incidents, vaccination**

programmes, herd/flock management, *zoning (regionalisation)/compartmentalisation*, surveillance, early response and notification systems, animal movement controls and health measures to facilitate trade”.

Other key concepts on usefulness of animal identification and animal traceability could be added, either in a dedicated paragraph or as additional examples:

- **“bio-safety management”**;
- **“monitoring of animal/herd health status”** (not only “management of disease outbreaks”);
- **quality management (“quality schemes”, “conformation of the animal/carcass”);**
- **different policy and economic considerations (management of premiums and taxes);**
- **and, last but not least “compensation schemes”.**

A new sentence could be added after paragraph 3 to highlight the fact that animal identification/traceability could be used for quality related purposes and consumer information (e.g., organic farming, particular breed of cattle, animal welfare, particular origin, etc):

The Community proposes the following wording:

**“Animal identification and animal traceability can also be used as tools to demonstrate the origin of the animal, and consequently of its products (e.g., religious concerns, organic farming, animal welfare concerns), and contribute to reinforce the confidence of the consumer as regards the information provided.”**

4. The objective(s) of *animal identification* and *animal traceability* for a particular country, *zone* or compartment, and the approach used, should be clearly defined, following an assessment of the risks to be addressed, and a consideration of the factors listed below. They should be defined through consultation between the *Veterinary Administration* and relevant sector(s)/stakeholders prior to implementation, and periodically reviewed.

**Community comments:**

**Bearing in mind ongoing discussions at the WTO/SPS committee on regionalisation, reference to “regionalisation” could appear here.**

The Community proposes the following wording:

**“4. The objective(s) of *animal identification* and *animal traceability* for a particular country, region, compartment or zone, and the approach used, should be clearly defined, following an assessment of the risks to be addressed, and a consideration of**

**the factors listed below. They should be defined in partnership between the Competent Authority and relevant sector(s)/stakeholders prior to implementation, and periodically reviewed.“**

5. There are various factors which may determine the chosen approach. Factors such as the outcomes of the risk assessment, the animal health situation (including zoonoses), animal population parameters (such as species and breeds, numbers and distribution), types of production, animal movement patterns, available technologies, trade in animals and animal products, cost/benefit analysis and other economic considerations, and cultural aspects, should be taken into account when designing the approach. Whatever approach is used, it should comply with relevant OIE standards to ensure that the defined objectives are able to be achieved.

**Community comments:**

**Bearing in mind ongoing discussions at the WTO/SPS “geographical parameters” could also be mentioned under paragraph 5.**

**The Community proposes the following wording:**

**“5. There are various factors which may determine the chosen approach. Factors such as the outcomes of the risk assessment, the zoning (regionalisation) policy, geographical parameters, the animal health situation (including zoonoses), animal population parameters (such as species and breeds, numbers and distribution), types of production, animal movement patterns, available technologies, trade in animals and animal products, cost/benefit analysis and other economic and environmental considerations, and cultural aspects, should be taken into account when designing the system. approach. Whatever approach is used, it should comply with relevant OIE standards to ensure that the defined objectives are able to be achieved.”**

6. *Animal identification and animal traceability* should be under the responsibility of the *Veterinary Administration*.
7. The *Veterinary Administration*, in consultation with relevant governmental agencies and the private sector, should establish a legal framework for the implementation and enforcement of *animal identification* and *animal traceability* in the country. In order to facilitate compatibility and consistency, relevant international standards and obligations should be taken into account. This legal framework should include elements such as the objectives, scope, organisational arrangements including the choice of technologies used for identification and registration, obligation of the parties, confidentiality, accessibility issues and the efficient exchange of information.



CHAPTER 2.5.4.

EQUINE INFECTIOUS ANAEMIA

**Community comments:**

**The Community can support this proposed but would like the points below taken on board.**

Article 2.5.4.1.

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

Article 2.5.4.2.

*Veterinary Administrations of importing countries* should require:

for equines imported on a permanent basis

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

1. the animals showed no clinical sign of equine infectious anaemia (EIA) on the day of shipment and during the 48 hours prior to shipment;
2. ~~for breeding animals only~~, no case of EIA has been associated with any premises where the animals were kept during the 3 months prior to shipment;
3. the animals were subjected to a diagnostic test for EIA with negative results during the 30 days prior to shipment.

**Community comments:**

**The following text is suggested:**

- “1. equine infectious anaemia is a notifiable disease in the exporting country**
- 2. the animals showed no clinical sign of equine infectious anaemia (EIA) on the day of shipment and during the 48 hours prior to shipment;**
- 3. ~~for breeding animals only~~, no case of EIA has been associated with any premises**

where the animals were kept during the 3 months prior to shipment;

4. the animals were subjected to a diagnostic test for EIA with negative results on blood samples taken during the 30 days prior to shipment, or the equine animals are imported on a temporary basis and the blood samples were taken within 90 days of export.”

~~Article 2.5.4.3.~~

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

~~for equines imported on a temporary basis~~

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

- ~~1. the animals showed no clinical sign of EIA on the day of shipment and during the 48 hours prior to shipment;~~
- ~~2. no case of EIA has been associated with any premises where the animals were kept during the 3 months prior to shipment;~~
- ~~3. the animals were subjected to a diagnostic test for EIA with negative results during the 30 days prior to shipment (the negative response to the serological test remains valid for 120 days).~~

— text deleted

## CHAPTER 2.5.6.

## EQUINE PIROPLASMOSIS

**Community comments:**  
**The Community can support this proposal.**

## Article 2.5.6.1.

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

## Article 2.5.6.2.

*Veterinary Administrations of importing countries* should require:

for equines

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

1. showed no clinical sign of equine piroplasmosis on the day of shipment;
2. were subjected to diagnostic tests for equine piroplasmosis (~~*Babesia*~~ *Theileria equi* and *B. Babesia caballi*) with negative results during the 30 days prior to shipment;
3. were maintained free from ticks during the 30 days prior to shipment.

~~treated against ticks within the 7 days prior to shipment (the importing country may decide to import only during seasons when ticks are not active on its territory).~~

## Article 2.5.6.3.

*Veterinary Administrations of importing countries* should consider the possibility of importing competition horses on a temporary basis and which are positive to the testing procedure referred to in point 2) of Article 2.5.6.2. under the following safeguards:

1. the horses are accompanied by a passport in conformity with the model contained in Appendix 4.1.5.;
2. the *Veterinary Administrations of importing countries* require the presentation of an *international veterinary certificate* attesting that the animals:
  - a) showed no clinical sign of equine piroplasmosis on the day of shipment;
  - b) were treated against ticks within the 7 days prior to shipment;
3. the horses are kept in an area where necessary precautions are taken to control ticks and that is under the direct supervision of the *Veterinary Authority*;
4. the horses are regularly examined for the presence of ticks under the direct supervision of the *Veterinary Authority*.

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— text deleted

CHAPTER 2.5.7.

EQUINE RHINOPNEUMONITIS

**Community comments:**

**The Community can support this proposal but would like to point out that the disease should be called “Equine herpes virus infection”**

Article 2.5.7.1.

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

Article 2.5.7.2.

*Veterinary Administrations of importing countries* should require:

for equines

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

1. showed no clinical sign of equine rhinopneumonitis on the day of shipment and during the 21 days ~~3 months~~ prior to shipment;
2. were kept for the 21 days ~~3 months~~ prior to shipment in an *establishment* where no *case* of equine rhinopneumonitis was ~~officially~~ reported during that period.

**Community Comments:**

**The points above must be replaced by the following wording:**

1. showed no clinical sign of equine herpes virus infection, such as abortion or paralysis, on the day of shipment and during the 21 days ~~3 months~~ prior to shipment;
2. were kept for the 21 days ~~3 months~~ prior to shipment in an *establishment* where no *case* of equine herpes virus infection has ~~officially~~ occurred during that period.

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— text deleted

CHAPTER 2.5.8.  
GLANDERS

**Community comments:**

**The Community can only support this proposal if the comment below taken into account.**

Article 2.5.8.1.

For the purposes of this *Terrestrial Code*, the *incubation period* for glanders shall be 6 months.

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

Article 2.5.8.2.

**Glanders free country**

A country may be considered free from glanders when:

1. glanders is notifiable in the country;
2. no case of glanders has been reported during ~~confirmed for at least the~~ past 3 ~~last 2~~ years.

~~When importing equines for immediate slaughter from an infected country (see Article 2.5.8.5), a glanders free country will not be considered as infected if one of the imported equines is found infected.~~

~~The conditions for such imports will require direct transport of the animals from the place of disembarkation to a designated abattoir and completion of cleansing and *disinfection* of the means of transport, the lairages and the abattoir immediately after use. These conditions should be prescribed and enforced by the *Veterinary Administration*.~~

**Community comments:**

**The Community asks the scientific background for the extension of the period during which the disease should not have been reported.**

**The following is suggested:**

**“2. either historical freedom can be documented, or no case of glanders has been reported for a period of at least 6 months and a surveillance programme is in place demonstrating the absence of the disease in accordance with general surveillance guidelines.”**

Article 2.5.8.3.

When importing from glanders free countries, *Veterinary Administrations* should require:

for equines

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

1. showed no clinical signs ~~evidence~~ of glanders on the day of shipment;
2. were kept since birth, or for the ~~past~~ 6 months prior to shipment, in the *exporting country*; or
3. were subjected to a test as prescribed in the *Terrestrial Manual* ~~the mallein test and/or the complementfixation test~~ for glanders with negative results, during the 15 days prior to shipment.

**Community comments:**

**The Community agrees with the proposed modifications.**

**However, taking into account the above suggestions, the following is suggested:**

**“2. were kept for the ~~past~~ 6 months prior to shipment, or since birth if less than six months of age, in the *exporting country*; or**

**3. were subjected to a test as prescribed in the *Terrestrial Manual* ~~the mallein test and/or the complementfixation test~~ for glanders with negative results, carried out on the animals or on samples taken from the animals during the 21 days prior to shipment.”**

Article 2.5.8.4.

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

for equines

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

1. showed no clinical sign of glanders on the day of shipment;
2. were kept for the 6 months prior to shipment in an *establishment* where no *case* of glanders was ~~officially~~ reported during that period;
3. were subjected to a test as prescribed in the *Terrestrial Manual* ~~the mallein test and the complement fixation test~~ for glanders with negative results, during the 15 days prior to shipment.

**Community comments**

**The Community agrees with the changes, however the following is suggested:**

**“2. were kept for the 6 months prior to shipment, or since birth if less than six months**

of age, in an *establishment* where no *case* of glanders was ~~officially~~ reported during that period, and

3. were subjected to a test as prescribed in the *Terrestrial Manual* ~~the mallein test and the complement fixation test~~ for glanders with negative results, carried out on the animals or on a sample taken from the animals during the 21 days prior to shipment.”

Article 2.5.8.5.

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

for equines for immediate slaughter

the presentation of an *international veterinary certificate* attesting that the animals showed no clinical sign of glanders on the day of shipment. ~~(See also Article 2.5.8.2.)~~

**Community comments:**

**The Community does not agree with the proposed modification.**

**Taking into account recent experience and the zoonotic potential of *B. malleus*, there should be no specific conditions for the export of equidae for direct slaughter and these equidae should simply have to comply with the conditions in Article 2.5.8.3. and 2.5.8.4.**

**It is therefore proposed to delete this Article.**

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— text deleted

CHAPTER 2.5.10.  
EQUINE VIRAL ARTERITIS

**Community comments:**

**The Community can only support this proposal if the comments below are taken on board and it would propose to amalgamate Articles 2.5.10.4 and 2.5.10.5 as there appears to be no reason to have two separate Articles for fresh and frozen semen as the content is the same!**

Article 2.5.10.1.

The *infective period* for equine viral arteritis (EVA) shall be 28 days for mares, ~~and~~ geldings, and sexually immature equines. The health status of seropositive stallions should be checked to ensure that they do not shed equine arteritis virus in their semen.

**Community comments:**

**The introduction should read as follows:**

**“The *infective period* for equine viral arteritis (EVA) shall be 28 days relating to aerosol transmission. However, as this period may be extended in case of virus shedding through semen, the health status of sero-positive stallions should be checked to ensure that they do not shed equine arteritis virus in their semen.”**

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

Article 2.5.10.2.

*Veterinary Administrations of importing countries* should require:

for uncastrated male equines imported on a temporary basis for breeding or on a permanent basis

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

1. showed no clinical sign of EVA on the day of shipment and during the 28 days prior to shipment;
2. were subjected to two tests for EVA as prescribed in the *Terrestrial Manual* ~~diagnostic~~ on blood samples at least 14 days apart with negative results, during the 28 days prior to shipment; or
3. were subjected between 6 and 12 months of age to a ~~diagnostic~~ test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with negative results, immediately vaccinated for EVA and regularly revaccinated; or
4. have been subjected to a ~~diagnostic~~ test for EVA as prescribed in the *Terrestrial Manual* on a blood



sample with positive results and then: either

- a) were subsequently test mated to two mares within 12 months prior to shipment which were subjected to two tests for EVA as prescribed in the *Terrestrial Manual* ~~diagnostie~~ with negative results on blood samples collected at the time of test mating and again 28 days after the mating; or
- b) were subjected to a ~~virus isolation~~ test for EVA as prescribed in the *Terrestrial Manual* with negative results (~~under study~~), carried out on semen collected during the 28 days prior to shipment.

**Community comments:**

**The following wording is suggested:**

- “2. were subjected with negative results to a test for EVA as prescribed in the *Terrestrial Manual* ~~diagnostie~~ on blood samples taken within 14 days prior to shipment; or**
- 3. were subjected between 6 and 9 months of age to a ~~diagnostie~~ test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with stable or decreasing titre, immediately vaccinated for EVA and regularly revaccinated; or**
- 4. were subjected to a ~~diagnostie~~ test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with negative results, immediately vaccinated for EVA, kept for 21 days following vaccination separated from other equidae and regularly revaccinated; or**
- 5. have been subjected to a ~~diagnostie~~ test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with positive results and then within 12 months prior to shipment either**
  - a) were subsequently test mated to two mares which were subjected during a 28 days isolation to two tests for EVA as prescribed in the *Terrestrial Manual* ~~diagnostie~~ with negative results on blood samples collected at the time of test mating and again 28 days after the mating; or**
  - b) were subjected to a ~~virus isolation~~ test for EVA as prescribed in the *Terrestrial Manual* with negative results (~~under study~~), carried out on aliquots of two consecutive ejaculates collected 4 to 7 days apart.”**

Article 2.5.10.3.

*Veterinary Administrations of importing countries* should require:

for uncastrated male equines imported on a temporary basis other than for breeding, and for equines other than uncastrated males

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

1. showed no clinical sign of EVA on the day of shipment and during the 28 days prior to shipment;

2. were subjected, during the 28 days prior to shipment, to two ~~diagnostic~~ tests for EVA as prescribed in the *Terrestrial Manual* on blood samples collected at least 14 days apart, which demonstrated negative results or a stable or declining antibody titres;
3. were subjected, between 6 and 12 months of age, to a ~~diagnostic~~ test for EVA as prescribed in the *Terrestrial Manual* on a blood sample, with negative results, and immediately vaccinated for EVA and regularly revaccinated.

**Community comments:**

**The Community agrees with the proposed modifications, however suggests the following:**

**Delete paragraphs 2 and 3, as these requirements appear to be irrelevant to the risk posed by non-reproductive equidae.**

Article 2.5.10.4.

*Veterinary Administrations of importing countries* should require:

for fresh semen

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

1. were kept for the ~~28~~ 30 days prior to semen collection in an *establishment* where no equine has shown any clinical sign of EVA during that period;
2. showed no clinical sign of EVA on the day of semen collection;
3. were subjected between 6 and 12 months of age to a ~~diagnostic~~ test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with negative results, and immediately vaccinated for EVA and regularly revaccinated; or
4. were subjected to a ~~diagnostic~~ test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with negative results within 14 days prior to semen collection, and had not been used for natural breeding from the time of the taking of the blood sample to the time of semen collection; or
5. were subjected to a ~~diagnostic~~ test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with positive results and then: either
  - a) were test mated, within 12 months ~~one year~~ prior to semen collection, to two mares which showed negative results to two ~~diagnostic~~ tests as prescribed in the *Terrestrial Manual* on blood samples collected at the time of test mating and again 28 days after the test mating, or
  - b) were subjected to a ~~virus isolation~~ test as prescribed in the *Terrestrial Manual* with negative results (~~under study~~), carried out on semen collected within one year prior to collection of the semen to be exported.

**Community comments:**

**The Community agrees with the proposed modifications, however suggest the following modifications:**

**“for fresh semen and frozen semen:**

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

1. were kept for the ~~28~~ 30 days prior to semen collection in an *establishment* where no equine has shown any clinical sign of EVA during that period;
2. showed no clinical sign of EVA on the day of semen collection;
3. were subjected between 6 and 9 months of age to a ~~diagnostic~~ test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with stable or decreasing titre, immediately vaccinated for EVA and regularly revaccinated; or
4. were subjected to a ~~diagnostic~~ test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with negative results, immediately vaccinated for EVA, kept for 21 days following vaccination separated from other equidae and regularly revaccinated; or
5. were subjected to a ~~diagnostic~~ test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with negative results within 14 days prior to semen collection, and had been separated from other equidae from the time of the taking of the blood sample to the time of semen collection; or
6. have been subjected to a ~~diagnostic~~ test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with positive results and then within 12 months prior to semen collection either
  - a) were subsequently test mated to two mares which were subjected during a 28 days isolation to two tests for EVA as prescribed in the *Terrestrial Manual* ~~diagnostic~~ with negative results on blood samples collected at the time of test mating and again 28 days after the mating; or
  - b) were subjected to a ~~virus isolation~~ test for EVA as prescribed in the *Terrestrial Manual* with negative results (~~under study~~), carried out on aliquots of two consecutive ejaculates collected 4 to 7 days apart.”

Article 2.5.10.5.

*Veterinary Administrations of importing countries* should require:

for frozen semen

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

1. showed no clinical sign of EVA on the day of semen collection;

2. were subjected to a ~~diagnostic~~ test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with negative results not less than 14 days after semen collection; or
3. were subjected, between 6 and 12 months of age, to a ~~diagnostic~~ test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with negative results, and immediately vaccinated for EVA and regularly revaccinated; or
4. were subjected to a ~~diagnostic~~ test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with positive results and then: either
  - a) were test mated, within 12 months ~~one year~~ prior to or as soon as possible after semen collection, to two mares which showed negative results to two ~~diagnostic~~ tests as prescribed in the *Terrestrial Manual* on blood samples collected at the time of test mating and again 28 days after the test mating, or
  - b) were subjected to a ~~virus isolation~~ test as prescribed in the *Terrestrial Manual* with negative results (~~under study~~), carried out on semen collected within one year prior to collection of the semen to be exported.

**Community comments:**

**The Community suggests to delete paragraph 3 and to amend the current paragraph 4 as follows:**

- “3. were subjected to a ~~diagnostic~~ test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with positive results and then: either**
- a) were test mated, within 30 days after semen collection, to two mares which showed negative results to two ~~diagnostic~~ tests as prescribed in the *Terrestrial Manual* on blood samples collected during a 28 days isolation at the time of test mating and again 28 days after the test mating, or**
  - b) were subjected to a ~~virus isolation~~ test as prescribed in the *Terrestrial Manual* with negative results (~~under study~~), carried out on semen collected within 30 days after collection of the semen to be exported.”**

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— text deleted

CHAPTER 2.X.X.

AFRICAN HORSE SICKNESS

**Community comments :**

**Although the Community welcomes the review of this chapter, it can only support this proposal if the changes outlined below are taken on board.**

**In addition the Community cautions about certain requirements that would entail a highly effective surveillance system which so far cannot be delivered in countries affected by the disease.**

**Certain changes should be better explained, such as shortening security distances or the period of quarantine isolation.**

**Following the philosophy of the current chapter on AHS there is a protection and surveillance zone with measures foreseen in both zones. The new text would in fact allow uncontrolled movement of equidae right next to the delineated free zone**

**The new text does not provide a clear understanding about the role of vaccination, and consequently any definition based on absence of cases, i.e. clinical signs, is obsolete.**

Article 2.x.x.1.

For the purposes of this *Terrestrial Code*, the *infective period* for African horse sickness (AHS) shall be 40 days for domestic horses.

All countries or *zones* adjacent to a country or *zone* not having free status should determine their AHS status from an ongoing surveillance programme (in accordance with Appendix 3.8.X.). The surveillance should be carried out over a distance of at least 100 kilometres from the border with that country or *zone*, but a lesser distance could be acceptable if there are relevant ecological or geographical features likely to interrupt the transmission of AHS.

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

**Community comments:**

**This article provides a new concept which firstly reduces the security distance from 150 km to 100 km.**

**Secondly for the case of a free zone within an infected country it is not clear where this surveillance should be carried out: on the territory of the free zone or within the perimeters of the infected zone. This clarification could have consequences for the minimum size of a declared free zone.**

**In accordance with General Definitions a surveillance zone is part of the free zone and entails intensified surveillance. A buffer zone would not only allow increased**

## surveillance but also movement controls and vaccination

Article 2.x.x.2.

### AHS free country or zone

1. A country or a *zone* may be considered free from AHS when the disease is notifiable in the whole country and either:
  - a) the country or *zone* is not adjacent to a country or *zone* not having a free status; or

#### Community comments:

#### Point (a) should read as follows:

**“1. A country or a *zone* may be considered free from AHS when the disease is notifiable in the whole country, systematic prophylactic vaccination is prohibited and either:**

**a) the country or *zone* has not reported any case of AHS during at least the previous 2 years and is not adjacent to a country or *zone* not having a free status; or”**

b) *historical freedom* as described in Appendix 3.8.1. has demonstrated no evidence of AHS in the country or *zone*; or

c) a surveillance programme as described in Appendix 3.8.X. has demonstrated no evidence of AHS in the country or *zone* during the past 2 years, including in wildlife; or

#### Community comments:

**Reference should be made to Appendix 3.8.1 and Appendix 3.8....(which is understood as specific guidelines for AHS).**

d) a surveillance programme has demonstrated no evidence of *Culicoides* likely to be competent AHS vectors in the country or *zone*.

#### Community comments:

#### Point (d) should read as follows:

**“d) the country or *zone* has not reported any case of AHS during at least the previous 3 months and a surveillance programme has demonstrated no evidence of *Culicoides* likely to be competent AHS vectors in the country or *zone*.”**

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

3. An AHS free country or *zone* in which surveillance has found evidence that *Culicoides* likely to be competent AHS vectors are present will not lose its free status through the importation of vaccinated or seropositive domestic horses from infected countries or *zones*, provided:
  - a) the animals have been vaccinated, in accordance with the *Terrestrial Manual*, at least 40 days prior to dispatch with a vaccine which covers all serotypes whose presence in the source population has been demonstrated through a surveillance programme as described in Appendix 3.8.X., and that the animals are identified in the accompanying certification as having been vaccinated; or
  - b) the animals are not vaccinated, and a surveillance programme as described in Appendix X.X.X. has been in place in the source population for a period of at least 40 days immediately prior to dispatch, and no evidence of AHS has been detected.

**Community comments:**

**Alternatively, a quarantine system under vector protection should be foreseen.**

4. An AHS free country or *zone* should be protected from an adjacent infected country or *zone* by a *buffer zone* in which surveillance is conducted as described in Appendix X.X.X.

**Community comments:**

**Paragraph 4 appears to be misplaced, as it should be the third paragraph of Article 2.x.x.1.**

Article 2.x.x.3.

**AHS seasonally free zone**

1. An AHS seasonally free *zone* is a part of an infected country or *zone* for which for part of a year, surveillance and *monitoring* demonstrate no evidence either of AHS transmission or of adult *Culicoides* likely to be competent AHS vectors.
2. For the application of Articles 2.x.x.7., 2.x.x. 10. and 2.x.x. 14., the seasonally free period is taken to commence the day following the last evidence of AHS transmission (as demonstrated by the surveillance programme), or of the cessation of activity of adult *Culicoides* likely to be competent AHS vectors.
3. For the application of Articles 2.x.x.7., 2.x.x. 10. and 2.x.x. 14., the seasonally free period is taken to conclude either:
  - a) at least 28 days before the earliest date that historical data show AHS virus activity has recommenced; or
  - b) immediately if current climatic data or data from a surveillance and monitoring programme indicate an earlier resurgence of activity of adult *Culicoides* likely to be competent AHS vectors.

**Community comments:**

**It is unclear how reliable such sudden changes would be certified**

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

*zones.*

5. An AHS seasonally free *zone* in which surveillance and monitoring has found evidence that *Culicoides* likely to be competent AHS vectors are present will not lose its free status through the importation of vaccinated or seropositive domestic horses from infected countries or *zones*, provided:
  - a) the animals have been vaccinated in accordance with the *Terrestrial Manual* at least 40 days prior to dispatch with a vaccine which covers all serotypes whose presence in the source population has been demonstrated through a surveillance programme as described in Appendix 3.8.X., and that the animals are identified in the accompanying certification as having been vaccinated; or
  - b) the animals are not vaccinated, and a surveillance programme as described in Appendix X.X.X. has been in place in the source population for a period of at least 40 days immediately prior to dispatch, and no evidence of AHS has been detected.

Article 2.x.x.4.

