

MEETING OF THE OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION**Paris, 17–24 February 2017**

List of participants**MEMBERS OF THE CODE COMMISSION**

Dr Etienne Bonbon*President*

Scientific Counsellor
 EU Delegation to the International
 Organisations in Paris
 12, avenue d'Eylau
 75116 Paris
 FRANCE
 Tel.: +33 1 44 05 31 68
 etienne.bonbon@eeas.europa.eu
 e.bonbon@oie.int

Prof. Emmanuel Couacy-Hymann

Virologist - Epidemiologist
 Laboratoire Centrale de Pathologie
 Animale
 BP 206 - Bingerville
 COTE D'IVOIRE
 chymann@hotmail.com

Dr Gaston Maria Funes*Vice-President*

Avenue Louise 225, 1050 Brussels
 Counsellor for Agricultural Affairs
 Embassy of Argentina to the EU
 BELGIUM
 funes@agricola-ue.org

Prof. Salah Hammami

Epidemiologist & Virologist
 Services of Microbiology-
 Immunology & General Pathology
 National School of Veterinary
 Medicine
 Sidi Thabet -2020
 TUNISIA
 Tel.: + 216 71 552 200
 hammami.salah@iresa.agrinet.tn
 saleehammami@yahoo.fr

Prof. Stuart MacDiarmid*Vice-President*

Adjunct Professor in Veterinary Biosecurity
 Massey University
 4 Karepa Street
 Wellington 6021
 NEW ZEALAND
 Tel.: +64 4 934 8322
 stuart.macdiarmid@paradise.net.nz

Dr Masatsugu Okita

Deputy Director
 Animal Products Safety Division
 Ministry of Agriculture, Forestry and
 Fisheries
 1-2-1 Kasumigaseki
 Chiyoda-ku
 Tokyo 100-8950
 JAPAN
 masatsugu_okita130@maff.go.jp

OIE HEADQUARTERS

Ms Ann Backhouse

Head
 Standards Department
 a.backhouse@oie.int

Dr Gillian Mylrea

Deputy Head
 Standards Department
 g.mylrea@oie.int

Dr Jae Myong Lee

Chargé de mission
 Standards Department
 j.lee@oie.int

Dr Patricia Pozzetti

Chargée de mission
 Standards Department
 p.pozzetti@oie.int

Dr Leopoldo Stuardo

Chargé de mission
 Standards Department
 l.stuardo@oie.int

Dr Harry Kwok

Intern
 Standards Department
 h.kwok@oie.int

MEETING OF THE OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION**Paris, 13–24 February 2017**

Agenda

- 1. Meeting with the Director General**
- 2. Adoption of the agenda**
- 3. Cooperation with other Specialist Commissions**
- 4. Texts proposed for adoption at the General Session in May 2017**
 - 4.1. Glossary Part A, A' and A''
 - 4.2. Criteria for the inclusion of diseases, infections and infestations in the OIE list (Article 1.2.1.)
 - 4.3. Diseases, infections and infestations listed by the OIE (the Preamble of Chapter 1.3.)
 - 4.4. Draft new chapter on criteria applied by the OIE for assessing the safety of commodities (Chapter 2.X.)
 - 4.5. High health status horse subpopulation (Article 4.16.3.)
 - 4.6. OIE procedures relevant to the Agreement on the Application of Sanitary and Phytosanitary Measures on the World Trade Organization (Chapter 5.3.)
 - 4.7. Draft new chapter on prevention and control of *Salmonella* in bovines (Chapter 6.X.)
 - 4.8. Draft new chapter on prevention and control of *Salmonella* in pigs (Chapter 6.Y.)
 - 4.9. Animal welfare and dairy cattle production systems (Article 7.11.6.)
 - 4.10. Welfare of working equids (Chapter 7.12.)
 - 4.11. Draft new chapter on infection with *Mycobacterium tuberculosis* complex (Chapter 8.X.)
 - 4.12. Infection with avian influenza viruses (Article 10.4.25.)
 - 4.13. Infection with lumpy skin disease (Chapter 11.11.)
 - 4.14. Infection with *Burkholderia mallei* (glanders) (Chapter 12.10.)
 - 4.15. Infection with African swine fever virus (Chapter 15.1.)
 - 4.16. Draft new chapter on infection with porcine reproductive and respiratory syndrome virus (PRRS) (Chapter 15.X.)
 - 4.17. Somatic cell nuclear transfer in production livestock and horses (Article 4.11.4.)
 - 4.18. Import risk analysis (Chapter 2.1.)
- 5. Texts circulated for Member Countries' comments**
 - 5.1. Glossary Part B
 - 5.2. Zoning and compartmentalisation (Chapter 4.3.)
 - 5.3. Draft new chapter on vaccination (Chapter 4.X.)
 - 5.4. Collection and processing of *in vitro* derived embryos from livestock and equids (Chapter 4.8.)