#### **AHS infected country or zone**

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

#### **Community comments:**

**This definition of an AHS-infected country appears to be incomplete.**

**For example, where AHS was reported in a country during a period of absence of vectors, for example in the northern hemisphere in winter, the restrictions should not apply for 2 years.**

**It would be preferable that there is an additional option which allows a country or zone to regain the free status after a shorter time subject to surveillance and documented proof that during the time the animal in question was infective, it was effectively protected from vector *Culicoides*, either because it was the vector free season or the vector is absent in the country or the animal was actively protected from vectors ( quarantine).**

**As the text stands at the moment, it could be that South Africa with a good vaccination is declared free and Greenland with an accident of AHS is considered infected.**

#### **Community suggestions:**

**“An AHS infected country or *zone* is a clearly defined area where evidence of AHS has been reported during the past 2 years or until at least 6 months have elapsed following the last case and a surveillance programme demonstrates the absence of the virus in the target and vector population.”**

Article 2.x.x.5.

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

1. equines;



2. equine semen;
3. equine embryos;
4. *pathological material* and biological products (from these species) (see Chapter 1.4.5. and Section 1.5.).

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

Article 2.x.x.6.

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

for domestic horses

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

1. showed no clinical sign of AHS on the day of shipment;
2. have not been vaccinated against AHS within the last 40 days;
3. were kept in an AHS free country or *zone* since birth or for at least 40 days prior to shipment;

AND

4. either:
  - a) did not transit through an infected country or *zone*; or
  - b) were protected from attack from *Culicoides* likely to be competent AHS vectors at all times when transiting through an infected country or *zone*.

**Community comments:**

**The Community cannot agree to 4(b).**

**The provided transit conditions, are not able to be policed and not compatible with the other rules on movement of equidae in and out of infected areas, notably the requirement for 40 days residence in a free country.**

Article 2.x.x.7.

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

for other equines

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

1. showed no clinical sign of AHS on the day of shipment;
2. have not been vaccinated against AHS within the last 40 days;
3. were kept in an AHS free country or *zone* since birth or for at least 40 days prior to shipment;

AND

if the animal originates from a *zone* or country adjacent to a *zone* or country considered infected with AHS:

4. were protected from attack from *Culicoides* likely to be competent AHS vectors for at least 40 days prior to shipment; and, either:
  - a) were subjected during that period to a serological test according to the *Terrestrial Manual* to detect antibody to the AHS group, with negative results on two occasions, with an interval of not less than 7 days between each test, the first test being carried out at least 21 days after introduction into the *quarantine station*; or
  - b) were subjected during that period to an agent identification test according to the *Terrestrial Manual* with negative results, on blood samples taken on two occasions, with an interval of not less than 7 days between each test, the first test being carried out at least 7 days after introduction into the *quarantine station*;

**Community comments:**

**Paragraph 4 is in contradiction to the definition of free country in Article 2.x.x.2. (1) (a)**

5. were protected from attack from *Culicoides* likely to be competent AHS vectors during transportation to and at the place of shipment.

Article 2.x.x.8.

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

for domestic horses

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

1. were kept during the seasonally free period in an AHS seasonally free *zone* for at least 40 days prior to shipment;
2. have not been vaccinated against AHS within the past 40 days;

AND

3. either:
  - a) did not transit through an infected country or *zone*; or
  - b) were protected from attack from *Culicoides* likely to be competent AHS vectors at all times when transiting through an infected country or *zone*.

**Community comments:**

**The Community cannot agree to 3(b).**

**The provided transit conditions, are not able to be policed and not compatible with the other rules on movement of equidae in and out of infected areas, notably the requirement for 40 days residence in a free country.**

Article 2.x.x.9.

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

for domestic horses

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

1. were protected from attack from *Culicoides* likely to be competent AHS vectors for at least 40 days prior to shipment; or
2. were protected from attack from *Culicoides* likely to be competent AHS vectors for at least 28 days prior to shipment, and were subjected during that period to a serological test in accordance with the *Terrestrial Manual* to detect antibody to the AHS group, with negative results on two occasions, with an interval of not less than 7 days between each test, the first test being carried out at least 21 days after introduction into the *quarantine station*; or

**Community comments:**

**Double testing makes sense only when also a stable or declining titre would be accepted as indicating previously acquired immunity.**

**If this was considered, it would be in line with the requirement in 4, as this requirement does not exclude vaccinated animals, it only says not vaccinated during the past 40 days.**

3. were protected from attack from *Culicoides* likely to be competent AHS vectors for at least 14 days prior to shipment, and were subjected during that period to an agent identification test in accordance with the *Terrestrial Manual* with negative results, on blood samples taken on two occasions, with an interval of not less than 7 days between each test, the first test being carried out at least 7 days after introduction into the *quarantine station*;

AND

4. have not been vaccinated against AHS within the last 40 days;
5. were protected from attack from *Culicoides* likely to be competent AHS vectors during transportation to and at the place of shipment.

Article 2.x.x.10.

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

for semen of domestic horses

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

1. showed no clinical sign of AHS on the day of collection of the semen and for the following 40 days;
2. had not been vaccinated against AHS within 40 days of the day of collection;
3. were kept in an AHS free country or *zone* for at least 40 days before commencement of, and during collection of the semen.

Article 2.x.x.11.

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

for semen of domestic horses

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

1. showed no clinical sign of AHS on the day of collection of the semen and for the following 40 days;
2. were not vaccinated against AHS within 40 days of the day of collection;
3. were kept during the seasonally free period in an AHS seasonally free *zone* for at least 40 days before commencement of, and during, collection of the semen.

Article 2.x.x.12.

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

for semen of domestic horses

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

1. showed no clinical sign of AHS on the day of collection of the semen and for the following 40 days;
2. were not vaccinated against AHS within 40 days of the day of collection;
3. were protected from attack from *Culicoides* likely to be competent AHS vectors for at least 40 days before commencement of, and during, collection of the semen.

Article 2.x.x.13.

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

for *in vivo* derived embryos of domestic horses

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

1. the donor females:
  - a) showed no clinical sign of AHS on the day of collection of the embryos and for the following 40 days;
  - b) have not been vaccinated against AHS within 40 days prior to collection;
  - c) were kept in an AHS free country or *zone* for at least the 40 days prior to, and at the time of, embryo collection;
2. the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.1.

Article 2.x.x.14.

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

for *in vivo* derived embryos of domestic horses

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

1. the donor females:
  - a) showed no clinical sign of AHS on the day of collection of the embryos and for the following 40 days;
  - b) have not been vaccinated against AHS within the 40 days prior to collection;
  - c) were kept during the seasonally free period in an AHS seasonally free zone for at least the 40 days prior to, and at the time of, collection of the embryos;
2. the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.1.

Article 2.x.x.15.

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

for *in vivo* derived embryos of domestic horses

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

1. the donor females:
  - a) showed no clinical sign of AHS on the day of collection of the semen and for the following 40 days;
  - b) have not been vaccinated against AHS within the 40 days prior to collection;
  - c) were protected from attack from *Culicoides* likely to be competent AHS vectors for at least 40 days before commencement of, and during, collection of the embryos;
2. the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.1.

Article 2.x.x.16.

### **Protecting animals from *Culicoides* attack**

When transporting equines through AHS infected countries or *zones*, *Veterinary Administrations* should require strategies to protect animals from attack from *Culicoides* likely to be competent AHS vectors during transport, taking into account the local ecology of the vector.

Potential risk management strategies include:

1. treating animals with chemical repellents prior to and during transportation;
2. loading, transporting and unloading animals at times of low vector activity (i.e. bright sunshine and low temperature);
3. ensuring vehicles do not stop en route during dawn or dusk, or overnight, unless the animals are held behind insect proof netting;
4. darkening the interior of the vehicle, for example by covering the roof and/or sides of vehicles with 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.
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**FUTURE WORK PROGRAMME FOR THE  
TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION**

**Community comments:**

The Community fully supports the future work programme of the OIE as laid down below however there appears to be a section on risk mitigating factors and inactivation of pathogens missing. This was included in the work programme and a commitment to this has been given on a number of occasions. The Community insists that the OIE re-examine the formalisation of numbering of outbreaks in member countries. It believes members need guidance on this and it would facilitate the following of reported outbreaks and give a reference point to laboratory typing of different types and sub-types.

**In addition guidelines for disease control should be produced and this would also be useful in consideration of BVD.**

<b>Topic</b>	<b>Action</b>	<b>How to be managed</b>
<b>Traceability</b>	<i>Ad hoc</i> Group to develop specific Chapter on animal identification and traceability	Animal Production Food Safety Working Group (APFS WG).
<b>Consolidation of Terrestrial and Aquatic Codes</b>	To work with the Aquatic Commission to maximise harmonisation of present Codes, with an ultimate goal of a single Code in three parts: horizontal chapters, terrestrial animal disease chapters and aquatic animal disease chapters.	The Secretariat will continue to harmonise horizontal chapters, and work towards their consolidation.  Each Commission to invite other Commission President to its meetings.
<b>Good farming practices</b>	To coordinate with the FAO's work to publish a single guideline on good farming practices for the guidance of Member Countries and the public.	APFS WG
<b>Control of hazards of animal health and public health importance through ante- and post-mortem meat inspection</b>	To develop Code guidelines	APFS WG

<b>Anthrax</b>	To develop an appendix on the inactivation of the bacillary and spore forms of <i>Bacillus anthracis</i> .	Secretariat
<b>BSE – safety of gelatine and tallow</b>	To update ‘safe commodities’ article	<i>ad hoc</i> Group
<b>BSE supporting document</b>	To update	expert
<b>BSE risk assessment</b>	To update	expert
<b>Current chapter on Veterinary Services</b>	To revise to better address the role of the Statutory Body, the early detection of disease and greater detail on how the auditing of Veterinary Services could be implemented.	expert
<b>Other <i>Terrestrial Code</i> texts in need of revision</b>	To update chapter on equine influenza	Reference Laboratory
	To update chapter on brucellosis	SCAD then APFS WG
	To update chapter on Newcastle disease	SCAD
	To update chapter on African swine fever	SCAD
<b><i>Terrestrial Code</i> texts identified as priorities by APFS WG</b>	Salmonellosis	SCAD
	Cysticercosis	SCAD
<b>Harmonisation of international health certificates</b>	To finalise with view of replacing existing Code certificates	APFS WG
<b>Dead animal disposal</b>	To finalise Code appendix	SCAD
<b>Animal welfare – companion animals and laboratory animals</b>	To draft new chapters	AW WG
<b>Alternative approaches to</b>	To develop alternative mechanism for providing guidance to Member	TCC, AW WG and APFS



<b>providing advice</b>	<b>OIE</b>	Countries on managing certain animal health and welfare issues outside the Code framework	WG
<b>Surveillance vectors</b>	<b>for</b>	To develop guidelines for the surveillance of vectors capable of transmitting animal diseases	SCAD

**EN**

**SANCO/10555R2/2005 (Animal Welfare Part)**

## APPENDIX 3.7.2.

**Community comments:**

**The Community is very pleased at the excellent progress being made in this important new area of work for the OIE. The ad hoc groups are to be commended on the preparation and improvement of these guidelines.**

**The Community wishes to emphasise the need for such animal welfare guidelines to have a solid scientific basis and looks forward to the OIE extending its work to cover other issues included within the OIE animal welfare mandate (e.g. farmed fish, animals used for experimental purposes etc.).**

**Some drafting comments on the guidelines are included in the text below.**

**The Community is pleased that very many of our comments already provided for the 2005 General Session are now proposed to be incorporated into these amended versions of the guidelines. Such incremental improvements to the text in the light of experience gained and ongoing scientific advances are to be welcomed.**

**As a general comment the guidelines should be worded in as clear and precise a fashion as possible. This will facilitate their more uniform interpretation and facilitate the work of the OIE member countries in disseminating information on these guidelines to veterinary authorities and other stakeholders and ensuring their application in practice.**

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.

**Community comments:**

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

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

Article 1

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

**Community comments:**

**The word “bis” should be deleted from the next article heading.**

**Justification: The word is not necessary.**

Article 3.7.2.1. bis

Responsibilities

**Community comments:**

**At the end of the first sentence it should be made clear that those persons involved are responsible for different and specific operations or parts of the journey. The following changes are proposed:**

**“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, *with the individual responsibilities of those persons being described in more detail below in line with their respective tasks.*”**

**Justification: The current wording is unclear.**

Once the decision to transport the animals by sea has been made, the welfare of the animals during their journey ~~transport~~ is the paramount consideration and is the joint responsibility of all people involved. These guidelines may also be applied to the transport of animals by water within a country.

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

The roles of each of those responsible are defined below:

**Community comments:**

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

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

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

2. The exporter has overall responsibility for the organisation, carrying out and completion of the journey, regardless of whether duties are subcontracted to other parties during transport. The exporter is also responsible for ensuring that equipment and medication are provided as appropriate for the species and journey, and for the presence during the journey of at least one *animal handler*<sup>49</sup> competent for the species being transported. The exporter is also responsible for ensuring compliance of the animals with any required veterinary certification and, in the case of animals for export, any other requirements of the *importing and exporting countries*.
3. Business or buying/selling agents have a joint responsibility with owners for the selection of animals that are fit to travel. They have a joint responsibility with masters of vessels and managers of facilities at the start and at the end of the journey for the availability of suitable facilities for the assembly, loading, transport, unloading and holding of animals, and for emergencies.
4. Animal handlers are responsible for the humane handling and care of animals, especially during loading and unloading. To carry out these responsibilities, they should have the authority to take prompt action.
5. The exporter, the shipping company and the master of the vessel are jointly responsible for planning the journey to ensure the care of the animals, including:
  - a) choosing appropriate vessels and ensuring that ~~competent~~ *animal handlers* are available to care for ~~loading and caring for~~ the animals ~~throughout the journey~~;
  - b) developing and keeping up to date contingency plans to address emergencies (including adverse weather conditions) and minimise stress during transport;
  - c) correct loading of the ship, regular inspections during the journey and for appropriate responses to problems arising;
  - d) disposal of carcasses according to international law.
6. To carry out these responsibilities, the people involved should be competent regarding transport regulations, equipment usage, and the humane handling and ~~the~~ care of animals.
7. Managers of facilities during loading of the animals are responsible for:
  - a) providing suitable premises for loading the animals;
  - b) providing ~~competent~~ *animal handlers* to load the animals ~~in a manner that causes~~ with minimum stress and injury;
  - c) providing appropriate facilities for emergencies;

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<sup>49</sup> ~~An *animal handler* is a person with a knowledge of the behaviour and needs of animals which, with appropriate experience and a professional and positive response to an animal's needs, results in effective management and good welfare; their competence should be demonstrated through independent assessment and certification.~~

- d) providing facilities and veterinarians or ~~competent~~ *animal handlers* capable of killing animals humanely when required.
8. Managers of facilities at the end of the journey are responsible for:
- a) providing suitable facilities for unloading the animals onto transport vehicles for immediate movement or securely holding the animals in lairage, with shelter, water and feed, when required, for transit;
  - b) providing ~~competent~~ *animal handlers* to unload the animals with minimum stress and injury;
  - c) minimising the opportunities for disease transmission while the animals are in the facilities;
  - d) providing appropriate facilities for emergencies;
  - e) providing facilities and veterinarians or ~~competent~~ *animal handlers* capable of killing animals humanely when required.
9. The responsibilities of the *Competent Authority* of the *exporting country* include:
- a) establishing minimum standards for animal welfare, including requirements for inspection of animals before and during their travel, and for certification and record keeping;
  - b) approving facilities, containers, vehicles/vessels for the holding and transport of animals;
  - c) setting competence standards for *animal handlers* and managers;
  - d) ensuring that the vessel transporting animals meets the required standards, including those of the *importing country*;
  - e) implementation of the standards, including through accreditation of / interaction with other organisations and Competent Authorities;
  - f) monitoring and evaluating health and welfare performance, including the use of any veterinary medications.
10. The responsibilities of the *Competent Authority* of the *importing country* include:
- a) establishing minimum standards for animal welfare, including requirements for inspection of animals after their travel, and for certification and record keeping;
  - b) approving facilities, containers and vehicles for the unloading, holding and transport of animals;
  - c) setting competence standards for *animal handlers* and managers;
  - d) implementation of the standards, including through accreditation of / interaction with other organisations and Competent Authorities;

- e) ensuring that the *exporting country* is aware of the required standards for the vessel transporting the animals;
- f) monitoring and evaluating health and welfare performance, including the use of any veterinary medications.

**Community comments:**

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

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

- 11. When travelling on vessels with the animals, veterinarians are responsible for the humane handling and treatment of the animals during the journey. To carry out these responsibilities, they should have the authority to act and report independently. The veterinarian should meet with the Master, Chief Officer and the senior *animal handler* on a daily basis.
- 12. The receiving *Competent Authority* should report back to the sending *Competent Authority* on significant animal welfare problems which occurred during the journey.

Article 3.7.2.2.

**Competence**

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

**Community comments:**

**The next sentence should be changed as follows: “The competence of animal handlers should be demonstrated through a current certificate from the Competent Authority or from an independent body accredited by a Competent Authority. The certificate should be issued based on verification of knowledge of the behaviour and needs of animals and practical skills of animal handling. The certificate should be in one of the OIE official languages if the international transport of animals is involved”.**

**Justification: The current wording excludes that a Competent Authority could issue such a certificate. This position is not appropriate. It is also important to state the basis for issuing such a certificate, hence the more precise and detailed wording proposed.**

2. ~~This~~ The competence of animal handlers should be demonstrated through a current certificate from an independent body accredited by a *Competent Authority*. The certificate should be in one of the OIE official languages if the international transport of animals is involved.
3. The assessment of competence ~~for~~ of animal handlers should at a minimum address knowledge, and ability to apply that knowledge, in the following areas:
  - a) responsibilities for animals during the journey;
  - b) sources of advice and assistance;
  - c) animal behaviour, general signs of disease, and indicators of poor animal welfare such as stress, pain and fatigue, and their alleviation;
  - d) assessment of fitness to travel;
  - e) relevant authorities and applicable transport regulations, and associated documentation requirements;
  - f) general disease prevention procedures, including cleaning and disinfection;
  - g) appropriate methods of animal handling during transport and associated activities such as assembling, loading, and unloading;
  - h) methods of inspecting animals, managing situations frequently encountered during transport such as adverse weather conditions, and dealing with emergencies;
  - i) species-specific aspects and age-specific aspects of animal handling and care, including feeding, watering and inspection;
  - j) ~~appropriate record keeping and~~ maintaining a journey log and other records.
4. Assessment of competence for exporters should at a minimum address knowledge, and ability to apply that knowledge, in the following areas:
  - a) planning a journey, including appropriate space allowances, and feed, water and ventilation requirements;
  - b) relevant authorities and applicable transport regulations, and associated documentation requirements;
  - c) appropriate methods of animal handling during transport and associated activities such as cleaning and *disinfection*, assembling, loading, and unloading;
  - d) species-specific aspects of animal handling and care, including appropriate equipment and medication;



- e) sources of advice and assistance;
- f) appropriate record keeping ~~and journey log~~;
- g) managing situations frequently encountered during transport, such as adverse weather conditions, and dealing with emergencies.

Article 3.7.2.3.

## Planning the journey

### 1. General considerations

- a) Adequate planning is a key factor affecting the welfare of animals during a journey.
- b) Before the journey starts, plans should be made in relation to:
  - i) preparation of animals for the journey;
  - ii) type of transport vessel required;
  - iii) route, taking into account distance, expected weather and sea conditions;
  - iv) nature and duration of journey;
  - v) daily care and management of the animals by providing the appropriate number of animal handlers;
  - vi) avoiding the mixing of animals from different sources in a single pen group;
  - vii) provision of appropriate equipment and medication for the numbers and species carried;
  - viii) emergency response procedures.

### 2. Preparation of animals for the journey

- a) When animals are to be provided with a novel diet e.g. for dry food, and or unfamiliar methods of supplying of feed and or water, they should be preconditioned may be required.
- b) There should be planning for water and feed availability during the journey. Feed should be of appropriate quality and composition for the species, age, condition of the animals, etc.
- c) Extreme weather conditions are hazards for animals undergoing transport and require appropriate vessel design to minimise risks. Special precautions should be taken for animals that have not been acclimatised or which are unsuited to either hot or cold conditions. In some extreme conditions of heat or cold, animals should not be transported at all.

- d) Animals more accustomed to contact with humans and with being handled are likely to be less fearful of being loaded and transported. Animals should be handled and loaded in a manner that reduces their fearfulness and improves their approachability.
- e) Behaviour-modifying or other medication should not be used routinely during transport. Such medicines should only be administered when a problem exists in an individual animal, and should be administered by a veterinarian or other person who has been instructed in their use by a veterinarian. Treated animals should be placed in a dedicated area.
- ~~e) Where there is a potential for spread of infectious disease, and when requested by the *Veterinary Authority* of the *importing country*, animals should be vaccinated against diseases to which they are likely to be exposed at their destination.~~
- ~~h) There should be an emergency management plan that identifies the important adverse events that may be encountered during the journey, the procedures for managing each event and the action to be taken in an emergency. For each important event, the plan should document the actions to be undertaken and the responsibilities of all parties involved, including communications and record keeping.~~

### 3. Control of disease

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

- a) when possible and agreed by the *Veterinary Authority* of the *importing country*, animals should be vaccinated against diseases to which they are likely to be exposed at their destination;
- b) medications used prophylactically or therapeutically should only be administered by a veterinarian or other person who has been instructed in their use by a veterinarian;
- c) mixing of animals from different sources in a single consignment should be minimized.

### 4. Vessel and container design and maintenance

- a) Vessels used for the sea transport of animals should be designed, constructed and fitted as appropriate to the species, size and weight of the animals to be transported. Special attention should be paid to the avoidance of injury to animals through the use of secure smooth fittings free from sharp protrusions and the provision of non-slip flooring. The avoidance of injury to *animal handlers* while carrying out their responsibilities should be emphasised.
- b) Vessels should be designed to permit thorough cleaning and *disinfection*, and the management of faeces and urine.
- c) Vessels and their fittings should be maintained in good mechanical and structural condition.

<b>Community comments:</b>
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**In the last sentence of point (d) the requirement for an alarm system should be added in order to be able to receive a signal if the system fails. The last sentence should be changed as follows: “An alarm system and an emergency power supply should be.....”.**

**Justification: It is important and in line with basic good practices that an alarm system should be available to alert personnel to malfunctioning ventilation equipment, which could have serious welfare consequences for the animals if going unnoticed etc.**

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

**Community comments:**

**The need for lighting to facilitate inspection of the animals needs to be mentioned. The following wording is proposed: “Vessels should be properly illuminated to allow animals to be observed and inspected.”**

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

- e) The feeding and watering system should be designed to permit adequate access to feed and water appropriate to the species, size and weight of the animals, and to minimise soiling of pens.
- f) Vessels should be designed so that the faeces or urine from animals on upper levels do not soil animals on lower levels, or their feed or water.
- g) Loading and stowage of feed and bedding should be carried out in such a way to ensure protection from fire hazards, the elements and sea water
- h) Where appropriate, suitable bedding, such as straw or sawdust, should be added to vessel floors to assist absorption of urine and faeces, provide better footing for animals and protect animals (especially young animals) from hard or rough flooring surfaces and adverse weather conditions.
- i) The above principles apply also to containers used for the transport of animals.
5. Special provisions for transport in road vehicles on roll-on/roll-off vessels or for containers
- a) Road vehicles and containers should be equipped with a sufficient number of adequately designed, positioned and maintained securing points enabling them to be securely fastened to the vessel.
- b) Road vehicles and containers should be secured to the ship before the start of the sea journey to prevent them being displaced by the motion of the vessel.

- c) Vessels should have adequate ventilation to meet variations in climate and the thermo-regulatory needs of the animal species being transported, especially where the animals are transported in a secondary vehicle/container on enclosed decks.
- d) Due to the risk of limited airflow on certain vessels' decks, a road vehicle or container may require a forced ventilation system of greater capacity than that provided by natural ventilation.

**Community comments:**

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

**An additional point should be added:**

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

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

6) Nature and duration of the journey

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

- a) the ability of the animals to cope with the stress of transport (such as very young, old, lactating or pregnant animals);
- b) the animals’ previous transport experience;
- c) the likely onset of fatigue;
- d) the need for special attention;
- e) the need for feed and water;
- f) the increased susceptibility to injury and disease;
- g) space allowance and vessel design;
- h) weather conditions.

7. Space allowance

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

**Community position:**

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

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

- c) Calculations for the space allowance for each animal should be carried out, using the figures given in ~~these guidelines~~ Appendix XXX or, in their absence, in a relevant national or international document. The size of pens will affect the number of animals in each.
  - d) The same principles apply when animals are transported in containers.
8. Ability to observe animals ~~en route~~ during the journey
- a) Animals should be positioned to enable them to be observed regularly and clearly by the *animal handler* or other responsible person, during the journey to ensure their safety and good welfare.
  - b) ~~To allow an adequate inspection of animals en route, it should be possible for each animal to be clearly observed by the *animal handler* or other responsible person.~~

9. Emergency response procedures

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

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

Article 3.7.2.4.

**Documentation**

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

**Community comments:**

**The word “including” should be changed to “and”.**

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

- a) journey travel plan (including an emergency management plan);
- b) time, date and place of loading;
- c) the journey log – a daily record of inspection and important events which includes records of morbidity and mortality and actions taken, climatic conditions, food and water consumed, medication provided, mechanical defects;
- d) expected time, date and place of arrival and unloading;
- e) veterinary certification, when required;
- f) animal identification to allow traceback of individual animals to the premises of departure, and, where possible, to the premises of origin;

**Community comments:**

**In the next bullet point the cross-reference should be amended to “Article 3.7.2.5.3 e)”.**

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

**Community comments:**

**The words “Animals considered at risk” should be changed to “Animals considered at particular risk of suffering poor welfare during transport”.**

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

- g) details of any animals considered ‘at risk’ (Article 3.7.2.5);
  - h) number of *animal handlers* on board, and their competencies;
  - i) stocking density estimate for each load in the consignment.
3. When veterinary certification ~~should~~ is required to accompany consignments of animals ~~and, it should~~ address:
- a) when required, cleaning and details of disinfection carried out of the vessel;

- b) fitness of the animals to travel;
- c) animal identification (description, number, etc.) ;
- d) health status including any tests, treatments and vaccinations carried out, ~~if required~~.

Article 3.7.2.5.

### Pre-journey period

#### 1. General considerations

- a) Before each journey, vessels should be thoroughly cleaned and, if necessary, treated for animal and public health purposes, using chemicals approved by the *Competent Authority*. When cleaning is necessary during a journey, this should be carried out with the minimum of stress to the animals.
- b) In some circumstances, animals may require pre-journey assembly. In these circumstances, the following points should be considered:
  - i) Pre-journey rest is necessary if the welfare of animals has become poor during the collection period because of the physical environment or the social behaviour of the animals.
  - ii) For animals such as pigs which are susceptible to motion sickness, and in order to reduce urine and faeces production during the journey, a short period of feed deprivation prior to loading is desirable.
  - ii) ~~When animals will be provided with a novel diet or method of water provision during or after transport, an adequate period of pre-exposure is necessary. Preconditioning to the feed to be used on the vessel may be necessary in such cases.~~
  - iii) When animals are to be provided with a novel diet or unfamiliar methods of supplying of feed or water, they should be preconditioned.
- c) Where an *animal handler* believes that there is a significant risk of disease among the animals to be loaded or significant doubt as to their fitness to travel, the animals should be examined by a veterinarian.
- d) Pre-journey assembly /holding areas should be designed to:
  - i) securely contain the animals;
  - ii) maintain an environment safe from hazards, including predators and disease;
  - iii) protect animals from exposure to adverse weather conditions; ~~and~~

iv) allow for maintenance of social groups; and

v) allow for rest, watering and feeding.

## 2. Selection of compatible groups

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

- a) animals of different species should not be mixed unless they are judged to be compatible;
- b) animals of the same species can be mixed unless there is a significant likelihood of aggression; aggressive individuals should be segregated (recommendations for specific species are described in detail in Article 3.7.2.10.) For some species, animals from different groups should not be mixed because poor welfare occurs unless they have established a social structure;
- c) young or small animals may need to be separated from older or larger animals, with the exception of nursing mothers with young at foot;
- d) animals with horns or antlers should not be mixed with animals lacking horns or antlers, unless judged to be compatible;
- e) animals reared together should be maintained as a group; animals with a strong social bond, such as a dam and offspring, should be transported together.

## 3. Fitness to travel

- a) Animals should be inspected by a veterinarian or an animal handler to assess fitness to travel. If its fitness to travel is in doubt, the animal should be examined by a veterinarian. Animals found unfit to travel before travel and those found unfit to travel by farm staff, an animal handler or a veterinarian, should not be loaded onto a vessel.
- b) Humane and effective arrangements should be made by the owner or agent for the handling and care of any animal rejected as unfit to travel.
- c) Animals that are unfit to travel include:
  - i) those that are sick, injured, weak, disabled or fatigued;
  - ii) those that are unable to stand unaided ~~and~~ or bear weight on each leg;
  - iii) those that are blind in both eyes;
  - iv) those that cannot be moved without causing them additional suffering;
  - v) newborn with an unhealed navel;
  - vi) females travelling without young which have given birth within the previous 48 hours;



- vii) pregnant animals which would be in the final 10% of their gestation period at the planned time of unloading.
- d) Risks during transport can be reduced by selecting animals best suited to the conditions of travel and those that are acclimatised to expected weather conditions.

**Community comments:**

**The words “at risk” should be changed to “at particular risk of suffering poor welfare during transport”.**

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

- e) Animals at risk, and requiring better conditions and additional attention during transport include:
  - i) very large or obese individuals;
  - ii) very young or old animals;
  - iii) excitable or aggressive animals;
  - iv) animals subject to motion sickness;
  - v) animals which have had little contact with humans;
  - vi) females in the last third of pregnancy or in heavy lactation.
- f) Hair or wool length ~~needs consideration~~ should be considered in relation to the weather conditions expected during transport.

Article 3.7.2.6.

**Loading**

1. Experienced Competent supervision

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

**Community comments:**

**The words “loading should be supervised by the Competent Authority” need to be carefully considered.**

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

- b) Loading should be supervised by the *Competent Authority* and ~~managed~~ conducted by ~~an~~ *animal handler(s)*. Animal handlers should ensure that animals are loaded quietly and without unnecessary noise, harassment or force, and that untrained assistants or spectators do not impede the process.
- e) ~~Ventilation during loading and the journey should provide for fresh air, and the removal of excessive heat, humidity and noxious fumes (such as ammonia and carbon monoxide). Under warm and hot conditions, ventilation should allow for the adequate convective cooling of each animal. In some instances, adequate ventilation can be achieved by increasing the space allowance for animals.~~

## 2. Facilities

- a) The facilities for loading including the collecting area at the wharf, races and loading ramps should be designed and constructed to take into account of the needs and abilities of the animals with regard to dimensions, slopes, surfaces, absence of sharp projections, flooring, sides, etc.
- b) Ventilation during loading and the journey should provide for fresh air, and the removal of excessive heat, humidity and noxious fumes (such as ammonia and carbon monoxide). Under warm and hot conditions, ventilation should allow for the adequate convective cooling of each animal. In some instances, adequate ventilation can be achieved by increasing the space allowance for animals.
- c) ~~All~~ Loading facilities should be properly illuminated to allow the animals to be easily inspected by the *animal handler(s)*, and to allow the animals' ease of movement at all times. Facilities should provide uniform lighting light levels directly over approaches to sorting pens, chutes, loading ramps, with brighter lighting light levels inside vehicles / containers, in order to minimise baulking. Dim lighting light levels may be advantageous for the catching of some animals. Artificial lightening may be required.

## 3. Goads and other aids

The following principles should apply:

- a) ~~Goads (aids for encouraging animals to move) should not be used on~~ Animals that have little or no room to move should not be subjected to physical force or goads and other aids which compel movement.
- b) Useful and permitted goads include panels, flags, plastic paddles, flappers (a length of cane with a short strap of leather or canvas attached), plastic bags and metallic rattles; they should be used in a manner sufficient to encourage and direct movement of the animals ~~but without physical contact with them.~~

- c) Painful procedures (including whipping, tail twisting, use of nose twitches, pressure on eyes, ears or external genitalia), or the use of unsuitable goads or other aids (including sticks with sharp ends, lengths of metal piping, fencing wire or heavy leather belts), should not be used to move animals.
- e) ~~Unsuitable goads such as large wooden sticks, sticks with sharp ends, lengths of metal piping, fencing wire or heavy leather belts should not be used to strike animals.~~
- d) The use of goads which administer electric shocks should be discouraged, and restricted to that necessary to assist movement of the animal. ~~If Such use is necessary, it~~ should be limited to battery-powered goads on the hindquarters of pigs and large ruminants, and never on sensitive areas such as the eyes, mouth, ears, anogenital region or belly. Such instruments should not be used on horses, sheep and goats of any age, or on calves or piglets.
- e) Shouting or yelling at animals or making loud noises eg through the cracking of whips to encourage them to move should not occur, as such actions may make the animals agitated, leading to crowding or falling.
- f) The use of well trained dogs to help with the *loading* of some species may be acceptable.
- g) Manual lifting is permissible for young animals that may have difficulty negotiating ramps, but the lifting of animals by body parts such as their tail, head, horns, ears, limbs, wool or hair should not be permitted. The throwing or dropping of animals should not be permitted.

Article 3.7.2.7.

**Travel**

1. General considerations

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

**Community comments:**

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

**Justification: In many cases stocking density will not need to be changed during the journey. If it is necessary to make changes to the stocking density during the journey, this implies that additional free space should be held in reserve if the aforementioned stocking density changes are necessary. For these reasons the current wording should be changed.**

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

- c) Each pen of animals should be observed on a daily basis for normal behaviour, health and welfare, and the correct operation of ventilation, watering and feeding systems. There should also be a night patrol. Any necessary corrective action should be undertaken promptly.
- d) Adequate access to suitable feed and water should be ensured for all animals in each pen.

**Community comments:**

**The text “Sick and injured” should be changed to “Sick or injured”.**

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

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

2. Sick and injured animals

**Community comments:**

**1. The words: “if possible” should be deleted.**

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

**2. The text “Sick and injured” should be changed to “Sick or injured”.**

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

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

**Community comments:**

**The text “Sick and injured” should be changed to “Sick or injured”.**

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

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

**Community comments**

**The next bullet point “c” should not be deleted.**

**Justification: It should be recorded and documented what, if any, treatments the animals have received. A record of such treatment can be used as an indicator of the welfare of the animals during sea transport. If food safety issues occur, one should know the veterinary history of an animal. Therefore such records are very important and should be kept.**

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

### 3. Cleaning and disinfection

- a) ~~Vessels and containers used to carry the animals should be cleaned before re-use through the physical removal of manure and bedding by scraping, washing and flushing vessels and containers with water. This should be followed by *disinfection* when there are concerns about disease transmission.~~
- b) ~~Manure, litter and bedding should be disposed of in such a way as to prevent the transmission of disease and in compliance with all relevant health and environmental legislation.~~
- e) ~~Where cleaning or *disinfestation* is necessary during travel, it should be carried out with the minimum stress to the animals.~~

Article 3.7.2.8.

## Unloading and post-journey handling

### 1. General considerations

- a) The required facilities and the principles of animal handling detailed in Article 3.7.2.6. apply equally to unloading, but consideration should be given to the likelihood that the animals will be fatigued.
- b) Unloading should be carefully planned as it has the potential to be the cause of poor welfare in transported animals.
- c) A livestock vessel should have priority attention when arriving in port and have priority access to a berth with suitable unloading facilities. As soon as possible after the ship's arrival at the port and acceptance of the consignment by the *Competent Authority*, animals should be unloaded into appropriate facilities.
- d) The accompanying veterinary certificate and other documents should meet the requirements of the *importing country*. Veterinary inspections should be completed as quickly as possible.

- e) Unloading should be supervised by the *Competent Authority* and ~~managed~~ conducted by an ~~competent~~ *animal handler(s)*. The *animal 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 ~~be properly illuminated~~ have sufficient lighting to allow the animals to be easily inspected by the *animal handler(s)*, and to allow the animals' ease of movement at all times.

### **Community comments**

**In the next point the sentence should be rephrased as follows: “In case of emergencies arrangements should be available to provide animals with appropriate care and comfort, adequate space.....”. The words “port facilities” should be deleted”.**

**Justification: It is not practical to provide such facilities within the confines of every port in all OIE member countries at which animals could be loaded. Equally effective care can be provided by the prompt transfer of animals requiring such attention to nearby appropriate animal-handling facilities. Often the activities of busy port facilities provide an inhospitable and inappropriate environment to properly care for such animals requiring emergency attention. Very small ports may often be used for animal transport which, by their very nature, have minimal animal handling and stocking facilities available on-site.**

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

### **Community comments**

**In the next point in the heading the word “and” should be changed in “or”.**

**Justification: As stated previously an animal can be sick without necessarily being injured.**

## 3. Sick and injured animals

- a) An animal that has become sick, injured or disabled during a journey should be appropriately treated or humanely killed (see Appendix 3.7.6.). When necessary, veterinary advice should be sought in the care and treatment of these animals.
- b) In some cases, where animals are non-ambulatory due to fatigue, injury or sickness, it may be in the best welfare interests of the animal to be treated or euthanased aboard the vessel.
- c) If unloading is in the best welfare interests of animals that are fatigued, injured or sick, there should be appropriate facilities and equipment for the humane unloading of such animals. These animals should be unloaded in a manner that causes the least amount of suffering. After unloading, separate pens and other appropriate facilities and treatments should be provided for sick or injured animals.

#### 4. Cleaning and disinfection

- a) Vessels and containers used to carry the animals should be cleaned before re-use through the physical removal of manure and bedding, by scraping, washing and flushing vessels and containers with water until visibly clean. This should be followed by disinfection when there are concerns about disease transmission.
- b) Manure, litter and bedding should be disposed of in such a way as to prevent the transmission of disease and in compliance with all relevant health and environmental legislation.
- c) Where cleaning or *disinfestation* is necessary during travel, it should be carried out with the minimum of stress to the animals.

Article 3.7.2.9.

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

1. The welfare of the animals should be the first consideration in the event of a refusal to import.
2. When ~~a shipment has~~ animals have been refused import, the *Competent Authority* of that country should make available suitable isolation facilities to allow the unloading of animals from a vessel and their secure holding, without posing a risk to the health of the national herd, pending resolution of the situation. In this situation, the priorities should be:
  - a) the *Competent Authority* of the *importing country* should provide urgently in writing the reasons for the refusal;
  - b) in the event of a refusal for animal health reasons, the *Competent Authority* of the *importing country* should provide urgent access to an OIE-appointed veterinarian(s) to assess the animals' health status with regard to the *importing country's* concerns, and the necessary facilities and approvals to expedite the required diagnostic testing;
  - c) the *Competent Authority* of the *importing country* should provide access to allow continued assessment of the ongoing health and welfare situation;
  - d) if the matter cannot be promptly resolved, the *Competent Authority* of the *exporting* and *importing countries* should call on the OIE to mediate.
3. In the event that the animals are required to remain on the *vessel*, the priorities should be:

- a) the *Competent Authority* of the *importing country* should allow reprovision of the vessel with water and feed as necessary;
  - b) the *Competent Authority* of the *importing country* should provide urgently in writing the reasons for the refusal;
  - c) in the event of a refusal for animal health reasons, the *Competent Authority* of the *importing country* should provide urgent access to an OIE-appointed veterinarian(s) to assess the animals' health status with regard to the *importing country's* concerns, and the necessary facilities and approvals to expedite the required diagnostic testing;
  - d) the *Competent Authority* of the *importing country* should provide access to allow continued assessment of the ongoing health and ~~welfare situation~~ other aspects of the welfare of the animals, and the necessary actions to deal with any issues which arise;
  - e) if the matter cannot be urgently resolved, the *Competent Authorities* of the *exporting* and *importing countries* should call on the OIE to mediate.
4. The OIE should utilise its dispute settlement mechanism to identify a mutually agreed solution which will address the animal health and welfare issues in a timely manner.

Article 3.7.2.10.

**Community comments:**

**This text should be replicated at the end of Annex 3.7.1.**

**Justification: This text contains useful descriptions of issues of general interest and information, not specifically related to the transport of animals by sea. As such it could be useful to bring it to the attention of persons reading the other OIE animal welfare guidelines. Only presenting this text in the sea transport guidelines means that persons only reading the other animal welfare guidelines will be unaware of these important descriptions of species-specific issues.**

**Species specific issues**

**Cattle** are sociable animals and may become agitated if they are singled out. Social order is usually established at about two years of age. When groups are mixed, social order has to be re-established and aggression may occur until a new order is established. Crowding of cattle may also increase aggression as the animals try to maintain personal space. Social behaviour varies with age, breed and sex; *Bos indicus* and *B. indicus*-cross animals are usually more temperamental than European breeds. Young bulls, when moved in groups, show a degree of playfulness (pushing and shoving) but become more aggressive and territorial with age. Adult bulls have a minimum personal space of six square metres. Cows with young calves can be very protective, and handling calves in the presence of their mothers can be dangerous.

**Goats** should be handled calmly and are more easily led or driven than if they are excited. When goats are moved, their gregarious tendencies should be exploited. Activities which frighten, injure or cause agitation to animals should be avoided. Bullying is particularly serious in goats. Housing strange goats together could result in fatalities, either through physical violence, or subordinate goats being refused access to food and water.

**Sheep** are sociable animals with good eyesight and tend to “flock together”, especially when they are agitated. They should be handled calmly and their tendency to follow each other should be exploited when they are being moved. Sheep may become agitated if they are singled out for attention and will strive to rejoin the group. Activities which frighten, injure or cause agitation to sheep should be avoided. They can negotiate steep ramps.



**Pigs** have poor eyesight, and may move reluctantly in strange surroundings. They benefit from well lit loading bays. Since they negotiate ramps with difficulty, these should be as level as possible and provided with secure footholds. Ideally, a hydraulic lift should be used for greater heights. Pigs also negotiate steps with difficulty. A good ‘rule-of-thumb’ is that no step should be higher than the pig’s front knee. Serious aggression may result if unfamiliar animals are mixed. Pigs are highly susceptible to heat stress.

**Horses** in this context include all solipeds, donkeys, mules, hinnies and zebra. They have good eyesight and a very wide angle of vision. They may have a history of loading resulting in good or bad experiences. Good training should result in easier loading, but some horses can prove difficult, especially if they are inexperienced or have associated loading with poor transport conditions. In these circumstances, two experienced handlers can load an animal by linking arms or using a strop below its rump. Blindfolding may even be considered. Ramps should be as shallow as possible. Steps are not usually a problem when horses mount a ramp, but they tend to jump a step when descending, so steps should be as low as possible. Horses benefit from being individually stalled, but may be transported in compatible groups. When horses are to travel in groups, their shoes should be removed.

**Camelids** in this context comprise llamas, alpacas, guanaco and vicuna. They have good eyesight and, like sheep, can negotiate steep slopes, though ramps should be as shallow as possible. They load most easily in a bunch as a single animal will strive to rejoin the others. Whilst they are usually docile, they have an unnerving habit of spitting in self-defence. During transport, they usually lie down. They frequently extend their front legs forward when lying, so gaps below partitions should be high enough so that their legs are not trapped when the animals rise.

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— text deleted

APPENDIX 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.

**Community comments:**

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

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

Article 1

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

**Community comments:**

**The word “bis” should be deleted from the next article heading.**

**Justification: The word is not necessary.**

Article 3.7.3.1. bis

## Responsibilities

### Community comments:

**At the end of the first sentence it should be made clear that those persons involved are responsible for different and specific operations or parts of the journey. The following changes are proposed:**

**“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, *with individual responsibilities of those persons being described in more detail below and in line with their respective tasks.*”**

**Justification: The current wording is unclear. For these OIE guidelines to be properly interpreted and applied it is important that all of those in the transport chain understand their individual responsibilities, i.e. “who is responsible for what”. The text should be clarified and a tabular presentation inserted to describe all of those persons involved in animal transport and their respective roles and responsibilities. In the current text many responsibilities are described in a confused and overlapping manner e.g. managers of facilities. It is unclear as to who is being referred to when describing market owner-managers, business-buying-selling agent. This causes serious difficulties in correctly interpreting the text and the obligations of these various persons.**

Once the decision to transport the animals has been made, the welfare of the animals during their journey transport is the paramount consideration and is the joint responsibility of all people involved.

The roles of each of those responsible are defined below:

1. The owners and managers of the animals are responsible for the general health of the animals and their fitness for the journey, and for their overall welfare during the journey, regardless of whether duties are subcontracted to other parties during transport. They are also responsible for ensuring compliance with any required veterinary or other certification, and for the presence during the journey of at least one *animal handler*<sup>50</sup> competent for the species being transported, with the authority to take prompt action. They are also responsible for ensuring that equipment and veterinary assistance are provided as appropriate for the species and journey.

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<sup>50</sup> ~~An *animal handler* is a person with a knowledge of the behaviour and needs of animals which, with appropriate experience and a professional and positive response to an animal's needs, results in effective management and good welfare; their competence should be demonstrated through independent assessment and certification.~~

**Community comments:**

**For clarity the words “including for any stops at resting points during the journey” should be added before the words “and for emergencies” in the next point.**

**Justification: Animals are often loaded and unloaded at rest points along the journey and the guidelines need to take account of this fact and normal industry practices.**

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

**Community comments:**

**An extra bullet point should be added with the following text: “Transport companies are also responsible for the welfare of the animals during the actual transport”.**

**Justification: Transport companies have very important responsibilities concerning the transport of animals by land. Practical experience has shown the considerable animal welfare gains that can be achieved where transport companies promote a positive approach to ensuring the welfare of animals transported.**

- a) transport companies and vehicle owners are responsible for choosing appropriate vehicles and ensuring that properly trained staff are available for loading and caring for animals;

- b) transport companies and vehicle owners are responsible for developing and keeping up to date contingency plans to address emergencies and minimise stress during transport;

**Community comments:**

**In point c) below:**

- 1. the words “and vehicle owners” should be deleted.**

**Justification: Vehicle owners are usually natural persons or commercial haulage agencies not directly involved in planning and carrying out the transport.**

- 2. The word “itinerary” should be added after “journey duration”.**

**Justification: It is important that the description of the minimum requirements of the journey plan should be widened to include an itinerary, which is important for the driver to complete the journey in an efficient manner with appropriate animal welfare safeguards.**

- c) transport companies and vehicle owners are responsible for producing a journey plan which includes a loading plan, journey duration and location of resting places;
- d) drivers are responsible for loading only those animals which are fit to travel, for their correct loading into the vehicle and their inspection during the journey, and for appropriate responses to problems arising. If its fitness to travel is in doubt, the animal should be examined by a veterinarian in accordance with point 5 a) of Article 3.7.3.5.

**Community comments:**

- 1. “Managers of facilities” should be defined in point 5.**

**Justification: In order to ensure that these guidelines can be applied it is important that they are drafted in as clear and precise a manner as possible, especially with regard to the responsibilities of those involved in the animal transport chain.**

**2. The first phrase of 5 should be replaced by “Drivers should only load and unload animals in places:”.**

**Justification: Drivers are a key actor in the animal transport chain and have important responsibilities in ensuring that the welfare of transported animals is properly safeguarded.**

5. Managers of facilities at the start and at the end of the journey and at resting points are responsible for:

a) providing suitable premises for loading, unloading and securely holding the animals, with water and feed when required, until further transport, sale or other use (including rearing or slaughter);

**Community comments:**

**Point (b) should be replaced with the following text**

**“- providing appropriate personnel to hold and care for the animals in a manner that causes minimum stress and injury**

**- providing appropriate personnel including animal handlers to load unload, hold and care for animals in the facility in a manner that causes minimum stress and injury”.**

**Justification: The responsibility of managers of facilities should be changed, because loading, unloading and driving are the responsibility of animal handlers and/or drivers rather than the manager of the facilities. Also cooperation between the animal handler (driver) and personnel of the facility during loading and unloading should take place.**

b) providing competent *animal handlers* to load, unload, drive and hold animals in a manner that causes minimum stress and injury;

- c) minimising the opportunities for disease transmission;
- d) providing appropriate facilities, with water and feed when required;
- e) providing appropriate facilities for emergencies;
- f) providing facilities for washing and disinfecting vehicles after unloading;
- g) providing facilities and competent staff to allow the humane killing of animals when required;
- h) ensuring proper rest times and minimal delay during stops.

**Community comments:**

**The words: “Competent authorities should give animal consignments priority at frontiers in order to allow them to pass without unnecessary delay” should be added as an extra point.**

**Justification: The responsibilities of the Competent Authorities should include giving priority to animal consignments at frontiers in order to allow them to pass without undue delay. This should be recognised in the text.**

6. The responsibilities of *Competent Authorities* include:

**Community p comments:**

**Points a and b should be combined.**

**Justification: For linguistic reasons a) and b) should be combined, otherwise the impression is given of an obligation for the competent authorities to approve all vehicles which transport animals, which is likely to be unachievable for all vehicles transporting animals in the OIE’s 167 member countries.**

- a) establishing minimum standards for animal welfare, including requirements for inspection of animals before, during and after their travel, and appropriate certification and record keeping;
- b) approving facilities, containers and vehicles for the transport of animals;

**Community comments:**

**For consistency, the word “manager” in c) and d) should be changed to “managers of facilities”.**

**Justification: This is needed to ensure the clear and consistent use of terminology throughout the text.**

- c) setting standards for the competence of drivers, *animal handlers* and managers;
  - d) ensuring appropriate awareness and training of drivers, *animal handlers* and managers;
  - e) implementation of the standards, including through accreditation of / interaction with other organisations;
  - f) monitoring and evaluating the effectiveness of standards of health and other aspects of welfare;
  - g) monitoring and evaluating the use of veterinary medications.
7. All individuals, including veterinarians, involved in transporting animals and the associated handling procedures should receive appropriate training and be competent to meet their responsibilities.
8. The receiving *Competent Authority* should report back to the sending *Competent Authority* on significant animal welfare problems which occurred during the journey.

Article 3.7.3.2.



## Competence

1. All people ~~handling animals, or who are otherwise~~ responsible for animals during *journeys*, should be competent according to their responsibilities listed in Article 3.7.3.1. Competence may be gained through formal training and/or practical experience. Competence in areas other than animal welfare would need to be addressed separately.

### Community comments:

**In point 2 the sentence should be changed as follows: “The competence of animal handlers should be demonstrated through a current certificate from the Competent Authority or from an independent body accredited by a Competent Authority. The certificate may be issued based on verification of knowledge of the behaviour and needs of animals and practical skills of animal handling. ....”**

**Justification: See earlier comment on sea transport guidelines. The current wording excludes the valid possibility that a Competent Authority may undertake the task of issuing such certificates. It is important to give clear guidance on the criteria which could be used for the issuing of such certificates of competence.**

2. The competence of *animal handlers* should be demonstrated through a current certificate from an independent body, accredited by the *Competent Authority*. The certificate should be in one of the OIE official languages if the international transport of animals is involved.
3. The assessment of the competence of *animal handlers* should at a minimum address knowledge, and ability to apply that knowledge, in the following areas:
  - a) planning a journey, including appropriate space allowance, and feed, water and ventilation requirements;

### Community comments:

**In point b) the words: “including loading and unloading” should not be deleted.**

**Justification: Loading and unloading are often the most stressful events during the journey. In addition such operations represent serious risks for the welfare of the animals (e.g. risks of injury) and allow an important opportunity for the handler to assess if the animals are fit for transport.**

- b) responsibilities for animals during the journey, ~~including loading and unloading~~;
- c) sources of advice and assistance;
- d) animal behaviour, general signs of disease, and indicators of poor animal welfare such as stress, pain and fatigue, and their alleviation;
- e) assessment of fitness to travel;
- f) relevant authorities and applicable transport regulations, and associated documentation requirements;
- g) general disease prevention procedures, including cleaning and disinfection;
- h) appropriate methods of driving;
- i) methods of inspecting animals, managing situations frequently encountered during *transport* such as adverse weather conditions, and dealing with emergencies;
- j) species-specific and age-specific aspects of animal handling and care, including feeding, watering and inspection;
- k) maintaining a journey log and other records.

Article 3.7.3.3.

### Planning the journey

**Community comments:**

**The following points should be added under 1b:**

**“xi) Weather forecasting (e.g. conditions being too hot or cold to travel during certain periods of the day)**

**xii) Transfer time when changing mode of transport**

**xiii) Waiting time at frontiers and inspection points”**

**Justification: planning should also incorporate forecasting of expected weather conditions and expected transfer time when changing mode of transport (e.g. from vehicle to aeroplane or to roll-on roll-off vessel). Expected waiting time at frontiers/ inspection points should also be taken into account. These could have an impact on the welfare of the animals. Therefore it is important to include the afore-mentioned 3 additional bullet points.**

1. General considerations

- a) Adequate planning is a key factor affecting the welfare of animals during a journey.
- b) Before the journey starts, plans should be made in relation to:
  - i) preparation of animals for the journey;
  - ii) choice of road or rail;
  - iii) nature and duration of the journey;
  - iv) vehicle / container design and maintenance, including roll-on roll-off vessels;
  - v) required documentation;

- vi) space allowance;
  - vii) rest, water and feed;
  - viii) observation of animals en route;
  - ix) control of disease; and
  - x) emergency response procedures.
- c) Regulations concerning drivers (for example, maximum driving periods) should be harmonised with maximum transport journey intervals appropriate for the species.

## 2. Preparation of animals for the journey

### **Community comments:**

**The last part of the last sentence can be changed as follow: “.....of feed deprivation, for example 10-12 hours for pigs prior to loading may be desirable”.**

**Justification: To avoid different interpretations of the last sentence “a short period” should be more clearly defined or otherwise the whole sentence should be deleted. According to the Report of the Scientific Committee on Animal Health and Animal welfare adopted on 11 March 2002, 10 to 12 hours fasting is recommended.**

- a) When animals are to be provided with a novel diet or method of water provision during transport, an adequate period of adaptation should be planned. For animals such as pigs which are susceptible to motion sickness, and in order to reduce urine and faeces production during the journey, a short period of feed deprivation prior to loading may be desirable.
- b) ~~Animals should be exposed to appropriate contact with humans and handling conditions (including methods of restraint) prior to transport to reduce their fearfulness and improve their approachability (see Article 3.7.3.5.).~~ Since animals more accustomed to contact with humans and with being handled are

likely to be less fearful of being loaded and transported. People handling animals should handle and load animals in a manner that reduces their fearfulness and improves their approachability.

- c) Behaviour-modifying compounds (such as tranquillisers) should not be used routinely during transport. Such compounds should only be administered when a problem exists in an individual animal, and should be administered by a veterinarian or other person who has been instructed in their use by a veterinarian.

**Community comments:**

**The list of factors described under point 3 to determine the maximum duration of a journey is incomplete and should be placed “under study” pending further analysis and preparation of a more complete list of determining factors. The first sentence should be rephrased as follows: “The maximum duration of a journey should be determined in relation to the overall welfare of the animal taking into account factors such as:”**

**An additional point should be added:**

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

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

3. Nature and duration of the journey

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

- a) the ability of the animals to cope with the stress of transport (such as very young, old, lactating or pregnant animals);
- b) the animals’ previous transport experience;
- c) the onset of fatigue;

- d) the need for special attention;
- e) the need for feed and water;
- f) the increased susceptibility to injury and disease;
- g) space allowance, vehicle design, road conditions and driving quality;
- h) weather conditions.

4. Vehicle and container design and maintenance

- a) Vehicles and containers used for the transport of animals should be designed, constructed and fitted as appropriate to the species, size and weight of the animals to be transported; special attention should be paid to the avoidance of injury to animals through the use of secure smooth fittings free from sharp protrusions. The avoidance of injury to drivers and *animal handlers* while carrying out their responsibilities should be emphasised.
- b) Vehicles and containers should be designed with the structures necessary to provide protection from adverse weather conditions and to minimise the opportunity for animals to escape.
- c) In order to minimise the likelihood of the spread of ~~pathogenic agents~~ infectious disease during transport, vehicles and containers should be designed to permit thorough cleaning and *disinfection*, and the containment of faeces and urine during a journey.
- d) Vehicles and containers should be maintained in good mechanical and structural condition.

**Community comments:**

**1. At the end of the sentence “vehicles is stationary” should be changed to “vehicle is stationary”**

**Justification: Grammatical correctness.**

**2. And the last part of the last sentence should not be deleted**

**Justification: The temperature can change during the journey. Therefore the airflow should be adjustable.**

- e) Vehicles and containers should have adequate ventilation to meet variations in climate and the thermo-regulatory needs of the animal species being transported; the ventilation system should be ~~capable of operating~~ effective when the vehicles is stationary ~~and the air flow should be adjustable~~.
  - f) Vehicles should be designed so that the faeces or urine from animals on upper levels do not soil animals on lower levels, nor their feed and water.
  - g) When vehicles are carried on board ferries, facilities for adequately securing them should be available.
  - h) If feeding or watering while the vehicle is moving is required, adequate facilities on the vehicle should be available.
  - i) When appropriate, suitable bedding should be added to vehicle floors to assist absorption of urine and faeces, to minimise slipping by animals, and protect animals (especially young animals) from hard flooring surfaces and adverse weather conditions.
5. Special provisions for transport in vehicles (road and rail) on roll-on/roll-off vessels or for containers
- a) Vehicles and containers should be equipped with a sufficient number of adequately designed, positioned and maintained securing points enabling them to be securely fastened to the vessel.
  - b) Vehicles and containers should be secured to the ship before the start of the sea journey to prevent them being displaced by the motion of the vessel.
  - c) Roll-on/roll-off vessels should have adequate ventilation to meet variations in climate and the thermo-regulatory needs of the animal species being transported, especially where the animals are transported in a secondary vehicle/container on enclosed decks.
6. Space allowance

- a) The number of animals which should be transported on a vehicle or in a container and their allocation to ~~different~~ compartments should be determined before ~~the vehicle or container is loaded~~ loading.
- b) The space required on a vehicle or in a container depends upon whether or not the animals need to lie down (for example, pigs, camels and poultry), or to stand (horses). Animals which will need to lie down often stand when first loaded or when the vehicle is driven with too much lateral movement or sudden braking.
- c) When animals lie down, they should all be able to adopt a ~~comfortable~~, normal lying posture which allows necessary thermoregulation.

**Community comments:**

**“(Article XXX)” should be deleted in point d).**

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

- d) When animals are standing, they should have sufficient space to adopt a balanced position as appropriate to the climate and species transported (Article XXX).

**Community comments:**

**The words “and there should be sufficient headroom to allow adequate airflow over the animals” should be added to the end of the next bullet point.**

**Justification: If the space is not sufficient this can limit the airflow, with potentially serious welfare consequences.**

- e) The amount of headroom necessary depends on the species of animal. Each animal should be able to assume its natural position for transport (including during loading and unloading) without coming into contact with the roof or upper deck of the vehicle.



**Community comments:**

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

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

f) Calculations ~~according to~~ for the space allowance ~~permitted~~ for each animal should be carried out using the figures given in Appendix XXX or, in their absence, in a relevant national or international document. ~~The size of already established groups will affect the number and size of the pens, and the distribution of animals in pens on the vehicle. The number and size of pens on the vehicle should be varied to where possible accommodate already established groups of animals while avoiding group sizes which are too large.~~

g) Other factors which may influence space allowance include:

- i) vehicle / container design;
- ii) length of journey;
- iii) need to provide feed and water on the vehicle;
- iv) quality of roads;
- v) expected weather conditions.

7. Rest, water and feed

a) There should be planning for the availability of suitable water and feed ~~during the journey. Feed should be of appropriate quality and composition for the species, age, condition of the animals, climatic conditions, etc~~ as appropriate and needed for the species, age, and condition of the animals, as well as the duration of the journey, climatic conditions, etc.

b) ~~Animals should be rested~~ There should be planning for the resting of animals at resting points at appropriate intervals during the journey. The type of transport, the age and species of the animals being transported should determine the frequency of rest stops and whether the animals ~~are~~ should be unloaded. There should be planning for water and feed availability during rest stops.

8. Ability to observe animals en-route in relation to during the journey duration

a) Animals should be positioned to enable each animal to be observed regularly during the journey to ensure their safety and good welfare.

**Community comments:**

**In point b):**

**1. “If” should be changed to “However” and this point (b) combined with bullet point (a).**

**Justification: This change is necessary for linguistic reasons and to improve readability and clarity, which are very important if the guidelines are to be correctly interpreted, understood and ultimately applied by the OIE’s member countries.**

**2. “(i.e. less than 1.3 m)” should be deleted.**

**Justification: The basis for deciding on an absolute figure of 1.3 m is not clear, would an alternative figure of 1.2 or 1.4 m be acceptable under some circumstances ? Therefore this provision should be deleted.**

b) If the animals are in crates or on multi-tiered vehicles which do not allow free access for observation, for example where the roof of the tier is too low (i.e. less than 1.3 m), animals cannot be inspected adequately, and serious injury or disease could go undetected. In these circumstances, a shorter journey duration should be allowed, and the maximum duration will vary according to the rate at which problems arise in the species and under the conditions of transport.

9. Control of disease

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

- a) mixing of animals from different sources in a single consignment should be minimised;
- b) contact at resting points between animals from different sources should be avoided;
- c) when possible, animals should be vaccinated against diseases to which they are likely to be exposed at their destination;
- d) medications used prophylactically or therapeutically should only be administered by a veterinarian or other person who has been instructed in their use by a veterinarian and agreed by the Veterinary Authority of the importing country.

10. Emergency response procedures

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

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

11. Other considerations

- a) Extreme weather conditions are hazardous for animals undergoing transport and require appropriate vehicle design to minimise risks. Special precautions should be taken for animals that have not been acclimatised or which are unsuited to either hot or cold conditions. In some extreme conditions of heat or cold, animals should not be transported at all.
- b) In some circumstances, transportation during the night may reduce thermal stress or the adverse effects of other external stimuli.

Article 3.7.3.4.

**Documentation**

1. Animals should not be loaded until the ~~required~~ documentation required to that point is complete.

2. The documentation accompanying the consignment should include:

**Community comments:**

**In the next bullet point the word “including” should be changed to “and”.**

**Justification: An emergency plan is not necessarily part of the journey travel plan, which is the meaning implied by the current wording of the text.**

- a) journey travel plan (including an emergency management plan);
- b) date, time, and place of loading and unloading;
- c) veterinary certification, when required;
- d) driver’s competencies;
- e) identities of the animals transported to allow traceback of individual animals to the premises of departure and, where possible, to the premises of origin;

**Community comments:**

**In point f) the words “Animals considered at risk” should be changed to “Animals considered at particular risk of suffering poor welfare during transport”.**

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

- f) details of any animals considered ‘at risk’ (Article 3.7.3.5);
- g) documentation of the period of rest, and access to feed and water, prior to the journey;

- h) stocking density estimate for each load in the consignment;
  - i) the journey log - daily record of inspection and important events, including records of morbidity and mortality and actions taken, climatic conditions, rest stops, travel time and distance, feed and water offered and estimates of consumption, medication provided, and mechanical defects.
3. When veterinary certification is required to accompany consignments of animals, it should include address:
- a) fitness of animals to travel;
  - b) appropriate animal identification (description, number, etc.);
  - c) health status including any tests, treatments and vaccinations status carried out;
  - d) when required, details of *disinfection* carried out.

At the time of certification, the veterinarian should notify the *animal handler* of any factors affecting the animals' fitness to travel for a particular journey.

Article 3.7.3.5.

**Pre-journey period**

- 1. General considerations
  - a) Pre-journey rest is necessary if the welfare of animals has become poor during the collection period because of the physical environment or the social behaviour of the animals.
  - b) Pre-journey assembly/holding areas should be designed to:
    - i) securely hold the animals;

- ii) maintain a safe environment from hazards, including predators and disease;
  - iii) protect animals from exposure to severe weather conditions;
  - iv) allow for maintenance of social groups, and
  - v) allow for rest, and appropriate water and feed.
- c) Consideration should be given to an animal's previous transport experience, training and conditioning if known as these may reduce fear and stress in animals.
- d) Feed and water should be provided pre-journey if the journey duration is greater than the normal inter-feeding and drinking interval for the animal. Recommendations for specific species are described in detail in Article 3.7.3.10.
- e) When animals ~~will~~ are to be provided with a novel diet or method of feed or water provision during ~~or after transport,~~ an adequate period of adaptation should be planned. ~~pre-exposure is necessary.~~
- f) Before each journey, vehicles and containers should be thoroughly cleaned and, if necessary, treated for animal health and public health purposes, using methods approved by the *Competent Authority*. When cleaning is necessary during a journey, this should be carried out with the minimum of stress to the animals.
- g) Where an *animal handler* believes that there is a significant risk of disease among the animals to be loaded or significant doubt as to their fitness to travel, the animals should be examined ~~inspected~~ by a veterinarian.

## 2. Selection of compatible groups

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

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

- b) animals of the same species ~~should not~~ can be mixed if unless there is a significant likelihood of aggression; aggressive individuals should be segregated (recommendations for specific species are described in detail in Article 3.7.3.10.). For some species, animals from different groups should not be mixed because poor welfare occurs unless they have established a social structure;
- c) young or small animals should be separated from older or larger animals, with the exception ~~that dam and offspring should be transported together~~ of nursing mothers with young at foot;
- d) animals with horns or antlers should not be mixed with animals lacking horns or antlers unless judged to be compatible;
- e) animals of different species should not be mixed unless they are judged to be compatible.

### 3. Shelter in the assembly/holding area

Assembly/holding areas should be designed to:

- a) ~~securely hold the animals~~;
- b) ~~maintain a safe environment from hazards, including predators and disease~~;
- c) ~~protect animals from exposure to severe weather conditions~~;
- d) ~~allow for maintenance of social groups, and~~
- e) ~~allow for rest, and appropriate water and feed.~~

### 4. Effect of travel experience, long and short term

- a) ~~Consideration should be given to an animal's previous transport experience, training and conditioning as these may reduce fear and stress in animals. Animals that are carefully and regularly transported may show less adverse responses to transport.~~

b) ~~Exposure to familiar personnel should reduce the fearfulness of animals and improve their approachability during transport procedures.~~

5. Fitness to travel

a) Each animal should be inspected by a veterinarian or an *animal handler* to assess fitness to travel. If its fitness to travel is in doubt, the animal should be examined by a veterinarian. Animals found unfit to travel should not be loaded onto a vehicle, except for transport to receive veterinary treatment.

**Community comments:**

**The next bullet point should be clarified.**

**Justification: Sharing the responsibilities between different agents “e.g. the owner or agent” is likely to give rise to confusion and ineffective handling of animal welfare problems when they arise.**

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

c) Animals that are unfit to travel include:

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

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

iii) those that are blind in both eyes;

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

v) newborn with an unhealed navel;



- vi) ~~pregnant animals which are likely to give birth during the journey~~ pregnant animals which would be in the final 10% of their gestation period at the planned time of unloading;
  - vii) females travelling without young which have given birth within the previous 48 hours;
  - viii) those whose body condition would result in poor welfare because of the expected climatic conditions.
- d) Risks during transport can be reduced by selecting animals best suited to the conditions of travel and those that are acclimatised to expected weather conditions.

**Community comments:**

**In point e) the words “Animals at risk” should be changed to “Animals at particular risk of suffering poor welfare during transport and which require special conditions.....”.**

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

- e) Animals ‘at risk’ which require special conditions (such as in the design of facilities and vehicles, and the length of the journey) and additional attention during transport, may include:
- i) large or obese individuals;
  - ii) very young or old animals;
  - iii) excitable or aggressive animals;
  - iv) animals which have had little contact with humans;

- v) animal subject to motion sickness;
- vi) females in late pregnancy or heavy lactation, dam and offspring;
- vii) ~~those animals~~ with a history of exposure to stressors or pathogenic agents prior to transport.

#### 6. Specific species requirements

Transport procedures should be able to take account of variations in the behaviour of the species. Flight *zones*, social interactions and other behaviour vary significantly among species and even within species. Facilities and handling procedures that are successful with one species are often ineffective or dangerous with another.

Recommendations for specific species are described in detail in Article 3.7.3.10.

Article 3.7.3.6.

#### **Loading**

##### 1. Experienced Competent supervision

- a) ~~Since loading has been shown to be the procedure most likely to be the cause of poor welfare in transported animals, the methods to be used should be carefully planned. Loading should be carefully planned as it has the potential to be the cause of poor welfare in transported animals.~~

#### **Community comments:**

**The next bullet point should be clarified.**

**Justification: Stating that “loading should be supervised and/or conducted by animal handlers” is confusing and gives rise to the question of who will actually conduct and supervise the loading. To ensure proper application of the guidelines such responsibilities need to be clearly and carefully described.**

- b) Loading should be supervised and/or conducted by *animal handlers*. These *animal handlers* should ensure that animals are loaded quietly and without unnecessary noise, harassment or force, and that untrained assistants or spectators do not impede the process.
- c) When containers are loaded onto a vehicle, this should be carried out in such a way to avoid poor animal welfare.

## 2. Facilities

- a) The facilities for loading including the collecting area, races and loading ramps should be designed and constructed to take into account the needs and abilities of the animals with regard to dimensions, slopes, surfaces, absence of sharp projections, flooring, etc.
- b) Loading facilities should be properly illuminated to allow the animals to be observed by the *animal handler(s)*, and to allow the animals' ease of movement at all times. Facilities should provide uniform lighting light levels directly over approaches to sorting pens, chutes, loading ramps, with brighter lighting light levels inside vehicles / containers, in order to minimise baulking. Dim lighting light levels may be advantageous for the catching of poultry and some other animals. Artificial lightening may be required.
- c) Ventilation during loading and the journey should provide for fresh air, the removal of excessive heat, humidity and noxious fumes (such as ammonia and carbon monoxide), and the prevention of accumulations of ammonia and carbon dioxide. Under warm and hot conditions, ventilation should allow for the adequate convective cooling of each animal. In some instances, adequate ventilation can be achieved by increasing the space allowance for animals.

## 3. Goads and other aids

The following principles should apply:

- a) Animals which have little or no room to move should not be subjected to physical force or goads and other aids which compel movement.
- b) Useful and permitted aids include panels, flags, plastic paddles, flappers (a length of cane with a short strap of leather or canvas attached), plastic bags and metallic rattles; they should be used in a manner sufficient to encourage and direct movement of the animals ~~but without physical contact with them.~~
- c) Painful procedures (including whipping, tail twisting, use of nose twitches, pressure on eyes, ears or external genitalia), or the use of unsuitable goads or other aids (including sticks with sharp ends, lengths of metal piping, fencing wire or heavy leather belts), should not be used to move animals.

- d) The use of goads which administer electric shocks should be discouraged, and restricted to that necessary to assist movement of the animal. Such use should be limited to battery-powered goads on the hindquarters of adult pigs and cattle, and never on sensitive areas such as the eyes, mouth, ears, anogenital region or belly. Such instruments should not be used on other animals.
- e) The use of well trained dogs to help with the loading of some species may be acceptable.
- f) The throwing or dropping of animals, or their lifting or dragging by body parts such as their tail, head, horns, ears, limbs, wool, hair or feathers, should not be permitted. The manual lifting of small animals is permissible.
- g) Shouting or yelling at animals or making loud noises e.g. through the cracking of whips to encourage them to move should not occur, as such actions may make the animals agitated, leading to crowding or falling.

Article 3.7.3.7.

## Travel

### 1. General considerations

#### **Community comments:**

**The words “especially at rest or re-fuelling stops when the vehicle is stationary” should be added to the end of the next bullet point.**

**Justification: Drivers or conveyors of animals should be encouraged to take any available opportunity when the vehicle is stationary for a period of time in order to examine the animals.**

- a) Drivers and *animal handlers* should check the load immediately before departure to ensure that the animals have been properly loaded. Each load should be checked again early in the trip and adjustments made as appropriate. Periodic checks should be made throughout the trip.
  - b) Drivers should utilise smooth, defensive driving techniques, without sudden turns or stops, to minimise uncontrolled movements of the animals.
2. Methods of restraining or containing animals

- a) Methods of restraining animals should be appropriate to the species and age of animals involved and the training of the individual animal.
- b) Recommendations for specific species are described in detail in Article 3.7.3.10.

3. Regulating the environment within vehicles or containers

**Community comments:**

**The last sentence of the next bullet point should be deleted.**

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

- a) Animals should be protected against harm from hot or cold conditions during travel. Effective ventilation procedures for maintaining the animals' environment within vehicles or containers will vary according to whether conditions are cold, hot and dry or hot and humid, but in all conditions a build-up of noxious gases should be prevented. Specific temperature and humidity parameters are described in detail in Appendix XXX.
- b) The animals' environment in hot weather can be regulated by the flow of air produced by the movement of the vehicle. In warm and hot weather, the duration of journey stops should be minimised and vehicles should be parked under shade, with ~~maximal~~ adequate and appropriate ventilation.
- c) To minimise slipping and soiling, and maintain a healthy environment, urine and faeces should be removed from floors when necessary and disposed of in such a way as to prevent the transmission of disease and in compliance with all relevant health and environmental legislation.

4. Sick, injured and dead animals

- a) A driver or *animal handler* finding sick, injured or dead animals should act according to a predetermined emergency response plan.
- b) If possible, sick or injured animals should be segregated.
- c) Ferries (roll-on roll-off) should have procedures to treat sick or injured animals during the journey.
- d) In order to reduce the likelihood that animal transport will increase the spread of infectious disease, contact between transported animals, or the waste products of the transported animals, and other farm animals should be minimised.

- e) During the journey, when disposal of a dead animal becomes necessary, this should be carried out in such a way as to prevent the transmission of disease and in compliance with all relevant health and environmental legislation.
- f) When euthanasia is necessary, the driver or *animal handler* should ensure that it is carried out as quickly as possible and ~~humanely, and results in immediate death.~~ ~~When necessary,~~ assistance should be sought from a veterinarian or other person(s) competent in humane euthanasia procedures. Recommendations for specific species are described in Appendix 3.7.6. on humane killing of animals for disease control purposes.

5. Water and feed requirements

- a) If journey duration is such that feeding or watering is required or if the species requires feed or water throughout, access to suitable feed and water for all the animals (appropriate for their species and age) carried in the vehicle should be provided. There should be adequate space for all animals to move to the feed and water sources and due account taken of likely competition for feed.
- b) Recommendations for specific species are described in detail in Article 3.7.3.10.

6. Rest periods and conditions including hygiene

- a) Animals that are being transported should be rested at appropriate intervals during the journey and offered feed and water, either on the vehicle or, if necessary, unloaded into suitable facilities.
- b) Suitable facilities should be used en route, when resting requires the unloading of the animals. These facilities should meet the needs of the particular animal species and should allow access of all animals to feed and water.

7. In-transit observations

**Community comments:**

**In the next point “With a maximum interval of 5 hours” should be deleted.**

**Justification: No clear basis is given for the figure of “with a maximum interval of 5 hours” and someone could equally propose a figure of 3-4-6-7 hours. In such internationally agreed guidelines it is important that recommendations should have a clear and objective scientific basis, rather than discretionary subjective figures being used.**

- a) Animals being transported by road should be observed soon after a journey is commenced and whenever the driver has a rest stop (with a maximum interval of 5 hours). After meal breaks and refuelling stops, the animals should be observed immediately prior to departure.

**Community comments:**

**In the next point “5 hours since” should be deleted.**

**Justification: No clear basis is given for the figure of “5 hours” and someone could equally propose figures of 3-4-6-7 hours. In such internationally agreed guidelines it is important that recommendations should have a clear and objective scientific basis, rather than discretionary subjective figures being used.**

- b) Animals being transported by rail should be observed at each scheduled stop nearest to 5 hours since the last observation. The responsible rail transporter should monitor the progress of trains carrying animals and take all appropriate action to minimise delays.
- c) During stops, it should be ensured that the animals continue to be properly confined, have appropriate feed and water, and their physical condition is satisfactory.

Article 3.7.3.8.

**Unloading and post-journey handling**

1. General considerations

- a) The required facilities and the principles of animal handling detailed in Article 3.7.3.6. apply equally to unloading, but consideration should be given to the likelihood that the animals will be fatigued.
- b) Unloading should be supervised and/or conducted by an *animal handler* with knowledge and experience of the behavioural and physical characteristics of the species being unloaded. Animals should be unloaded from the vehicle into appropriate facilities as soon as possible after arrival at the destination but sufficient time should be allowed for unloading to proceed quietly and without unnecessary noise, harassment or force.
- c) Facilities should provide all animals with appropriate care and comfort, adequate space and ventilation, access to feed (if appropriate) and water, and shelter from extreme weather conditions.
- d) For details regarding the unloading of animals at a slaughterhouse, see Appendix 3.7.5. on slaughter of animals for human consumption.

**Community comments:**

**In the next heading the word “and” should be changed to “or”.**

**Justification: A sick animal is not necessarily injured.**

2. Sick and injured animals

- a) An animal that has become sick, injured or disabled during a journey should be appropriately treated or humanely killed (see Appendix 3.7.6. on humane killing of animals for disease control purposes). When necessary, veterinary advice should be sought in the care and treatment of these animals. In some cases, where animals are non-ambulatory due to fatigue, injury or sickness, it may be in the best welfare interests of the animal to be treated or euthanased aboard the vehicle.
- b) At the destination, the *animal handler* during transit should ensure that responsibility for the welfare of sick, injured or disabled animals is transferred to a suitable person.
- c) There should be appropriate facilities and equipment for the humane unloading of animals that are non-ambulatory due to fatigue, injury or sickness. These animals should be unloaded in a manner that causes the least amount of suffering. After unloading, separate pens and other appropriate facilities should be available for sick or injured animals.
- d) Feed, if appropriate, and water should be available for each sick or injured animal.

3. Addressing disease risks

The following should be taken into account in addressing the greater risk of disease due to animal transport and the possible need for segregation of transported animals at the destination:

- a) increased contact among animals, including those from different sources and with different disease histories;
- b) increased shedding of pathogens and increased susceptibility to infection related to stress and impaired defences against disease, including immunosuppression;
- c) exposure of animals to pathogens which may contaminate vehicles, resting points, markets, etc.

4. Cleaning and disinfection



- a) Vehicles, crates, containers, etc. used to carry the animals should be cleaned before re-use through the physical removal of manure and bedding by scraping, washing and flushing vehicles and containers with water and detergent. This should be followed by *disinfection* when there are concerns about disease transmission.
- b) ~~Manure, litter and bedding should be disposed of in such a way as to prevent the transmission of disease and in compliance with all relevant health and environmental legislation.~~
- e) ~~When disposal of a dead animal becomes necessary, this should be carried out in such a way as to prevent the transmission of disease and in compliance with all relevant health and environmental legislation.~~
- b) Manure, litter, bedding and the bodies of any animals which die during the journey should be disposed of in such a way as to prevent the transmission of disease and in compliance with all relevant health and environmental legislation.
- c) Establishments like livestock markets, slaughterhouses, resting sites, railway stations, etc. where animals are unloaded should be provided with appropriate areas for the cleaning and *disinfection* of vehicles.
- d) Where *disinfestation* is necessary, it should be carried out with the minimum stress to the animals.

Article 3.7.3.9.

**Actions in the event of a refusal to allow the completion of the journey**

1. The welfare of the animals should be the first consideration in the event of a refusal to allow the completion of the journey.
2. When the animals have been refused import, the *Competent Authority* of that country should make available suitable isolation facilities to allow the unloading of animals from a vehicle and their secure holding, without posing a risk to the health of national herd or flock, pending resolution of the situation. In this situation, the priorities should be:
  - a) the *Competent Authority* of the *importing country* should provide urgently in writing the reasons for the refusal;

- b) in the event of a refusal for animal health reasons, the *Competent Authority* of the *importing country* should provide urgent access to a veterinarian, where possible an OIE veterinarian(s) appointed by the Director General, to assess the animals' health status with regard to the *importing country's* concerns, and the necessary facilities and approvals to expedite the required diagnostic testing;
- c) the *Competent Authority* of the *importing country* should provide access to allow continued assessment of the health and other aspects of the welfare of the animals;
- d) if the matter cannot be promptly resolved, the *Competent Authorities* of the *exporting* and *importing countries* should call on the OIE to mediate.

3. In the event that a *Competent Authority* requires the animals to remain on the vehicle, the priorities should be:

**Community comments:**

**In the next point “reprovisionsing” should be replaced by “reprovisioning”.**

**Justification: Linguistic spelling correction.**

- a) the *Competent Authority* should allow reprovisionsing of the vehicle with water and feed as necessary;
  - b) the *Competent Authority* should provide urgently in writing the reasons for the refusal;
  - c) in the event of a refusal for animal health reasons, the *Competent Authority* should provide urgent access to an independent veterinarian(s) to assess the animals' health status, and the necessary facilities and approvals to expedite the required diagnostic testing;
  - d) the *Competent Authority* should provide access to allow continued assessment of the health and other aspects of the welfare of the animals, and the necessary actions to deal with any animal issues which arise.
4. The OIE should utilise its dispute settlement mechanism to identify a mutually agreed solution which will address animal health and any other welfare issues in a timely manner.

Article 3.7.3.10.

Species specific issues

(To be developed)

**Community comments:**

**The text on species specific issues included in the sea transport guidelines should be replicated here.**

**Justification: This text contains useful descriptions of issues of general interest and information, not specifically related to the transport of animals by sea. As such it could be useful to bring it to the attention of persons reading the other OIE animal welfare guidelines. Only presenting this text in the sea transport guidelines means that persons only reading the other animal welfare guidelines will be unaware of these important descriptions of species-specific issues.**

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— text deleted

APPENDIX 3.7.5.

GUIDELINES FOR THE SLAUGHTER OF  
ANIMALS FOR HUMAN CONSUMPTION

Article 3.7.5.1.

**General principles**

1. Object

These guidelines address the need to ensure the welfare of food animals during pre-slaughter and slaughter processes, until they are dead.

**Community comments:**

**In the next paragraph Camelids should be added to the list of species mentioned in the first sentence: "These guidelines apply to the slaughter in slaughterhouses of the following those domestic animals ~~commonly slaughtered in slaughterhouses, that is:~~ cattle, buffalo, sheep, goats, camelids, deer, horses, pigs, ratites and poultry."**

**Justification: There are numerous references to this species later in the document.**

These guidelines apply to the slaughter in slaughterhouses of the following those domestic animals ~~commonly slaughtered in slaughterhouses, that is:~~ cattle, buffalo, sheep, goats, deer, horses, pigs, ratites and poultry. Other animals, wherever they have been reared, and all animals slaughtered outside slaughterhouses should be managed to ensure that their transport, lairaging, restraint and slaughter is carried out without causing undue stress to the animals; the principles underpinning these guidelines apply also to these animals.

2. Personnel

Persons engaged in the unloading, moving, lairaging, care, restraining, stunning, slaughter and bleeding of animals play an important role in the welfare of those animals. For this reason, there should be a sufficient number of personnel, who should be patient, considerate, competent and familiar with the guidelines outlined in the present Appendix and their application within the national context.

**Community comments:**

**New sentence suggested to be added to the end of the next paragraph: "Such a certificate should be granted if the applicant has demonstrated sufficient knowledge, with due regard to the tasks, methods, equipments and species concerned by the applicant responsibilities as laid down in these guidelines."**

**Justification: The introduction of a certificate of competence is welcomed but it should explicitly refer to the knowledge of these guidelines.**

Competence may be gained through formal training and/or practical experience. This competence should be demonstrated through a current certificate from an independent body accredited by the *Competent Authority*.

The management of the slaughterhouse and the Veterinary Services should ensure that slaughterhouse staff are competent and carry out their tasks in accordance with the principles of animal welfare.

The management of the slaughterhouse and the *Veterinary Services* should ensure that slaughterhouse staff carry out their tasks in accordance with the principles of animal welfare.

3. Animal behaviour

Animal handlers should be experienced and competent in handling and moving farm livestock, and understand the behaviour patterns of animals and the underlying principles necessary to carry out their tasks.

The behaviour of individual animals or groups of animals will vary, depending on their breed, sex, temperament and age and the way in which they have been reared and handled. Despite these differences, the following behaviour patterns which are always present to some degree in domestic animals, should be taken into consideration in handling and moving the animals.

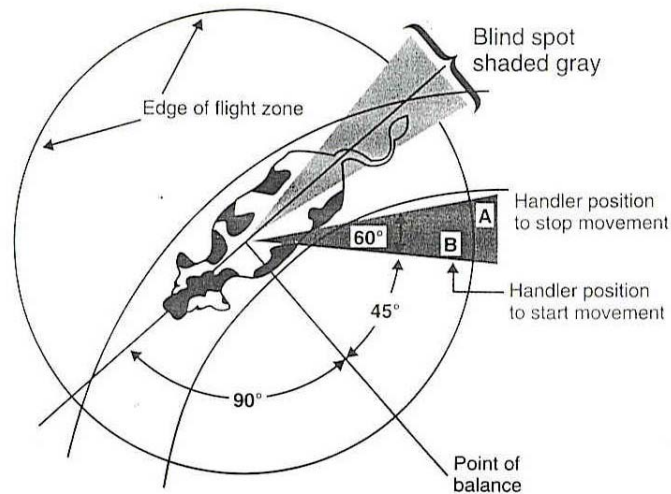
Most domestic livestock are kept in herds and follow a leader by instinct.

Animals which are likely to be hostile to each other in a group situation should not be mixed at slaughterhouses.

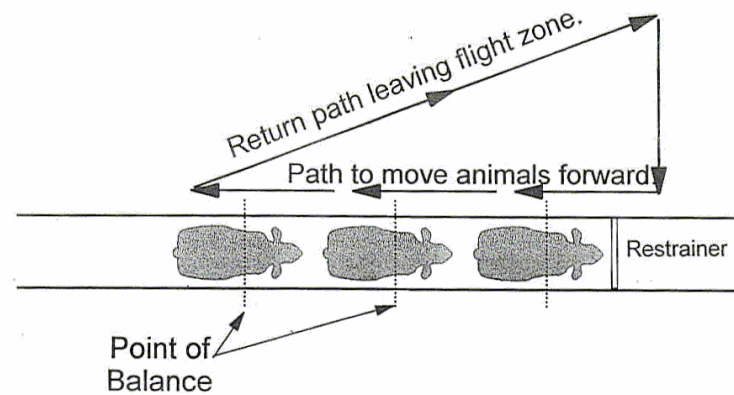
The desire of some animals to control their personal space should be taken into account in designing facilities.

Domestic animals will try to escape if an *animal handler* approaches closer than a certain distance. This critical distance, which defines the flight *zone*, varies among species and individuals of the same species, and depends upon previous contact with humans. Animals reared in close proximity to humans i.e. tame have ~~no~~ a small flight *zone*, whereas those kept in free range or extensive systems may have flight *zones* which may vary from one metre to many metres. Animal handlers should avoid sudden penetration of the flight *zone* which may cause a panic reaction which could lead to aggression or attempted escape.

**An example of a flight zone (cattle)**



### Handler movement pattern to move cattle forward



Animal handlers should use the point of balance at an animal's shoulder to move animals, adopting a position behind the point of balance to move an animal forward and in front of the point of balance to move it backward.

Domestic animals have wide-angle vision but only have limited forward binocular vision and poor perception of depth. This means that they can detect objects and movements beside and behind them, but can only judge distances directly ahead.

Although all domestic animals have a highly sensitive sense of smell, they react in different ways to the smells of slaughterhouses. Smells which cause fear or other negative responses should be taken into consideration when managing animals.

Domestic animals can hear over a greater range of frequencies than humans and are more sensitive to higher frequencies. They tend to be alarmed by constant loud noise and by sudden noises, which may cause them to panic. Sensitivity to such noises should also be taken into account when handling animals.

#### 4. Distractions and their removal

Distractions that may cause approaching animals to stop, baulk or turn back should be designed out from new facilities or removed from existing ones. Below are examples of common distractions and methods for eliminating them:

- a) reflections on shiny metal or wet floors - move a lamp or change lighting;
- b) dark entrances to chutes, races, stun boxes or conveyor restrainers - illuminate with indirect lighting which does not shine directly into the eyes of approaching animals;
- c) animals seeing moving people or equipment up ahead - install solid sides on chutes and races or install shields;
- d) chains or other loose objects hanging in chutes or on fences - remove them;
- e) uneven floors or a sudden drop in floor levels at the entrance to conveyor restrainers – avoid uneven floor surfaces or install a solid false floor under the restrainer to provide an illusion of a solid and continuous walking surface;
- f) sounds of air hissing from pneumatic equipment - install silencers or use hydraulic equipment or vent high pressure to the external environment using flexible hosing;
- g) clanging and banging of metal objects - install rubber stops on gates and other devices to reduce metal to metal contact;
- h) air currents from fans or air curtains blowing into the face of animals - redirect or reposition equipment.

Article 3.7.5.2.

#### **Moving and handling animals**

##### 1. General considerations



Animals should be transported to slaughter in a way that minimises adverse animal health and welfare outcomes, and the transport should be conducted in accordance with the OIE guidelines for the transportation of animals (Chapters 3.7.2 and 3.7.3).

The following principles should apply to unloading animals, moving them into lairage pens, out of the lairage pens and up to the slaughter point:

- a) The conditions of the animals should be assessed upon their arrival for any animal welfare and health problems.
- b) Injured or sick animals, requiring immediate slaughter, should be killed humanely, preferably at the site where they are found in accordance with the OIE guidelines for the killing of animals for disease control purposes (Chapter 3.7.6).
- c) The use of force on animals that have little or no room to move should not occur.

**Community comments:**

**Add to the beginning of the next sentence in d) "Electric goads and prods should only be used in extreme cases and not on a routine basis to move animals. They should not be used repeatedly on the same animal which may be unable to move due to other factors".**

**Justification**

**These OIE guidelines should take into account existing good practices applied in the industry.**

- d) The use of instruments which administer electric shocks (e.g. goads and prods) and their power output should be restricted to that necessary to assist movement of an the animals and only when an animal has a clear path ahead to move. If such use is necessary, it should be limited to the hindquarters of pigs and large ruminants, and never on sensitive areas such as the eyes, mouth, ears, anogenital region or belly. Such instruments should not be used on horses, sheep and goats of any age, or on calves or piglets, nor on animals that have little or no room to move.
- e) Performance standards should be established in which numerical scoring is used to evaluate the use of such instruments, and to measure the percentage of animals moved with an electric instrument and the percentage of animals slipping or falling at a point in the slaughterhouse; the slaughterhouse should be investigated for faults in flooring, raceway design, lighting or handling, and these should be rectified to enable free movement of the animals without the need to use such instruments.

Performance standards should be established in which numerical scoring is used to evaluate the use of such instruments and to measure the percentage of animals moved with an electric instrument. In properly designed and constructed facilities with competent *animal handlers*, it should be possible to move 75% or more of the animals without the use of electric instruments.

**Community comments:**

**Add "but without physical contact with them" at the end of the following paragraph.**

**Justification: This was included in the original wording and we do not agree with its deletion.**

- f) ~~Useful and permitted aids for moving animals include panels, flags, plastic paddles, flappers (a length of cane with a short strap of leather or canvas attached), plastic bags and metallic rattles; they should be used in a manner sufficient to encourage and direct movement of the animals but without physical contact with them.~~ Aids for moving animals such as panels, flags, plastic paddles, flappers (a length of cane with a short strap of leather or canvas attached), plastic bags and metallic rattles should be used in a manner sufficient to encourage and direct movement of the animals.
- g) Shouting or yelling at animals or making loud noises e.g. through the cracking of whips to encourage them to move should not occur as such actions may make the animals agitated, leading to crowding or falling.
- h) Implements which cause pain and suffering such as large sticks, sticks with sharp ends, metal piping, fencing wire or heavy leather belts should not be used to move animals.
- i) Animals should be grasped or lifted in a manner which avoids pain or suffering and physical damage (e.g. bruising, fractures, dislocations). In the case of quadrupeds, manual lifting by a person should only be used in young animals or small species, and in a manner appropriate to the species; grasping or lifting such animals only by their wool, hair, feet, neck, ears or tails causing pain or suffering should not be permitted, except in an emergency where animal welfare or human safety may otherwise be compromised.
- j) Conscious animals should not be thrown or dragged.
- k) Animals should not be forced to move at a speed greater than their normal walking pace, in order to minimise injury through falling or slipping. Performance standards should be established where numerical scoring of the prevalence of animals slipping or falling is used to evaluate whether animal moving practices and/or facilities should be improved. In properly designed and constructed facilities with competent *animal handlers*, it should be possible to move 99% of animals without their falling.

- l) ~~Animal handlers should not force an animal to walk over the top of other animals.~~ Animals for slaughter should not be forced to walk over the top of other animals.
- m) Under no circumstances should *animal handlers* resort to violent acts to move animals, such as crushing or breaking animals' tails, grasping animals' eyes or pulling them by their ears. Animal handlers should never apply an injurious object or irritant substance to animals and especially not to sensitive areas such as eyes, mouth, ears, anogenital region or belly. The throwing or dropping of animals, or their lifting or dragging by body parts such as their tail, head, horns, ears, limbs, wool, hair or feathers, should not be permitted. The manual lifting of small animals is permissible.

2. Provisions relevant to animals delivered in containers

**Community comments:**

**Add at the end of the paragraph (a):**

**"In any case they should be moved and stored in an upright position as indicated by specific marks."**

**Justification: When transporting animals in containers it is very important for their welfare that they are kept upright and not mis-handled. This is in line with basic good practices already widely applied in the transport sector.**

- a) Containers in which animals are transported should be handled with care, and should not be thrown, dropped or knocked over. Where possible, they should be loaded and unloaded horizontally and mechanically.
- 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

**Community comments:**

**The Community proposes the following modification below:**

**"a) Appropriate restraint shall be applied to the animals before they are stunned or immediately killed. In particular individual restraint is necessary in the case where a captive-bolt is used or when electrodes are placed on the animals. In addition restraint shall be applied to animals that are slaughtered without stunning.**

**b) The method of restraint should be adapted to the size and species of animals concerned as well as to the stunning/killing method to be used.**

**c) The method of restraint should be designed and operated in order to optimise the application of the stunning/killing method."**

**Justification: To ensure that animals are effectively stunned and to ensure their welfare the importance of appropriate restraint cannot be underestimated. See EFSA report:**

**[http://www.efsa.eu.int/science/ahaw/ahaw\\_opinions/495/opinion\\_ahaw\\_02\\_ej45\\_stunning\\_report\\_v2\\_en1.pdf](http://www.efsa.eu.int/science/ahaw/ahaw_opinions/495/opinion_ahaw_02_ej45_stunning_report_v2_en1.pdf)**

a) Provisions relevant to restraining animals for stunning or slaughter without stunning, to help maintain animal welfare, include:

i) provision of a non-slip floor;

ii) avoidance of excessive pressure applied by restraining equipment that causes struggling or vocalisation in animals;

iii) equipment engineered to reduce noise of air hissing and clanging metal;

iv) absence of sharp edges in restraining equipment that would harm animals;

v) avoidance of jerking or sudden movement of restraining device.

b) Methods of restraint causing avoidable suffering, such as the following, should not be used in conscious animals because they cause severe pain and stress:

- i) suspending or hoisting animals (other than poultry) by the feet or legs;
- ii) indiscriminate and inappropriate use of stunning equipment;
- iii) mechanical clamping of an animal's legs or feet (other than shackles used in poultry and ostriches) as the sole method of restraint;
- iv) breaking legs, cutting leg tendons or blinding animals in order to immobilise them;
- v) severing the spinal cord, for example using a puntilla or dagger, to immobilise animals using electric currents to immobilise animals, except for proper stunning.

Article 3.7.5.3.

### **Lairage design and construction**

#### 1. General considerations

The lairage should be designed and constructed to hold an appropriate number of animals in relation to the throughput rate of the slaughterhouse without compromising the welfare of the animals.

In order to permit operations to be conducted as smoothly and efficiently as possible without injury or undue stress to the animals, the lairage areas should be designed and constructed so as to allow the animals to move freely in the required direction, using their behavioural characteristics and without undue penetration of their flight *zone*.

The following guidelines may help to achieve this.

#### 2. Design of lairages

- a) The lairage should be designed to allow a one-way flow of animals from unloading to the point of slaughter, with a minimum number of abrupt corners to negotiate.
- b) In red meat slaughterhouses, pens, passageways and races should be arranged in such a way as to permit inspection of animals at any time, and to permit the removal of sick or injured animals when considered to be appropriate, for which separate appropriate accommodation should be provided.
- c) Each animal should have room to stand up and lie down and, when confined in a pen, to turn around. The lairage should have sufficient accommodation for the number of animals intended to be held. Drinking water should always be available to the animals, and the method of delivery should be appropriate to the type of animal held. Troughs should be designed and installed in such a way as to minimise the risk of fouling by faeces, without introducing risk of bruising and injury in animals, and should not hinder the movement of animals.
- d) Holding pens should be designed rectangular rather than square, to allow as many animals as possible to stand or lie down against a wall. Where feed troughs are provided, they should be sufficient in number and feeding space to allow adequate access of all animals to feed. The feed trough should not hinder the movement of animals.
- e) Where tethers, ties or individual stalls are used, these should be designed so as not to cause injury or distress ~~especially when the animals are lying down, standing up, drinking and feeding~~ to the animals and should also allow the animals to stand, lie down and access any food or water that may need to be provided.
- f) Passageways and races should be either straight or ~~slightly~~ consistently curved, as appropriate to the animal species. Passageways and races should have solid sides, but when there is a double race, the shared partition should allow adjacent animals to see each other. For pigs and sheep, passageways should be wide enough to enable two or more animals to walk side by side for as long as possible. At the point where passageways are reduced in width, this should be done by a means which prevents excessive bunching of the animals.
- g) Animal handlers should be positioned alongside races and passageways on the inside radius of any curve, to take advantage of the natural tendency of animals to circle an intruder. Where one-way gates are used, they should be of a design which avoids bruising. Races should be horizontal but where there is a slope, they should be constructed to allow the free movement of animals without injury.
- h) There should be a waiting pen, with a level floor and solid sides, between the holding pens and the race leading to the point of stunning or slaughter, to ensure a steady supply of animals for stunning or slaughter and to avoid having *animal 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 ~~ramp~~ should be well drained, ~~non-~~slippery with secure footholds and adjustable to facilitate easy movement of animals without causing distress or injury.

### 3. Construction of lairages

- a) Lairages should be constructed and maintained so as to provide protection from unfavourable climatic conditions, using strong and resistant materials such as concrete and metal which has been treated to prevent corrosion. Surfaces should be easy to clean. There should be no sharp edges or protuberances which may injure the animals.
- b) Floors should be well drained and not slippery; they should not cause injury to the animals' feet. Where necessary, floors should be insulated or provided with appropriate bedding. Drainage grids should be placed at the sides of pens and passageways and not where animals would have to cross them. Discontinuities or changes in floor patterns or texture which could cause baulking in the movement of animals should be avoided.
- c) Lairages should be provided with adequate lighting, but care should be taken to avoid harsh lights and shadows, which frighten the animals or affect their movement. The fact that animals will move more readily from a darker area into a well-lit area might be exploited by providing for lighting that can be regulated accordingly.
- d) Lairages should be ~~well ventilated, and the air flow should be arranged so that odours and draughts do not adversely affect the health and welfare of the animals~~ 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.
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.

**Community comments:**

**The word “separated” should be added to the last sentence of the following paragraph:**

**"9. The condition and state of health of the animals in a lairage should be inspected at least every morning and evening by a veterinarian or, under the latter’s responsibility, by another competent person. Animals which are sick, weak, injured or showing visible signs of distress should be separated, treated or humanely killed immediately."**

**Justification: Sick, weak or injured animals need to be isolated as they are not able to protect themselves from the other animals.**

9. The condition and state of health of the animals in a lairage should be inspected at least every morning and evening by a veterinarian or, under the latter’s responsibility, by another competent person. Animals which are sick, weak, injured or showing visible signs of distress should be treated or humanely killed immediately.
10. Lactating dairy animals should be slaughtered as soon as possible. Dairy animals with obvious udder distension should be milked to minimise udder discomfort.

**Community comments:**

**Paragraph 11 should be replaced by the following text:**

**"11. ~~Pregnant~~ Animals ~~giving~~ which have given birth during the journey or in the lairage should be slaughtered as soon as possible or provided with conditions which are appropriate for suckling for its welfare and the welfare of the newborn. Under normal circumstances, animals which are expected to give birth during a journey should not be transported."**

**Justification: If an animal has given birth it is no longer pregnant. It is basic good practice that pregnant animals expected to give birth during the journey should not normally be transported. For a scientific elaboration on this point see SCAHAW report:**

11. Pregnant animals giving birth during the journey or in the lairage should be slaughtered as soon as possible or provided with conditions which are appropriate for suckling for its welfare and the welfare of the newborn. Under normal circumstances, animals which are expected to give birth during a journey should not be transported.

12. Animals with horns or tusks capable of injuring other animals, if aggressive, should be penned separately.

Recommendations for specific species are described in detail in Articles 3.7.5.5. to 3.7.5.8.

Article 3.7.5.5.  
(under study)

**Community comments:**

**1) The introductory sentence should be replaced by the following text:**

**"Pregnant animals that are likely to give birth should not be transported or slaughtered under normal circumstances. In any case, the welfare of foetuses during slaughter needs to be safeguarded."**

**2) There is no consistency between the time limit set out in paragraphs 1 and 3 (5 or 15-20 minutes).**

**This article needs to be kept under study and latest scientific information from Prof. David Mellor et al. carefully analysed. See for example:**

**D.J Mellor and N.G. Gregory (2003)**

**Responsiveness, behavioural arousal and awareness in fetal and newborn lambs: experimental, practical and therapeutic implications. New Zealand Veterinary Journal 51 (1) 2-13**

**David J Mellor, Tamara J Diesch, Alistair J Gunn, Laura Bennet (2005)**

**The importance of 'awareness' for understanding foetal pain. Brain Research Reviews 47 (3) 455-471**

**Justification: Latest scientific evidence needs to be analysed, and pending that this article 3.7.5.5 should be retained “under study”. It should be emphasised that under normal circumstances animals in an advanced state of pregnancy should neither be transported nor slaughtered in slaughterhouses.**

#### **Management of foetuses during slaughter of pregnant animals**

The welfare of foetuses during slaughter of pregnant animals needs to be safeguarded.

1. Foetuses should not be removed from the uterus sooner than five minutes after the maternal neck or chest cut, to ensure absence of consciousness. A foetal heartbeat will usually still be present and foetal movements may occur at this stage, but these are only a cause for concern if the exposed foetus successfully breathes air.
2. If a live mature foetus is removed from the uterus, it should be prevented from inflating its lungs and breathing air (e.g. by clamping the trachea).
3. When uterine, placental or foetal tissues, including foetal blood, are not to be collected as part of the post-slaughter processing of pregnant animals, all foetuses should be left inside the unopened uterus until they are dead. When uterine, placental or foetal tissues are to be collected, where practical, foetuses should not be removed from the uterus until at least 15-20 minutes after the maternal neck or chest cut.
4. If there is any doubt about consciousness, the foetus should be killed with a captive bolt or a blow to the head with a suitable blunt instrument.

The above guidelines do not refer to foetal rescue. Foetal rescue, the practice of attempting to revive foetuses found alive at evisceration of the dam, should not be attempted during normal commercial slaughter as it may lead to serious welfare complications in the newborn animal. These include impaired brain function resulting from oxygen shortage before rescue is completed, compromised breathing and body heat production because of foetal immaturity, and an increased incidence of infections due to a lack of colostrum.

Summary of acceptable handling and restraining methods and the associated animal welfare issues

**Community comments:**

**1. The use of rotating box (i.e. restraining by inversion for cattle) should not be recommended. Therefore the two rows referring to restraining by inversion should be deleted in the table.**

**Justification:** The rotating box represents serious animal welfare concerns while alternative methods are available which provide better welfare conditions without additional costs. See p. 25 EFSA – AHAW/04-027 "Welfare aspects of stunning and killing methods" Scientific report of the Scientific Panel for Animal Health and Welfare on a request from the Commission related to welfare aspects of animal stunning and killing methods - [http://www.efsa.eu.int/science/ahaw/ahaw\\_opinions/495\\_en.html](http://www.efsa.eu.int/science/ahaw/ahaw_opinions/495_en.html)

**2. The word “acceptable” should be deleted from the table’s heading**

**Justification:** Acceptable implies a value judgement or subjective analysis. In any given situation a variety of handling and restraining methods may be available and the best animal welfare outcome needs to be considered on a case-by-case basis. Therefore a given method may be “acceptable” under certain circumstances and “unacceptable” under a different set of conditions.

	Presentation of animals	Specific procedure	Specific purpose	AW concerns/implications	Key AW requirements	Applicable species
No restraint	Animals are grouped	Group container	Gas stunning	Specific procedure is suitable only for gas stunning	Competent <i>animal handlers</i> in lairage;	Pigs, poultry

					facilities; stocking density	
		In the field	Free bullet	<del>Shooting distance, calibre and</del> Inaccurate targeting and inappropriate ballistics <u>not achieving outright kill with first shot</u>	Operator competence	Deer
		Group stunning pen	Head-only electrical Captive bolt	Uncontrolled movement of animals impedes use of hand operated electrical and mechanical stunning methods	Competent <i>animal handlers</i> 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 <i>animal handlers</i>	Cattle, buffalo, sheep, goats, horses, pigs, deer, camelids, ratites
Restraining methods	Head restraint, upright	Halter/ head collar/bridle	Captive bolt Free bullet	Suitable for halter-trained animals; stress in untrained animals	Competent <i>animal handlers</i>	Cattle, buffalo, horses, camelids
	Head restraint, upright	Neck yoke	Captive bolt Electrical-head-only Free bullet Slaughter	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 <i>animal handlers</i> , prompt stunning or slaughter	Cattle

			without stunning			
	Leg restraint	Single leg tied in flexion (animal standing on 3 legs)	Captive bolt Free bullet	Ineffective control of animal movement, misdirected shots	Competent <i>animal handler</i>	Breeding pigs (boars and sows)

Summary of acceptable handling and restraining methods and the associated animal welfare issues (contd)

	Presentation of animals	Specific procedure	Specific purpose	AW concerns/implications	Key AW requirements	Applicable species
Restraining methods	Upright restraint	Beak holding	Captive bolt Electrical-head-only	Stress of capture	Sufficient competent <i>animal handlers</i>	Ostriches
		Head restraint in electrical stunning box	Electrical-head-only	Stress of capture and positioning	Competent <i>animal handler</i>	Ostriches
	Holding body upright-manual	Manual restraint	Captive bolt Electrical-head-only Slaughter without stunning	Stress of capture and restraint; accuracy of stunning/slaughter	Competent <i>animal handlers</i>	Sheep, goats, calves, ratites, small camelids, poultry



	Holding body upright mechanical	Mechanical clamp / crush / squeeze/ V-restrainer (static)	Captive bolt Electrical methods Slaughter without stunning	Loading of animal and overriding; excessive pressure	Proper design and operation of equipment	Cattle, buffalo, sheep, goats, deer, pigs, ostriches
	Lateral restraint – manual or mechanical	Restrainer/cradle/crush	Slaughter without stunning	Stress of restraint	Competent <i>animal handlers</i>	Sheep, goats, calves, camelids, cattle
	Upright restraint mechanical	Mechanical straddle (static)	Slaughter without stunning Electrical methods Captive bolt	Loading of animal and overriding	Competent <i>animal handlers</i>	Cattle, sheep, goats, pigs
	Upright restraint – manual or mechanical	Wing shackling	Electrical	Excessive tension applied prior to stunning	Competent <i>animal handlers</i>	Ostriches

Summary of acceptable handling and restraining methods and the associated animal welfare issues (contd)

	Presentation of animals	Specific procedure	Specific purpose	AW concerns/implications	Key AW requirements	Applicable species
Restraining and /or conveying methods	Mechanical - upright	V-restrainer	Electrical methods  Captive bolt  Slaughter without stunning	Loading of animal and overriding; excessive pressure, size mismatch between restrainer and animal	Proper design and operation of equipment	Cattle, calves, sheep, goats, pigs
	Mechanical- upright	Mechanical straddle – band restrainer (moving)	Electrical methods  Captive bolt  Slaughter without stunning	Loading of animal and overriding, size mismatch between restrainer and animal	Competent <i>animal handlers</i> , proper design and layout of restraint	Cattle, calves, sheep, goats, pigs
	Mechanical - upright	Flat bed/deck Tipped out of containers on to conveyors	Presentation of birds for shackling prior to electrical stunning	Stress and injury due to tipping in dump-module systems  height of tipping conscious	Proper design and operation of equipment	Poultry

			Gas stunning	poultry broken bones and dislocations		
	Suspension and/or inversion	Poultry shackle	Electrical stunning Slaughter without stunning	Inversion stress; pain from compression on leg bones	Competent <i>animal handlers</i> ; proper design and operation of equipment	Poultry
	Suspension and/or inversion	Cone	Electrical head-only – Captive bolt Slaughter without stunning	Inversion stress	Competent <i>animal handlers</i> ; proper design and operation of equipment	Poultry
	Upright restraint	Mechanical leg clamping	Electrical head-only –	Stress of resisting restraint in ostriches	Competent <i>animal handlers</i> ; proper equipment design and operation	Ostriches

Summary of acceptable handling and restraining methods and the associated animal welfare issues (contd)

	Presentation of animals	Specific procedure	Specific purpose	AW concerns/implications	Key AW requirements	Applicable species
Restraining by inversion	Rotating box	Fixed side(s) (e.g. Weinberg pen)	Slaughter without stunning	Inversion stress; stress of resisting restraint, prolonged restraint, <u>inhalation of blood and ingesta</u> . Keep restraint as brief as possible	Proper design and operation of equipment	Cattle
		Compressible side(s)	Slaughter without stunning	Inversion stress, stress of resisting restraint, prolonged restraint  Preferable to rotating box with fixed sides  Keep restraint as brief as possible	Proper design and operation of equipment	Cattle
Body restraint	Casting/hobbling	Manual	Mechanical stunning methods  Slaughter	Stress of resisting restraint; animal temperament; bruising.  Keep restraint as short as possible	Competent <i>animal handlers</i>	Sheep, goats, calves, small camelids, pigs

			without stunning			
Leg restraints		Rope casting	Mechanical stunning methods Slaughter without stunning	Stress of resisting restraint; prolonged restraint, animal temperament; bruising Keep restraint as short as possible	Competent <i>animal</i> handlers	Cattle, camelids
		Tying of 3 or 4 legs	Mechanical stunning methods Slaughter without stunning	Stress of resisting restraint; prolonged restraint, animal temperament; bruising Keep restraint as short as possible	Competent <i>animal</i> handlers	Sheep, goats, small camelids, pigs

## 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;
- g) backup stunning devices are available for immediate use if the primary method of stunning fails.

In addition, such persons should be able to recognise when an animal is not correctly stunned and should take appropriate action.

### 2. Mechanical stunning

A mechanical device should be applied usually to the front of the head and perpendicular to the bone surface. The following diagrams illustrate the proper application of the device for certain species.

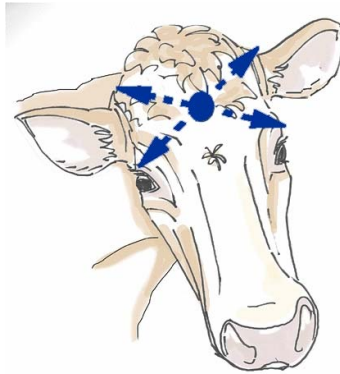
**Community comments:**

**A frontal view and lateral view of the correct stunning position should be displayed for all species mentioned here.**

**Justification: This would provide more comprehensive and clear information to operators on the recommended locations for appropriate stunning.**

Pictures are in particular available from organisations such as the Humane Slaughter Association or in the EFSA Scientific report of the Scientific Panel for Animal Health and Welfare on welfare aspects of animal stunning and killing methods - [http://www.efsa.eu.int/science/ahaw/ahaw\\_opinions/495\\_en.html](http://www.efsa.eu.int/science/ahaw/ahaw_opinions/495_en.html)

Cattle



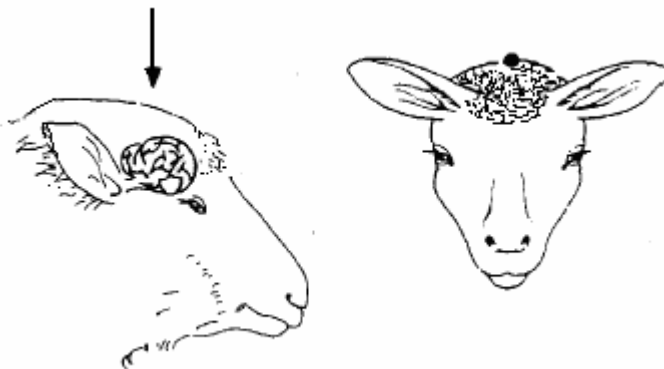
The optimum position for cattle is at the intersection of two imaginary lines drawn from the rear of the eyes to the opposite horn buds.

## Pigs



The optimum position for pigs is on the midline just above ~~the~~ eyes level, with ~~and directing~~ the shot directed down the line of the spinal cord.

## Sheep



The optimum position for hornless sheep and goats is on the midline ~~just above the eye level,~~ and ~~directing the shot down the line of the spinal cord.~~

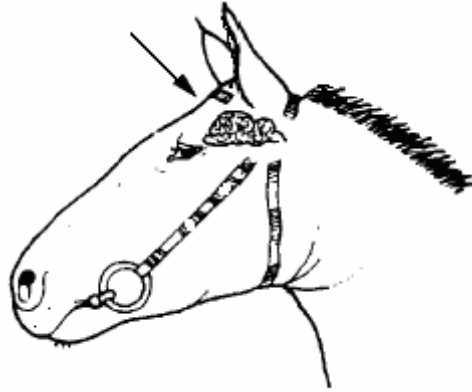


## Goats



The optimum position for heavily horned sheep and horned goats is behind the poll, aiming towards the angle of the jaw.

## Horses



~~Place the muzzle~~ The optimum position for horses is at right angles to the frontal surface, well above the point where imaginary lines from eyes to ears cross.

Signs of correct stunning using a mechanical instrument are as follows:

- a) the animal collapses immediately and does not attempt to stand up;
- b) the body and muscles of the animal become tonic (rigid) immediately after the shot;
- c) normal rhythmic breathing stops; and
- d) the eyelid is open with the eyeball facing straight ahead and is not rotated.

### 3. Electrical stunning

- a) General considerations

An electrical device should be applied to the animal in accordance with the following guidelines.

#### **Community comments:**

**1. In the third sentence of the following paragraph, "effectively stunned" should replace "stunned".**

**Justification: It is important to underline, when two-cycle stun/kill methods apply with e.g. cardiac fibrillation, that the second phase of the electrical application should only take place after having ascertained that the animals is already effectively stunned.**

**2. The sentence “they should be placed so that they span the brain” should be further expanded, clarified and accompanied by an illustration to show proper placement.**

**Justification: It is important that the guidelines demonstrate clearly the proper placement of electrodes**

**3. A further sentence should be added stating “The electrical parameters should be set so as to ensure effective stunning, given that immediate human intervention to correct any deficiencies may be curtailed by the design and operation of the equipment”.**

**Justification: It is important that the guidelines take account of the practical use and design of such stunning systems and the opportunities or restrictions for operator intervention (due to health and safety considerations or logistical-layout restrictions etc.).**

Electrodes should be designed, constructed, maintained and cleaned regularly to ensure that the flow of current is optimal and in accordance with ~~to~~ manufacturing specifications. They should be placed so that they span the brain. The application of electrical currents which bypass the brain is unacceptable unless the animal has been stunned. The use of a single current leg-to-leg is unacceptable as a stunning method.

If, in addition, it is intended to cause cardiac arrest, the electrodes should either span the brain and immediately thereafter the heart, on the condition that it has been ascertained that the animal is adequately stunned, or span brain and heart simultaneously.

Electrical stunning equipment should not be applied on animals as a means of guidance, movement, restraint or immobilisation, and shall not deliver any shock to the animal before the actual stunning or killing.

Electrical stunning apparatus should be tested prior to application on animals using appropriate resistors or dummy loads to ensure the power output is adequate to stun animals.

The apparatus should incorporate a device which monitors and displays stunning current delivered to the animals.

**Community comments:**

**Add a sentence above "In all cases electrodes should be applied rapidly and firmly and appropriate pressure maintained to facilitate proper contact and effective stunning".**

**Justification: Correct operator technique in applying the electrodes is very important to achieve effective stunning.**

Appropriate measures, such as removing excess wool or wetting the skin only at the point of contact, can be taken to minimise impedance of the skin and facilitate effective stunning.

**Community comments:**

**In the next paragraph "indicate" should be replaced by "indicated".**

**Justification: Grammatical correction.**

The stunning apparatus required for electrical stunning should be provided with adequate power to achieve continuously the minimum current level recommended for stunning as indicate in the table below:

**Community comments:**

1) The table below should specify that the minimum current levels apply for head-only stunning. Therefore the table heading "Minimum current levels" should be replaced by "Minimum current levels for head-only stunning".

2) For the purpose of this table "calves" and "lambs" should be defined more specifically as the application of insufficient current may affect the welfare of the animals.

The table should be amended as follows:

"calves" should be replaced by "bovine of less than six months of age"

**Justification:** See EFSA report for more detailed scientific basis

[http://www.efsa.eu.int/science/ahaw/ahaw\\_opinions/495/opinion\\_ahaw\\_02\\_ej45\\_stunning\\_report\\_v2\\_en1.pdf](http://www.efsa.eu.int/science/ahaw/ahaw_opinions/495/opinion_ahaw_02_ej45_stunning_report_v2_en1.pdf)

Species	Minimum current levels
Cattle	1.5 amps
Calves	1.0 amps
Pigs	1.25 amps
Sheep and goats	1.0 amps
<u>Lambs</u>	<u>0.7 amps</u>
Ostriches	0.4 amps

**Community comments:**

The following paragraph should be replaced by the following text:

"In all cases, the correct current level shall be attained within one second of the initiation of stun and maintained at least for ~~between one and three seconds~~ and in accordance with the manufacturer's instructions."

**Justification:** See EFSA report for more detailed scientific basis

[http://www.efsa.eu.int/science/ahaw/ahaw\\_opinions/495/opinion\\_ahaw\\_02\\_ej45\\_stunning\\_report\\_v2\\_en1.pdf](http://www.efsa.eu.int/science/ahaw/ahaw_opinions/495/opinion_ahaw_02_ej45_stunning_report_v2_en1.pdf)

In all cases, the correct current level shall be attained within one second of the initiation of stun and maintained at least for between one and three seconds and in accordance with the manufacturer's instructions.

b) Electrical stunning of birds using a waterbath

**Community comments:**

**The following text should be added here: "There should be no sharp bends or steep gradients in the shackle line and the shackle line should be as short as possible consistent with achieving acceptable line speeds, and ensuring that birds have settled by the time they reach the water bath. A breast comforter can be used effectively to reduce wing flapping and calm birds. The angle at which the shackle line approaches the entrance to the water bath, and the design of the entrance to the water bath, and the draining of excess 'live' water from the bath are all important considerations in ensuring birds are calm as they enter the bath, do not flap their wings, and do not receive pre-stun electric shocks."**

**Justification: See EFSA report for more detailed scientific basis**

**[http://www.efsa.eu.int/science/ahaw/ahaw\\_opinions/495/opinion\\_ahaw\\_02\\_ej45\\_stunning\\_report\\_v2\\_en1.pdf](http://www.efsa.eu.int/science/ahaw/ahaw_opinions/495/opinion_ahaw_02_ej45_stunning_report_v2_en1.pdf)**

In the case of birds suspended on a moving line, measures should be taken to ensure that the birds are not wing flapping at the entrance of the stunner. The birds should be secure in their shackle, but there should not be undue pressure on their shanks.

Waterbaths for poultry should be adequate in size and depth for the type of bird being slaughtered, and their height should be adjustable to allow for the head of each bird to be immersed. The electrode immersed in the bath should extend the full length of the waterbath. Birds should be immersed in the bath up to the base of their wings.

The waterbath should be designed and maintained in such a way that when the shackles pass over the water, they are in continuous contact with the earthed rubbing bar.

The control box for the waterbath stunner should incorporate an ammeter which displays the total current flowing through the birds.

The shackle-to-leg contact should be wetted preferably before the birds are inserted in the shackles. In order to improve electrical conductivity of the water it is recommended that salt be added in the waterbath as necessary. Additional salt should be added regularly as a solution to maintain suitable constant concentrations in the waterbath.

Using waterbaths, birds are stunned in groups and different birds will have different impedances. The voltage should be adjusted so that the total current is the required current per bird as shown in the table hereafter, multiplied by the number of birds in the waterbath at the same time. The following values have been found to be satisfactory when employing a 50 Hertz sinusoidal alternating current.

Birds should receive the current for at least 4 seconds.

Species	Current (milliamperes per bird)
Broilers	120
Layers (spent hens)	120
Turkeys	150

Ducks and Geese	130
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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.

**Community comments:**

**As mentioned in the previous paragraph, waterbath stunners may also use higher frequencies than 50 Hz. Therefore recommendations for those cases should also be provided. The EFSA opinion on the subject (Opinion of the Scientific Panel on Animal Health and Welfare on welfare aspects of the main systems of stunning and killing the main commercial species of animals, *The EFSA Journal* (2004), 45, 1-29) recommends particular figures (see p. 19). Based on this information, the following table should be added here:**

Frequency (Hz)	Chickens	Turkeys
< 200 Hz	100 mA	250 mA
From 200 to 400 Hz	150 mA	400 mA
From 400 to 1500 Hz	200 mA	400 mA

**Justification: See EFSA report for more detailed scientific basis**

**[http://www.efsa.eu.int/science/ahaw/ahaw\\_opinions/495/opinion\\_ahaw\\_02\\_ej45\\_stunning\\_report\\_v2\\_en1.pdf](http://www.efsa.eu.int/science/ahaw/ahaw_opinions/495/opinion_ahaw_02_ej45_stunning_report_v2_en1.pdf)**

Every effort shall be made to ensure that no conscious or live birds enter the scalding tank.

In the case of automatic systems, until fail-safe systems of stunning and bleeding have been introduced, a manual back-up system should be in place to ensure that any birds which have missed the waterbath stunner and/or the automatic neck-cutter are immediately stunned and/or killed immediately, and they are dead before entering scald tank.

To lessen the number of unstunned birds, reaching neck cutters, steps should be taken to ensure that small birds do not go on the line amongst bigger birds and that these small birds are stunned separately.

4. Gas stunning (under study)

**Community comments:**

**This section should be retained “under study” until further information is to hand.**

**Justification: New scientific data are continuing to emerge on this issue (e.g. from researchers based in Roslin-Silsoe institutes in UK, Swedish data etc.). Some of these papers are still “in press” and full publication details will be provided to the OIE once available. Examples of such studies already available and which could be usefully reviewed include:**

**“A Study of 2 Pig Abattoirs with Regard to CO<sup>2</sup> Concentration, CO<sup>2</sup> Exposure Time, Stun Group Size, Stun to Stick Interval, and Stun Effect, Sophie Atkinson, Swedish University of Agricultural Sciences Skara 2003”**

**"An investigative study of 2 pig abattoirs in Sweden with regard to CO<sub>2</sub> concentration, CO<sub>2</sub> exposure time, stun group size, stun to stick interval and stun effect." Bo Algers and Sophie Atkinson, Swedish University of Agricultural Sciences. Presented at ISAH (International Society for Animal Hygiene) congress October 2004.**

**Therefore it would be premature to finalise these provisions on CO<sub>2</sub> concentrations etc. pending the careful analysis of such new scientific data.**

- 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 occur 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.

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.

**Community comments:**

**The following text should be added here:**

**"Emergency stunning equipment should be available at the point of exit from the stunning chamber and used on any pigs that do not appear to be dead or completely stunned."**

**Justification:**

**The availability of emergency stunning equipment is a basic pre-requisite, in line with procedures of good practice etc. See EFSA report for more detailed scientific basis**

**[http://www.efsa.eu.int/science/ahaw/ahaw\\_opinions/495/opinion\\_ahaw\\_02\\_ej45\\_stunning\\_report\\_v2\\_en1.pdf](http://www.efsa.eu.int/science/ahaw/ahaw_opinions/495/opinion_ahaw_02_ej45_stunning_report_v2_en1.pdf)**

The chamber shall be equipped to continuously measure and display register at the point of stunning the CO<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.

b) Inert gas mixtures for stunning pigs

Inhalation of high concentrations of carbon dioxide is aversive and can be distressing to animals. Therefore, the use of non-aversive gas mixtures is being developed.

Such gas mixtures include:

- i) a maximum of 2% by volume of oxygen in argon, nitrogen or other inert gases, or

**Community comment:**

**Delete "to" at the beginning of the next sentence.**

**Justification: Grammatical correction, not included in (a) and is thus inconsistent in style.**

- ii) to a maximum of 30% by volume of carbon dioxide and a maximum of 2% by volume of oxygen in mixtures with carbon dioxide and argon, nitrogen or other inert gases.

Exposure time to the gas mixtures should be sufficient to ensure that no pigs regain consciousness before death supervenes through bleeding or cardiac arrest is induced.

c) Gas stunning of poultry

The main objective of gas stunning is to avoid the pain and suffering associated with shackling conscious poultry under water bath stunning and killing systems. Therefore, gas stunning should be limited to birds contained in crates or on conveyors only. The gas mixture should be non-aversive to poultry.

Gas stunning of poultry in their transport containers will eliminate the need for live bird handling at the processing plant and all the problems associated with the electrical stunning. Gas stunning of poultry on a conveyor eliminates the problems associated with the electrical water bath stunning.

Live poultry should be conveyed into the gas mixtures either in transport crates or on conveyor belts.

**Community comments:**

**The following text should be added here:**

**"The following gas procedures have been properly documented for chickens and turkeys but do not necessarily apply for other domestic birds. In any case the procedure should be designed as to ensure that all animals are properly**



**stunned without unnecessary suffering and gas concentration should be established so as to avoid convulsions (wing flapping)."**

**Justification :** See EFSA report for more detailed scientific basis

[http://www.efsa.eu.int/science/ahaw/ahaw\\_opinions/495/opinion\\_ahaw\\_02\\_ej45\\_stunning\\_report\\_v2\\_en1.pdf](http://www.efsa.eu.int/science/ahaw/ahaw_opinions/495/opinion_ahaw_02_ej45_stunning_report_v2_en1.pdf)

i) Gas mixtures used for stunning poultry include:

**Community comment:**

**"a" should precede each paragraph.**

**Justification; Linguistic correction, see previous bullet points for consistency of style etc.**

- minimum of 2 minutes exposure to 40% carbon dioxide, 30% oxygen and 30% nitrogen, followed by a minimum of one minute exposure to 80% carbon dioxide in air; or
- minimum of 2 minutes exposure to any mixture of argon, nitrogen or other inert gases with atmospheric air and carbon dioxide, provided that the carbon dioxide concentration does not exceed 30% by volume and the residual oxygen concentration does not exceed 2% by volume; or
- minimum of 2 minutes exposure to argon, nitrogen, other inert gases or any mixture of these gases in atmospheric air with a maximum of 2% residual oxygen by volume; or
- minimum of 2 minutes exposure to a minimum of 55% carbon dioxide in air.

ii) Requirements for effective use are as follows:

- compressed gases should be vaporised prior to administration into the chamber and should be at room temperature to prevent any thermal shock. Under no circumstances, should solid gases with freezing temperatures enter the chamber;
- gas mixtures should be humidified;

**Community comments:**

**The next indent should be replaced by the following text:**

**“ – appropriate gas concentrations of oxygen and, if necessary, carbon dioxide should be monitored and displayed continuously at the level of the birds inside the chamber to ensure that anoxia ensues.”**

**Justification: It is appropriate to measure both gas concentrations.**

See EFSA report for more detailed scientific basis [http://www.efsa.eu.int/science/ahaw/ahaw\\_opinions/495/opinion\\_ahaw\\_02\\_ej45\\_stunning\\_report\\_v2\\_en1.pdf](http://www.efsa.eu.int/science/ahaw/ahaw_opinions/495/opinion_ahaw_02_ej45_stunning_report_v2_en1.pdf)

- appropriate gas concentrations should be monitored and displayed continuously at the level of the birds inside the chamber.

Under no circumstances, should birds exposed to gas mixtures be allowed to regain consciousness. If necessary, the exposure time should be extended.

#### 5. Bleeding

##### **Community comments:**

**The following text should be amended as follows: "From the point of view of animal welfare, animals which are stunned with a reversible method should be bled without delay. Maximum time for bleeding the animals 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 bleeding time that ensures that no animals recover consciousness during bleeding. In any case the following time limits should be applied:"**

**Justification: The stun-to-stick interval depends on the parameters used for the stunning method, the species concerned and the bleeding method used (full cut or chest stick when possible).**

See EFSA report for more detailed scientific basis [http://www.efsa.eu.int/science/ahaw/ahaw\\_opinions/495/opinion\\_ahaw\\_02\\_ej45\\_stunning\\_report\\_v2\\_en1.pdf](http://www.efsa.eu.int/science/ahaw/ahaw_opinions/495/opinion_ahaw_02_ej45_stunning_report_v2_en1.pdf)

From the point of view of animal welfare, animals which are stunned with a reversible method should be bled without delay and in any case within the following time limits:

Stunning method	Maximum delay for bleeding to be started
Electrical methods and non penetrating <u>captive</u> bolt	20 seconds
CO <sub>2</sub>	60 seconds (after leaving the chamber)

**Community comments:**

**Replace "from the point of animal welfare" by "from the point of view of animal welfare".**

**Justification: Linguistic correction, consistency of style etc.**

All animals should be bled by incising both carotid arteries, or the vessels from which they arise (e.g. chest stick). However, when the stunning method used causes cardiac arrest, the incision of all of these vessels is not necessary from the point of animal welfare.

It should be possible for staff to observe, inspect and access the animals throughout the bleeding period. Any animal showing signs of recovering consciousness should be restunned.

After incision of the blood vessels, no scalding carcass treatment or dressing procedures should be performed on the animals for at least 30 seconds, or in any case until all brain-stem reflexes have ceased.

**Community comments:**

**1. The row on captive bolt non-penetrating should be replaced as follows:**

	Captive bolt - non-penetrating	Inaccurate targeting, velocity of bolt, potentially higher failure rate than penetrating captive bolt	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, sheep, goats, deer, pigs, camelids, ratites	<p><b><u>This method should only be used when alternative methods are not available for cattle and sheep.</u></b></p> <p>Presently available devices are not recommended for young bulls and animals with thick skull</p>
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**Justification:** According to the EFSA opinion (Opinion of the Scientific Panel on Animal Health and Welfare on welfare aspects of the main systems of stunning and killing the main commercial species of animals, *The EFSA Journal* (2004), 45, 1-29) the use of non-penetrating captive bolt is unreliable and should not be used for cattle (p. 9). In addition there is no available investigation for its use on adult sheep (p. 10) that would prove that it is suitable for them.

**2. Delete “acceptable” from the table heading.**

**Justification:** Acceptable implies a value judgement or subjective analysis. In any given situation a variety of handling and restraining methods may be available and the best animal welfare outcome needs to be considered on a case-by-case basis. Therefore a given method may be “acceptable” under certain circumstances and “unacceptable” under a different set of conditions.

**3. Reconsider the inclusion of free bullet as a “stunning method”.**

**Justification:** Free bullet if correctly applied will often kill the animal.

**4. To ensure consistency in the OIE’s approach to these issues please consider other parts of the OIE code dealing with related issues, e.g. the implications that stunning-killing methods applied may have on food safety, BSE control-testing etc**

**Justification: Consider EFSA and Scientific Steering Committee opinions on the risk of dissemination of brain material using penetrating stunning methods for example.**

Summary of acceptable stunning methods and the associated animal welfare issues

Method	Specific method	AW concerns/implications	Key AW requirements applicable	Species	Comment
Mechanical	Free bullet	Inaccurate targeting and inappropriate ballistics	<del>Accuracy; head shots only correct ballistics,</del> <u>Operator competence, achieving outright kill with first shot</u>	Cattle, calves, buffalo, deer, horses, pigs (boars and sows)	Personnel safety
	Captive bolt - penetrating	Inaccurate targeting, velocity and diameter of bolt	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, buffalo, sheep, goats, deer, horses, pigs, camelids, ratites	(Unsuitable for specimen collection from TSE suspects). A back-up gun should be available in the event of an ineffective shot
	Captive bolt - non-penetrating	Inaccurate targeting, velocity of bolt, potentially higher failure rate than penetrating captive bolt	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, sheep, goats, deer, pigs, camelids, ratites	Presently available devices are not recommended for young bulls and animals with thick skull
	Manual percussive blow	Inaccurate targeting; insufficient power; size of instrument	Competent <i>animal handlers</i> ; restraint;	Young and small mammals,	Mechanical devices potentially more reliable. Where manual percussive

			accuracy. Not recommended for general use	ostriches and poultry	blow is used, unconsciousness should be achieved with single sharp blow delivered to central skull bones
Electrical	Split application: 1. across head then head to chest; 2. across head then across chest	Accidental pre-stun electric shocks; electrode positioning; application of a current to the body while animal conscious; inadequate current and voltage	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, sheep, goats and pigs, ratites and poultry	Systems involving repeated application of head-only or head-to-leg with short current durations (<1 second) in the first application should not be used.  <del>Where cardiac arrest occurs, the carcass may not be suitable for Halal</del>

Summary of acceptable stunning methods and the associated animal welfare issues

Method	Specific method	AW concerns/implications	Key AW requirements applicable	Species	Comment
Electrical	Single application: 1. head only; 2. head to body; 3. head to leg	Accidental pre-stun electric shocks; inadequate current and voltage; wrong electrode positioning; recovery of consciousness	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, sheep, goats, pigs, ratites, poultry	<del>Where cardiac arrest occurs, the carcass may not be suitable for Halal</del>
	Waterbath	Restraint, accidental pre-stun electric shocks; inadequate current and voltage; recovery of consciousness	Competent operation and maintenance of equipment	Poultry only	<del>Where cardiac arrest occurs, the carcass may not be suitable for Halal</del>
Gaseous	CO <sub>2</sub> air/O <sub>2</sub> mixture; 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	<del>Gaseous methods may not be suitable for Halal</del>

	Inert gases	Recovery of consciousness	Concentration; duration of exposure; design, maintenance and operation of equipment; stocking density management	Pigs, poultry	<del>Gaseous methods may not be suitable for Halal</del>
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**Community comments:**

1) The row "bleeding out by severance of blood vessels in the neck without stunning" should be moved to the end of the table as it does not represent the most reliable and optimal method of slaughter in terms of ensuring the welfare of the animals.

2) In addition, particular attention should be drawn to the competence of the personnel and the quality of the restraint. As the animal remains conscious for a certain period of time, no further procedure should be carried out before the bleeding out is completed (see Article on bleeding provides for at least 30 s). In particular the practice to remove hypothetical blood clots just after the bleeding should be discouraged as it increases the suffering of the animals without providing a better bleeding.

Therefore this row should be moved to the end of the list and be replaced as follows:

Bleeding out by severance of blood vessels in the neck without stunning	Full frontal cutting across the throat	Failure to cut both common carotid arteries; occlusion of cut arteries.	<p><b><u>Operator competencies</u></b></p> <p>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.</p> <p>An incision which does not close over the knife during the throat cut.</p>	Cattle, buffalo, horses, camelids, sheep, goats, poultry, ratites	<p><b><u>No further procedure should be carried out before the bleeding out is completed (i.e. at least 30 seconds for mammals)</u></b></p> <p><b><u>The practice to remove hypothetical blood clots just after the bleeding should be discouraged since this may increase animal suffering.</u></b></p>
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3) In addition the row on "free bullet" listed within the stunning methods should be also listed here as free bullet often provides an instant killing.

4) the wording "ineffective stunning" in the column "AW concerns/implications" should be deleted as it applies to all slaughter methods.

**Justification: See EFSA report**

**5. Delete “acceptable” from the table heading.**

**Justification : Acceptable implies a value judgement or subjective analysis. In any given situation a variety of handling and restraining methods may be available and the best animal welfare outcome needs to be considered on a case-by-case basis. Therefore a given method may be “acceptable” under certain circumstances and “unacceptable” under a different set of conditions.**

Summary of acceptable slaughter methods and the associated animal welfare issues

Slaughter methods	Specific method	AW concerns / implications	Key requirements	Species	Comments
Bleeding out by severance of blood vessels in the neck without stunning	Full frontal cutting across the throat	Failure to cut both common carotid arteries; occlusion of cut arteries.	A very sharp blade or knife, of sufficient length so that the point of the knife remains outside the incision during the cut; the point of the knife should not be used to make the incision.  An incision which does not close over the knife during the throat cut.	Cattle, buffalo, horses, camelids, sheep, goats, poultry, ratites	<del>This method is applicable to Halal and Kosher slaughter for relevant species</del>
Bleeding with prior stunning	<u>Full frontal cutting across the throat</u>	<u>Failure to cut both common carotid arteries; occlusion of cut arteries; pain during and after the cut.</u>	<u>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.</u>  <u>An incision which does not close</u>	<u>Cattle, buffalo, horses, camelids, sheep, goats,</u>	

			<u>over the knife during the throat cut.</u>		
	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	

## Summary of acceptable slaughter methods and the associated animal welfare issues (contd)

Slaughter methods	Specific method	AW concerns / implications	Key requirements	Species	Comments
Bleeding with prior stunning (contd)	Chest stick into major arteries or hollow-tube knife into heart	Ineffective stunning;  Inadequate size of stick wound inadequate length of sticking knife; delay in sticking after reversible stunning	Prompt and accurate sticking	Cattle, sheep, goats, pigs	
	Chest stick into major arteries or hollow-tube knife into heart	Ineffective stunning;  Inadequate size of stick wound inadequate length of sticking knife; delay in sticking after reversible stunning	Prompt and accurate sticking	Cattle, sheep, goats, pigs	
	Neck skin cut followed by severance of vessels in the neck	Ineffective stunning; Inadequate size of stick wound; Inadequate length of sticking knife; delay in sticking after reversible	Prompt and accurate cutting of vessels	Cattle	

		stunning			
Bleeding with prior stunning	Automated mechanical cutting	Ineffective stunning; failure to cut and misplaced cuts. Recovery of consciousness following reversible stunning systems	Design, maintenance and operation of equipment; accuracy of cut; manual back-up	Poultry only	
	Manual neck cut on one side	Ineffective stunning; recovery of consciousness following reversible stunning systems	Prior non-reversible stunning	Poultry only	N.B. slow induction of unconsciousness under slaughter without stunning
	Oral cut	Ineffective stunning; recovery of consciousness following reversible stunning systems	Prior non-reversible stunning	Poultry only	N.B. slow induction of unconsciousness in non-stun systems

Slaughter methods	Specific method	AW concerns / implications	Key requirements	Species	Comments
Bleeding with prior stunning (contd)	Oral cut	Ineffective stunning; recovery of consciousness following reversible stunning systems	Prior non-reversible stunning	Poultry only	N.B. slow induction of unconsciousness in non-stun systems
Other methods without stunning	Decapitation with a sharp knife	Pain due to loss of consciousness not being immediate		Sheep, goats, poultry	This method is only applicable to Jhatka slaughter
	Manual neck dislocation and decapitation	Pain due to loss of consciousness not being immediate; difficult to achieve in large birds	Neck dislocation should be performed in one stretch to sever the spinal cord	Poultry only	Slaughter by neck dislocation should be performed in one stretch to sever the spinal cord
Cardiac arrest in a waterbath electric stunner	Bleeding by evisceration		Induction of cardiac arrest	Quail	
	Bleeding by neck cutting			Poultry	

Article 3.7.5.10.

Methods, procedures or practices unacceptable on animal welfare grounds

**Community comments:**

**In paragraph 1 below the word "puntilla" should not be deleted but explained with a more precise description such as for example "puntilla (i.e. severing the spinal cord)".**

**Justification: Puntillas have been used in certain situations and their use should be explained rather than ignored.**

1. The restraining methods which work through immobilisation by injury such as ‘~~puntilla~~’, breaking legs and ‘leg tendon cutting’, cause severe pain and stress in animals. Those methods are not acceptable in any species.
2. The use of the electrical stunning method with a single application leg to leg is ineffective and unacceptable in any species, as it is likely to be painful. The animal welfare concerns are:
  - a) accidental pre-stun electric shocks;
  - b) inadequate current and voltage;
  - c) wrong electrode positioning;
  - d) recovery of consciousness.
3. The slaughter method of brain stem severance by piercing through the eye socket or skull bone without prior stunning, is not acceptable in any species.

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— text deleted

## APPENDIX 3.7.6.

GUIDELINES FOR THE KILLING OF  
ANIMALS FOR DISEASE CONTROL PURPOSES

## Article 3.7.6.1.

**General principles**

~~This Appendix is~~ These guidelines are based on the premise that a decision to kill the animals has been made, and address the need to ensure the welfare of the animals until they are dead.

**Community comments:**

**The following paragraph could be completed as follows:**

**"Such a certificate should be delivered if the applicant has demonstrated sufficient knowledge, with due regard to the tasks, methods, equipments and species concerned by the applicant responsibilities as laid down in these guidelines."**

**Justification: The introduction of a certificate of competence is welcomed but it should explicitly refer to the knowledge of these guidelines.**

1. All personnel involved in the humane killing of animals should have the relevant skills and competencies. Competence may be gained through formal training and/or practical experience. This competence should be demonstrated through a current certificate from an independent body accredited by a *Competent Authority*.
2. As necessary, operational procedures should be adapted to the specific circumstances operating on the premises and should address, apart from animal welfare, operator safety, biosecurity and environmental aspects.
3. Following the decision to kill the animals, killing should be carried out as quickly as possible and normal husbandry should be maintained until the animals are killed.
4. The handling and movement of animals should be minimised and when done, it should be done in accordance with the guidelines described below.
5. Animal restraint should be sufficient to facilitate effective killing, and in accordance with animal welfare and operator safety requirements; when restraint is required, killing should follow with minimal delay.
6. When animals are killed for disease control purposes, methods used should result in immediate death or immediate loss of consciousness lasting until death; when loss of consciousness is not immediate, induction of unconsciousness should be non-aversive and should not cause anxiety, pain, distress or suffering in the animals.



7. For animal welfare considerations, young animals should be killed before older animals; for biosecurity considerations, infected animals should be killed first, followed by in-contact animals, and then the remaining animals.
8. There should be continuous monitoring of the procedures by the *Competent Authorities* to ensure they are consistently effective with regard to animal welfare, operator safety and biosecurity.
9. When the operational procedures are concluded, there should be a written report describing the practices adopted and their effect on animal welfare, operator safety and biosecurity.
10. ~~To the extent possible to minimise public distress, killing of animals and carcass disposal should be carried out away from public view.~~
44. These general principles should also apply when animals need to be killed for other purposes such as after natural disasters.

#### Article 3.7.6.2.

### Organisational structure

Disease control contingency plans should be in place at a national level and should contain details of management structure, disease control strategies and operational procedures; animal welfare considerations should be addressed within these disease control contingency plans. The plans should also include a strategy to ensure that an adequate number of personnel trained competent in the humane killing of animals is available. Local level plans should be based on national plans and be informed by local knowledge.

Disease control contingency plans should address the animal welfare issues that may result from animal movement controls.

The operational activities should be led by an official veterinarian who has the authority to appoint the personnel in the specialist teams and ensure that they adhere to the required animal welfare and biosecurity standards. When appointing the personnel, he/she should ensure that the personnel involved has the required competencies.

The official veterinarian should be responsible for all activities across one or more affected premises and should be supported by coordinators for planning (including communications), operations and logistics to facilitate efficient operations.

The official veterinarian should provide overall guidance to personnel and logistic support for operations on all affected premises to ensure consistency in adherence to the OIE animal welfare and animal health guidelines.

A specialist team, led by a team leader answerable to the *official veterinarian*, should be deployed to work on each affected premises. The team should consist of personnel with the competencies to conduct all required operations; in some situations, personnel may be required to fulfil more than one function. Each team should contain a veterinarian or have access to veterinary advice at all times.

In considering the animal welfare issues associated with killing animals, the key personnel, their responsibilities and competencies required are described in Article 3.7.6.3.

#### Article 3.7.6.3.

## Responsibilities and competencies of the specialist team

### 1. Team leader

#### a) Responsibilities

- i) plan overall operations on an affected premises;
- ii) determine and address requirements for animal welfare, operator safety and biosecurity;
- iii) organise, brief and manage team of people to facilitate humane killing of the relevant animals on the premises in accordance with national regulations and these guidelines;
- iv) determine logistics required;
- v) monitor operations to ensure animal welfare, operator safety and biosecurity requirements are met;
- vi) report upwards on progress and problems;
- vii) provide a written report at the conclusion of the killing, describing the practices adopted and ~~their effect on~~ animal welfare, operator safety and biosecurity outcomes.

#### b) Competencies

- i) appreciation of normal animal husbandry practices;
- ii) appreciation of animal welfare and the underpinning behavioural, anatomical and physiological processes involved in the killing process;
- iii) skills to manage all activities on premises and deliver outcomes on time;
- iv) awareness of psychological effects on farmer, team members and general public;
- v) effective communication skills.

### 2. Veterinarian

#### a) Responsibilities

- i) determine and implement the most appropriate killing method to ensure that animals are killed without avoidable pain and distress;
- ii) determine and implement the additional requirements for animal welfare, including the order of killing;
- iii) ensure that confirmation of animals deaths is carried out by competent persons at appropriate times after the killing procedure;

- iv) minimise the risk of disease spread within and from the premises through the supervision of biosecurity procedures;
- v) continuously monitor animal welfare and biosecurity procedures;
- vi) in cooperation with the leader, prepare a written report at the conclusion of the killing, describing the practices adopted and their effect on animal welfare.

b) Competencies

- i) ability to assess animal welfare, especially the effectiveness of stunning and killing, and to correct any deficiencies;
- ii) ability to assess biosecurity risks.

3. Animal handlers

a) Responsibilities

- i) review on-site facilities in terms of their appropriateness;
- ii) design and construct temporary animal handling facilities, when required;
- ii) move and restrain animals.

b) Competencies

- i) ~~An experience of~~ Animal handling in emergency situations and in close confinement is required;
- ii) an appreciation of biosecurity and containment principles.

4. ~~Slaughterers~~ Animal killing personnel

a) Responsibilities

Humane killing of the animals through effective stunning and killing should be ensured.

b) Competencies

**Community comments:**

**The following text should be added:**

**"v) above-mentioned competencies should be demonstrated through a certificate of competence as referred to in Article 3.7.6.1."**

**Justification: In the interests of consistency, reference to the certificate of competence mentioned in Article 3. 7. 6. 1. (paragraph 1) should be included here.**

- i) when required by regulations, licensed to use necessary equipment ~~or licensed to be slaughterers~~;
- ii) competent to use and maintain relevant equipment;
- iii) competent to use techniques for the species involved;
- iv) competent to assess effective stunning and killing.

5. Carcass disposal personnel

a) Responsibilities

An efficient carcass disposal (to ensure killing operations are not hindered) should be ensured.

b) Competencies

The personnel should be competent to use and maintain available equipment and apply techniques for the species involved.

6. Farmer/owner/manager

a) Responsibilities

- i) assist when requested.

b) Competencies

- i) specific knowledge of his/her animals and their environment.

Article 3.7.6.4.

**Considerations in planning the humane killing of animals**

Many activities will need to be conducted on affected premises, including the humane killing of animals. The team leader should develop a plan for humanely killing animals on the premises which should include consideration of:

**Community comments:**

**Two important considerations should be added to the list below:**

**"- The plan should minimise the negative welfare impacts of the killing by taking into account the different phases of the procedures to be applied for killing (choice of the killing sites, killing methods, etc.) and the measures restricting the movements of the animals.**

**- Competences and skills of the personnel handling and killing animals"**

**Justification: This is in line with basic good practices. For a scientific basis see EFSA report.**

1. minimising handling and movement of animals;
2. killing the animals on the affected premises; however, there may be circumstances where the animals may need to be moved to another location for killing; when the killing is conducted at an abattoir, the guidelines in the Chapter on slaughter of animal for human consumption should be followed;
3. the species, number, age and size of animals to be killed, and the order of killing them;
4. methods of killing the animals, and their cost;
5. housing and location of the animals;
6. the availability and effectiveness of equipment needed for killing of the animals;
7. the facilities available on the premises that will assist with the killing;
8. biosecurity and environmental issues;
9. the health and safety of personnel conducting the killing;
10. any legal issues that may be involved, for example where restricted veterinary drugs or poisons may be used, or where the process may impact on the environment; and
11. the presence of other nearby premises holding animals.

In designing a killing plan, it is essential that the method chosen be consistently reliable to ensure that all animals are humanely and quickly killed.

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 <del>killing</del> <u>death</u>	3.7.6.7.
	all except neonates	captive bolt - non-penetrating, followed by bleeding	yes	ineffective stunning, regaining of consciousness before <del>killing</del> <u>death</u>	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.

Species	Age range	Procedure	Restraint necessary	Animal welfare concerns with inappropriate application	Article reference
Sheep and goats (contd)	neonates only	nitrogen and/or inert gases	yes	slow induction of unconsciousness,	3.7.6.14.
	all	injection of barbiturates and other drugs	yes	non-lethal dose, pain associated with injection site	3.7.6.15.
Pigs	all	free bullet	no	non-lethal wounding	3.7.6.6.
	all except neonates	captive bolt - penetrating, followed by pithing or bleeding	yes	ineffective stunning, <u>regaining of consciousness before death</u>	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 <del>killing</del> <u>death</u>	3.7.6.11.

Species	Age range	Procedure	Restraint necessary	Animal welfare concerns with inappropriate application	Article reference
Poultry (contd)	all	CO <sub>2</sub> / air mixture Method 1 Method 2	yes no	slow induction of unconsciousness, aversiveness of induction	3.7.6.12.
	all	nitrogen and/or inert gas mixed with CO <sub>2</sub>	yes	slow induction of unconsciousness, aversiveness of induction	3.7.6.13.
	all	nitrogen and/or inert gases	yes	slow induction of unconsciousness	3.7.6.14.
	all	injection of barbiturates and other drugs	yes	non-lethal dose, pain associated with injection site	3.7.6.15.
	adults only	addition of anaesthetics to feed or water, followed by an appropriate killing method	no	ineffective or slow induction of unconsciousness	3.7.6.16.

\* The methods are described in the order of mechanical, electrical and gaseous, not in an order of desirability from an animal welfare viewpoint.

§ The only preclusion against the use of this method for neonates is the design of the stunning tongs that may not facilitate their application across such a small-sized head/body.

#### Article 3.7.6.6.

#### 4. FREE BULLET

##### 5. 1. INTRODUCTION

- a) A free bullet is a projectile fired from a shotgun, rifle, handgun or purpose-made humane killer.
- b) The most commonly used firearms for close range use are:
  - i) humane killers (specially manufactured/adapted single-shot weapons);

- ii) shotguns (12, 16, 20, 28 bore and .410);
  - iii) rifles (.22 rimfire);
  - iv) handguns (various calibres from .32 to .45).
- c) The most commonly used firearms for long range use are rifles (.22, .243, .270 and .308).
  - d) A free bullet used from long range should be aimed to penetrate the skull or soft tissue at the top of the neck of the animal, to cause irreversible concussion and death and should only be used by properly trained and competent marksmen.
6. 2. REQUIREMENTS FOR EFFECTIVE USE
- a) The marksman should take account of human safety in the area in which he/she is operating. Appropriate vision and hearing protective devices should be worn by all personnel involved.
  - b) The marksman should ensure that the animal is not moving and in the correct position to enable accurate targeting and the range should be as short as possible (5 –50 cm for a shotgun) but the barrel should not be in contact with the animal’s head.
  - c) The correct cartridge, calibre and type of bullet for the different species age and size should be used. Ideally the ammunition should expand upon impact and dissipate its energy within the cranium.
  - d) Shot animals should be checked to ensure the absence of brain stem reflexes.

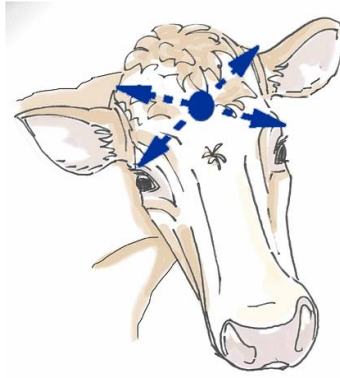
**Community comments:**

**A frontal view and a lateral view should be available for all species mentioned here.**

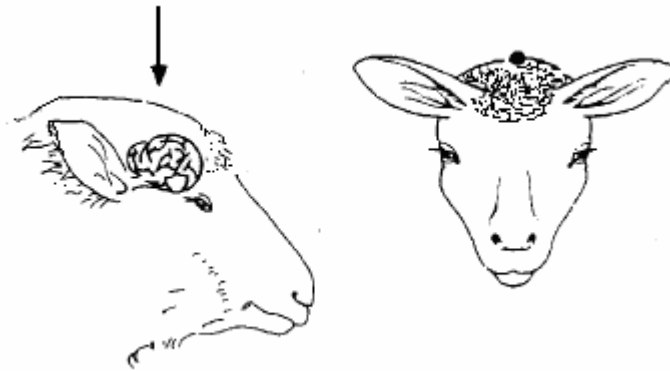
**Justification: This would provide more comprehensive and clear information on the recommended locations for appropriate stunning.**

**Pictures are in particular available from the Humane Slaughter Association or in the EFSA Scientific report of the Scientific Panel for Animal Health and Welfare on welfare aspects of animal stunning and killing methods - [http://www.efsa.eu.int/science/ahaw/ahaw\\_opinions/495\\_en.html](http://www.efsa.eu.int/science/ahaw/ahaw_opinions/495_en.html)**

**Figure 1.** The optimum shooting position for cattle is at the intersection of two imaginary lines drawn from the rear of the eyes to the opposite horn buds.



**Figure 2.** The optimum position for hornless sheep and goats is on the midline just above the eye level, and directing the shot down the line of the spinal cord.



**Figure 3.** The optimum shooting position for heavily horned sheep and horned goats is behind the poll aiming towards the angle of the jaw.



**Figure 4.** The optimum shooting position for pigs is just above ~~the eyes~~ level, with and directing the shot directed down the line of the spinal cord.

7.



8. 3. ADVANTAGES

- a) Used properly, a free bullet provides a quick and effective method for killing.
- b) It requires minimal or no restraint and can be use to kill from a distance.
- c) It is suitable for killing agitated animals in open spaces.

9. 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.

10. 4. CONCLUSIONS

The method is suitable for cattle, sheep, goats and pigs, including large animals in open spaces.

Article 3.7.6.7.

11. **PENETRATING CAPTIVE BOLT**

12. 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.

13. 2. REQUIREMENTS FOR EFFECTIVE USE

- a) For cartridge powered and compressed air guns, the bolt velocity and the length of the bolt should be appropriate to the species and type of animal, in accordance with the manufacturer's recommendations.
- b) Captive bolt guns should be frequently cleaned and maintained in good working condition.
- c) More than one gun may be necessary to avoid overheating and a back-up gun should be available in the event of an ineffective shot.
- d) Animals should be restrained; at a minimum they should be penned for cartridge powered guns and in a race for compressed air guns.
- e) The operator should ensure that the animal's head is accessible.

**Community comment:**

**In the interests of consistency it would be preferable to also refer to figure 2 in f) and transfer the comment on hornless sheep accordingly. The current text seems to apply to horned sheep and not to hornless sheep (see comment of figure 3).**

**Justification: To ensure better clarity in the text and facilitate proper interpretation of the provisions.**

- f) The operator should fire the captive bolt at right angles to the skull in the optimal position (see figures 1, 3 & 4. The optimum shooting position for hornless sheep is on the highest point of the head, on the midline and aim towards the angle of the jaw).
  - g) To ensure the death of the animal, pithing or bleeding should be performed as soon as possible after stunning.
  - h) Animals should be monitored continuously after stunning until death to ensure the absence of brain stem reflexes.
14. 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.
15. 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.
16. 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**

**Community comments:**

**The following text should be added at the beginning of the section:**

**"As this method is not reliable for cattle and adult sheep, it should only be used for those animals when alternative methods are not available."**

**Justification:** According to the EFSA opinion (Opinion of the Scientific Panel on Animal Health and Welfare on welfare aspects of the main systems of stunning and killing the main commercial species of animals, *The EFSA Journal* (2004), 45, 1-29) the use of non-penetrating captive bolt is unreliable and should not be used for cattle (p. 9).

**In addition there is no available investigation for its use on adult sheep (p. 10) that would prove that it is suitable for them. Consequently other methods should be used.**

17. 1. INTRODUCTION

A non-penetrating captive bolt is fired from a gun powered by either compressed air or a blank cartridge. There is no free projectile.

The gun should be placed on the front of the skull to deliver a percussive blow which produces unconsciousness in cattle (adults only), sheep, goats and pigs, and death in poultry and neonate sheep, goats and pigs. ~~In mammals~~, Bleeding should be performed as soon as possible after the blow to ensure the death of the animal.

18. 2. REQUIREMENTS FOR EFFECTIVE USE

- a) For cartridge powered and compressed air guns, the bolt velocity should be appropriate to the species and type of animal, in accordance with the manufacturer's recommendations.
- b) Captive bolt guns should be frequently cleaned and maintained in good working condition.
- c) More than one gun may be necessary to avoid overheating and a back-up gun should be available in the event of an ineffective shot.
- d) Animals should be restrained; at a minimum mammals should be penned for cartridge powered guns and in a race for compressed air guns; birds should be restrained in cones, shackles, crushes or by hand.
- e) The operator should ensure that the animal's head is accessible.
- f) The operator should fire the captive bolt at right angles to the skull in the optimal position (figures 1-4).
- g) To ensure death in non-neonate mammals, bleeding should be performed as soon as possible after stunning.
- h) Animals should be monitored continuously after stunning until death to ensure the absence of brain stem reflexes.

19. 3. ADVANTAGES

**Community comments:**

**In a) "Neonates" should be replaced by a more specific wording such as "neonatal sheep, goats and pigs for example".**

**Justification: For clarity, proper interpretation and in line with the scientific basis outlined in the EFSA report.**

- a) The method induces an immediate onset of unconsciousness, and death in birds and neonates.
- b) Mobility of equipment reduces the need to move animals



20. 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.

21. 5. CONCLUSIONS

- a) The method is suitable for poultry, and neonate sheep, goats and pigs.
- b) If bleeding does not present a biosecurity issue, this is a suitable method for cattle (adults only), and non-neonate sheep, goats and pigs when followed by bleeding.

Article 3.7.6.9.

## **Maceration**

21.1. 1. Introduction

Maceration, utilising a mechanical apparatus with rotating blades or projections, causes immediate fragmentation and death in day-old poultry and embryonated eggs.

21.2. 2. Requirements

- a) Maceration requires specialised equipment which should be kept in excellent working order.
- b) The rate of introducing the birds should not allow the equipment to jam, birds to rebound from the blades or the birds to suffocate before they are macerated.

21.3. 3. Advantages

- a) Procedure results in immediate death.
- b) Large numbers can be killed quickly.

21.4. 4. Disadvantages

- a) Specialised equipment is required.
- b) Macerated tissues may present a biosecurity issue.

21.5. 5. Conclusion

The method is suitable for killing day-old poultry and embryonated eggs.

Article 3.7.6.10.

**Electrical – two stage application**

21.6. 1. Introduction

A two stage application of electric current comprises firstly an application of current to the head by scissor-type tongs, immediately followed by an application of the tongs across the chest in a position that spans the heart.

The application of sufficient electric current to the head will induce 'tonic/clonic' epilepsy and unconsciousness. Once the animal is unconscious, the second stage will induce ventricular fibrillation (cardiac arrest) resulting in death. The second stage (the application of low frequency current across the chest) should only be applied to unconscious animals to prevent unacceptable levels of pain.



Figure 6. Scissor-type stunning

21.7. 2. Requirements for effective use

**Community comments:**

**Line (a) should be replaced by the following text:**

**"a) The stunner control device should generate a low frequency (AC sine wave 50 Hz) current with a minimum voltage and current as set out in the following table:**

Animal	Minimum voltage (V)	Minimum current (A)
Cattle	220	1.5
Sheep	220	1.0
Pigs > 6 weeks	220	1.3
Pigs < 6 weeks	125	0.5

**Justification: The EFSA scientists provided the following figures as regards the killing of animals for disease control situations. They always refer to a frequency AC sine wave 50 Hz.**

**See p. 198 EFSA – AHAW/04-027 "Welfare aspects of stunning and killing methods" Scientific report of the Scientific Panel for Animal Health and Welfare on welfare aspects of animal stunning and killing methods - [http://www.efsa.eu.int/science/ahaw/ahaw\\_opinions/495\\_en.html](http://www.efsa.eu.int/science/ahaw/ahaw_opinions/495_en.html))**

- a) The stunner control device should generate a low frequency (30 – 60 Hz) current with a minimum voltage of 250 volts true RMS under load.
- b) Appropriate protective clothing (including rubber gloves and boots) should be worn.
- c) Animals should be restrained, at a minimum free-standing in a pen, close to an electrical supply.
- d) Two team members are required, the first to apply the electrodes and the second to manipulate the position of the animal to allow the second application to be made.

**Community comments:**

**Paragraph (e) should be replaced by the following text:**

**"e) A stunning current should be applied via scissor-type stunning tongs in a position that spans the brain for a minimum of 10 seconds; immediately following the application to the head, the electrodes should be transferred to a position that spans the heart and the electrodes applied for a minimum of 10 seconds."**

**Justification: Duration of exposure should be extended here as disease control situation is usually not followed by another method of killing and monitoring the effectiveness of the killing may be neglected because of the large number of animals to be killed. A margin of security should therefore be provided in order to ascertain that the killing is ensured for all animals.**

- e) A stunning current should be applied via scissor-type stunning tongs in a position that spans the brain for a minimum of 3 seconds; immediately following the application to the head, the electrodes should be transferred to a position that spans the heart and the electrodes applied for a minimum of 3 seconds.
- f) Electrodes should be cleaned regularly and after use, to enable optimum electrical contact to be maintained.
- g) Animals should be monitored continuously after stunning until death to ensure the absence of brain stem reflexes.

**Community comments:**

**The following point should be added:**

**"h) Electrodes should be applied firmly for the intended duration of time and pressure not released until the stun is complete"**

**Justification: This is important to ensure the welfare of the animals**

21.8. 3. Advantages

- a) The application of the second stage minimises post-stun convulsions and therefore the method is particularly effective with pigs.
- b) Non-invasive technique minimises biosecurity risk.

21.9. 4. Disadvantages

- a) The method requires a reliable supply of electricity.

- b) The electrodes must be applied and maintained in the correct positions to produce an effective stun and kill.
- c) Most stunner control devices utilise low voltage impedance sensing as an electronic switch prior to the application of high voltages; in unshorn sheep, contact impedance may be too high to switch on the required high voltage (especially during stage two).
- d) The procedure may be physically demanding, leading to operator fatigue and poor electrode placement.

21.10. 5. Conclusion

The method is suitable for calves, sheep and goats, and especially for pigs (over one week of age).

Article 3.7.6.11.

**22. 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.

22.1.a) *Requirements for effective use*

- i) The stunner control device should generate a low frequency (30 – 60 Hz) current with a minimum voltage of 250 volts true RMS under load.
- ii) Appropriate protective clothing (including rubber gloves and boots) should be worn.
- iii) Animals should be individually and mechanically restrained close to an electrical supply as the maintenance of physical contact between the stunning electrodes and the animal is necessary for effective use.
- iv) The rear electrode should be applied to the back, above or behind the heart, and then the front electrode in a position that is forward of the eyes, with current applied for a minimum of 3 seconds.
- v) Electrodes should be cleaned regularly between animals and after use, to enable optimum electrical contact to be maintained.
- vi) Water or saline may be necessary to improve electrical contact with sheep.
- vii) An effective stun and kill should be verified by the absence of brain stem reflexes.

22.2.b) *Advantages*

- i) Method 1 stuns and kills simultaneously.
- ii) It minimises post-stun convulsions and therefore is particularly effective with pigs.
- iii) A single team member only is required for the application.
- iv) Non-invasive technique minimises biosecurity risk.

22.3.c) *Disadvantages*

- i) Method 1 requires individual mechanical animal restraint.
- ii) The electrodes must be applied and maintained in the correct positions to produce an effective stun and kill.
- iii) Method 1 requires a reliable supply of electricity.

22.4.d) *Conclusion*

Method 1 is suitable for calves, sheep, goats, and pigs (over 1 week of age).

2. Method 2

Method 2 stuns and kills by drawing inverted and shackled poultry through an electrified waterbath stunner. Electrical contact is made between the 'live' water and earthed shackle and, when sufficient current is applied, poultry will be simultaneously stunned and killed.

22.5.a) *Requirements for effective use*

- i) A mobile waterbath stunner and a short loop of processing line are required.

**Community comments:**

**The text of (ii) should be replaced as follows:**

**"ii) A low frequency (50-60 Hz) current applied for a minimum of 10 seconds is necessary to stun and kill the birds."**

**Justification: According to scientists of the EFSA minimum figures to be applied in this case should be 50-60 Hz and 10 seconds. See p. 199 of the report EFSA – AHAW/04-027 "Welfare aspects of stunning and killing methods" Scientific report of the Scientific Panel for Animal Health and Welfare on welfare aspects of animal stunning and killing methods - [http://www.efsa.eu.int/science/ahaw/ahaw\\_opinions/495\\_en.html](http://www.efsa.eu.int/science/ahaw/ahaw_opinions/495_en.html))**

- ii) A low frequency (30-60 Hz) current applied for a minimum of 3 seconds is necessary to stun and kill the birds.
- iii) Poultry need to be manually removed from their cage, house or yard, inverted and shackled onto a line which conveys them through a waterbath stunner with their heads fully immersed.
- iv) The required minimum currents to stun and kill dry birds are:
  - Quail - 100 mA/bird
  - Chickens – 160 mA/bird
  - Ducks & Geese – 200 mA/bird
  - Turkeys – 250 mA/bird.A higher current is required for wet birds.
- v) An effective stun and kill should be verified by the absence of brain stem reflexes.

22.6. b) *Advantages*

- i) Method 2 stuns and kills simultaneously.
- ii) It is capable of processing large numbers of birds reliably and effectively.
- iii) This non-invasive technique minimises biosecurity risk.

22.7. c) *Disadvantages*

- i) Method 2 requires a reliable supply of electricity.
- ii) Handling, inversion and shackling of birds are required.

22.8. d) *Conclusion*

Method 2 is suitable for large numbers of poultry.

3. Method 3

Method 3 comprises the single application of sufficient electrical current to the head of poultry in a position that spans the brain, causing unconsciousness; this is followed by a killing method (Article 17).

22.9. a) *Requirements for effective use*

**Community comments:**

**The following sentence should be replaced as follows:**

**"i) The stunner control device should generate sufficient current to stun.**

**For constant voltage a minimum RMS or average currents of 240 and 400 mA should be applied for a minimum of 7 seconds to chickens and turkeys respectively (110 V RMS 50 Hz). Killing should be performed within 15 seconds from the end of the stun.**

**For constant current stunner the following minimum currents are recommended:**

Since wave AC (Hz)	Minimum RMS current (mA)
50	100
400	150
1500	200"

**Justification: See EFSA report**

- i) The stunner control device should generate sufficient current (more than 300 mA/bird) to stun.
- ii) Appropriate protective clothing (including rubber gloves and boots) should be worn.
- iii) Birds should be restrained, at a minimum manually, close to an electrical supply.

**Community comments:**

**The following text (iv) should be deleted if the previous Community proposed amendment is accepted.**

**Justification: Covered by previous suggested amendment.**

- iv) A stunning current should be applied in a position that spans the brain for a minimum of 3 seconds; immediately following this application, the birds should be killed (Article 17).
- v) Electrodes should be cleaned regularly and after use, to enable optimum electrical contact to be maintained.
- vi) Birds should be monitored continuously after stunning until death to ensure the absence of brain stem reflexes.

22.10. *b) Advantages*

Non-invasive technique (when combined with ~~neck~~ cervical dislocation) minimises biosecurity risk.

22.11. *c) Disadvantages*

**Community comments:**

**The following text should be replaced by:**

**"i) Method 3 requires a reliable supply of electricity and is not suitable for large-scale operations."**

**Justification: According to the EFSA scientists this method is not suitable for large-scale operations (see p. 123-124 of the report).**

- i) Method 3 requires a reliable supply of electricity.
- ii) The electrodes must be applied and maintained in the correct position to produce an effective stun.
- iii) Birds must be individually restrained.
- iv) It must be followed by a killing method.

22.12. *d) Conclusion*

Method 3 is suitable for small numbers of poultry.

**Community comments:**

**The following text should be retained as being “under study” until further information is available.**

**Justification: Ongoing important scientific advances in this area make the proposed text premature. Accumulating scientific evidence needs to be further analysed by the OIE ad hoc group experts before firm conclusions can be drawn on this matter, gas concentrations to be recommended etc.**

Article 3.7.6.12.  
(under study)

23. CO<sub>2</sub> / AIR MIXTURE

24. 1. INTRODUCTION

Controlled atmosphere killing is performed by exposing animals to a predetermined gas mixture, either by placing them in a gas-filled container or apparatus (Method 1) or by the gas being introduced into a poultry house (Method 2).

Inhalation of carbon dioxide (CO<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.

25. 2. METHOD 1

The animals are placed in a gas-filled container or apparatus.

26. A) REQUIREMENTS FOR EFFECTIVE USE IN A CONTAINER OR APPARATUS

- i) Containers or apparatus should allow the required gas concentration to be maintained and accurately measured.
- ii) When animals are exposed to the gas individually or in small groups in a container or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the animals and allow them to be observed.
- iii) Animals should be introduced into the container or apparatus after it has been filled with the required CO<sub>2</sub> concentration, and held in this atmosphere until death is confirmed.
- iv) Team members should ensure that there is sufficient time allowed for each batch of animals to die before subsequent ones are introduced into the container or apparatus.
- v) Containers or apparatus should not be overcrowded and measures are needed to avoid animals suffocating by climbing on top of each other.

27. B) ADVANTAGES

- i) CO<sub>2</sub> is readily available.
- ii) Application methods are simple.



28. C) DISADVANTAGES

- i) The need for properly designed container or apparatus ~~special equipment~~
- 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.

29. D) CONCLUSION

Method 1 is suitable for use in poultry and neonatal sheep, goats and pigs.

30. 3. METHOD 2

The gas is introduced into a poultry house.

31. 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 ~~highest level~~ maximum height accommodation of birds.

32. 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.

33. 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.

34. D) CONCLUSION

Method 2 is suitable for use in poultry in closed-environment sheds

## **Nitrogen and/or inert gas mixed with CO<sub>2</sub>**

### 1. Introduction

CO<sub>2</sub> may be mixed in various proportions with nitrogen or an inert gas eg argon, and the inhalation of such mixtures leads to hypercapnic-hypoxia and death when the oxygen concentration by volume is  $\leq 2\%$ . 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

- 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.

## **Nitrogen and/or inert gasses**

### 1. Introduction

This method involves the introduction of animals into a container or apparatus containing nitrogen or an inert gas such as argon. The controlled atmosphere produced leads to unconsciousness and death from hypoxia.

Research has shown that hypoxia is not aversive to pigs and poultry, and it doesn't induce any signs of respiratory distress prior to loss of consciousness.

### 2. Requirements for effective use

- a) Containers or apparatus should allow the required gas concentrations to be maintained, and the O<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.

## **Lethal injection**

### 1. Introduction

A lethal injection using high doses of anaesthetic and sedative drugs causes CNS depression, unconsciousness and death. In practice, barbiturates in combination with other drugs are commonly used.

## 2. Requirements for effective use

- a) Doses and routes of administration that cause rapid loss of consciousness followed by death should be used.
- b) Prior sedation may be necessary for some animals.
- c) Intravenous administration is preferred, but intraperitoneal or intramuscular administration may be appropriate, especially if the agent is non-irritating.
- d) Animals should be restrained to allow effective administration.
- e) Animals should be monitored to ensure the absence of brain stem reflexes.

## 3. Advantages

- a) The method can be used in all species.
- b) Death can be induced smoothly.

## 4. Disadvantages

- a) Restraint and/or sedation may be necessary prior to injection.
- b) Some combinations of drug type and route of administration may be painful, and should only be used in unconscious animals.
- c) Legal requirements may restrict use to veterinarians.
- d) Contaminated carcasses may present a risk to other wild or domestic animals.

## 5. Conclusion

The method is suitable for killing small numbers of cattle, sheep, goats, pigs and poultry.

Article 3.7.6.16.

## **Addition of anaesthetics to feed or water**

### 1. Introduction

An anaesthetic agent which can be mixed with poultry feed or water may be used to kill poultry in houses. Poultry which are only anaesthetised need to be killed by another method such as cervical dislocation.

### 2. Requirements for effective use

- a) Sufficient quantities of anaesthetic need to be ingested rapidly for effective response.
- b) Intake of sufficient quantities is facilitated if the birds are fasted or water is withheld.

c) Must be followed by killing (see Article 3.7.6.17) if birds are anaesthetised only.

3. Advantages

- a) Handling is not required until birds are anaesthetised.
- b) There may be biosecurity advantages in the case of large numbers of diseased birds.

4. Disadvantages

- a) Non-target animals may accidentally access the medicated feed or water when provided in an open environment.
- b) Dose taken is unable to be regulated and variable results may be obtained.
- c) Animals may reject adulterated feed or water due to illness or adverse flavour.
- d) The method may need to be followed by killing.
- e) Care is essential in the preparation and provision of treated feed or water, and in the disposal of uneaten treated feed/water and contaminated carcasses.

5. Conclusion

The method is suitable for killing large numbers of poultry in houses.

Article 3.7.6.17.

**Killing methods in unconscious animals**

1. Method 1: Cervical dislocation (manual and mechanical)

*34.1.a) Introduction*

Poultry may be killed by either manual cervical dislocation (stretching) or mechanical neck crushing with a pair of pliers. Both methods result in death from asphyxiation and/or cerebral anoxia.

**Community comments:**

**The following text should be added here:**

**"Conscious birds of less than 250 grams may be killed using cervical dislocation in such a way that the blood vessels of the neck are severed and death is instantaneous"**

**Justification: Cervical dislocation is an effective method of killing without prior stunning if used by skilled operators on small birds and for a limited number of animals as to prevent operators' fatigue. See EFSA report for further considerations.**

*34.2.b) Requirements for effective use*

- i) Killing should be performed either by manually or mechanically stretching the neck to sever the spinal cord or by using mechanical pliers to crush the cervical vertebrae with consequent major damage to the spinal cord.

- ii) Consistent results require strength and skill so team members should be rested regularly to ensure consistently reliable results.
- iii) Birds should be monitored continuously until death to ensure the absence of brain stem reflexes.

34.3.c) *Advantages*

- i) It is a non-invasive killing method.
- ii) It can be performed manually on small birds.

34.4.d) *Disadvantages*

- i) Operator fatigue.

**Community comments:**

**Paragraph ii) should be replaced by the following text:**

**"ii) The method is more difficult in larger birds and its use should be avoided in any case for birds over 3 kg of live weight".**

**Justification: The method should be avoided on birds weighing more than 3 kg as the physical efforts required to properly perform it increase with the size of the birds. See EFSA report for scientific basis.**

- ii) The method is more difficult in larger birds.

34.5.e) *Conclusion*

This method is suitable for killing unconscious poultry.

2. Method 2: Decapitation

34.6.a) *Introduction*

Decapitation results in death by cerebral ischaemia using a guillotine or knife.

34.7.b) *Requirements for effective use*

The required equipment should be kept in good working order.

34.8.c) *Advantages*

The technique is effective and does not require monitoring.

34.9.d) *Disadvantages*

The working area is contaminated with body fluids.

34.10. e) *Conclusion*

This method is suitable for killing unconscious poultry.

3. Method 3: Pithing

34.11. a) *Introduction*

Pithing is a method of killing animals which have been stunned by a penetrating captive bolt, without immediate death. Pithing results in the physical destruction of the brain and upper regions of the spinal cord, through the insertion of a rod or cane through the bolt hole.

34.12. b) *Requirements for effective use*

- i) Pithing cane or rod is required.
- ii) An access to the head of the animal and to the brain through the skull is required.
- iii) Animals should be monitored continuously until death to ensure the absence of brain stem reflexes.

34.13. c) *Advantages*

The technique is effective in producing immediate death.

34.14. d) *Disadvantages*

- i) A delayed and/or ineffective pithing due to convulsions may occur.
- ii) The working area is contaminated with body fluids.

34.15. e) *Conclusion*

This method is suitable for killing unconscious animals which have been stunned by a penetrating captive bolt.

4. Method 4: Bleeding

34.16. a) *Introduction*

**Community comments:**

**Add the following sentence to the end of the next paragraph:**

**"Bleeding out should be completed and any incision made should ensure the complete severance of both carotid arteries, or the vessels from which they arise (e.g. chest stick)."**

**Justification: See EFSA report for scientific elaboration on this point.**

Bleeding is a method of killing animals through the severance of the major blood vessels in the neck or chest that results in a rapid fall in blood pressure, leading to cerebral ischaemia and death.

34.17. b) *Requirements for effective use*

- i) A sharp knife is required.
- ii) An access to the neck or chest of the animal is required.
- iii) Animals should be monitored continuously until death to ensure the absence of brain stem reflexes.

34.18. c) *Advantages*

The technique is effective in producing death after an effective stunning method which does not permit pithing.

34.19. d) *Disadvantages*

- a) A delayed and/or ineffective bleeding due to convulsions may occur.
- b) The working area is contaminated with body fluids.

34.20. e) *Conclusion*

This method is suitable for killing unconscious animals.

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