Annex 2 (contd)

- 5.5. Report of the December 2016 meeting of the Animal Production Food Safety Working Group meeting
 - 5.6. The role of the Veterinary Services in food safety (Chapter 6.1.)
 - 5.7a). Report of the January 2017 meeting of the *ad hoc* Group on Antimicrobial Resistance
 - 5.7b). Harmonisation of national antimicrobial resistance surveillance and monitoring programmes (Chapter 6.7.)
 - 5.8. Draft new article on guiding principles on the use of animal based measures (Article 7.1.X.)
 - 5.9. Report of the January 2017 meeting of the *ad hoc* Group and the draft new chapter on animal welfare and pig production systems (Chapter 7.X.)
 - 5.10. Infection with bluetongue virus (Chapter 8.3.)
 - 5.11. Infection with foot and mouth disease virus (Chapter 8.8.)
 - 5.12. Bovine spongiform encephalopathy (Chapter 11.4.)
- 6. New amendments or draft new chapters proposed for the *Terrestrial Code***
- 6.1. Procedures for self-declaration and for official recognition by the OIE (Chapter 1.6.)
 - 6.2. Draft new chapter on introduction to recommendations for veterinary public health (Chapter 6.Z.)
 - 6.3. Draft new chapter on management of outbreaks of listed diseases (Chapter 4.Y.)
 - 6.4. The draft new chapter on slaughter and killing of farmed reptiles for their skins and meat (Chapter 7.Y.)
 - 6.5. Infection with *Brucella abortus*, *B. melitensis* and *B. suis* (Chapter 8.4.)
 - 6.6. Infection with rinderpest virus (Article 8.15.2.)
 - 6.7. Infection with classical swine fever virus (Chapter 15.2.)
 - 6.8. Report of the November 2016 meeting of the *ad hoc* Group on Animal Welfare and Laying Hens Production Systems
 - 6.9. Proposed amendment of OIE definition of ‘*animal welfare*’ by Animal Welfare Working Group
- 7. Other issues**
- 7.1. Report of the November 2016 meeting of the *ad hoc* Group on Veterinary Paraprofessionals
 - 7.2. General comments of Member Countries on the texts circulated after the Code Commission’s September 2016 meeting
 - 7.3. Update of the Code Commission’s work programme
 - 7.4. Editorial corrections for the 2017 Edition of the *Terrestrial Code* including proposed replacement of similar terms currently used in the Code with ‘pathogenic agent’
 - 7.5. Date of next meetings

Report of the joint meeting between the OIE Scientific Commission for Animal Diseases and the OIE Terrestrial Animal Health Standards Commission

16 February 2017 at the OIE Headquarters in Paris

A joint meeting of the Scientific Commission for Animal Diseases (Scientific Commission) and the Terrestrial Animal Health Standards Commission (Code Commission) was convened at the OIE Headquarters in Paris on 16 February 2017.

Dr Monique Eloit, the Director General, at the outset, extended her warm welcome to all the members. In her opening remarks she emphasised the significance and importance of the work of the Specialist Commissions and supported greater collaboration and coordination of issues of common interest and concern to better address the needs of the Member Countries. After the opening remarks of the Director General, agenda items were taken up for discussion. The meeting was then chaired by Dr Matthew Stone, Deputy Director General of the OIE.

Summary of the discussions

1. Issues of mutual interests – *Terrestrial Code*

a) Horizontal chapters

i) Chapter 4.3. Zoning and compartmentalisation

The President of the Code Commission noted that this was a key horizontal chapter of the OIE *Terrestrial Code* as it has an impact on the disease-specific chapters and as such it was the appropriate place to include the new concepts on zoning. In view of the importance of this chapter, it was agreed that a representative of the Scientific Commission would participate in the Code Commission meeting in order to assist with the discussion of some of the critical issues of the chapter.

The meeting identified certain issues of immediate attention and proposed to look at those issues as a priority during the discussion at the Code Commission. The areas identified were:

- how to define the *protection zone*;
- ways to allow more than one *containment zone* in a country;
- new zoning concepts proposed by the *ad hoc* Group on FMD in response to Member Countries' comments.

ii) Draft new chapter on management of outbreaks of listed diseases

It was noted that the new chapter on management of outbreaks of listed disease had already been drafted by the Code Commission.

The meeting agreed that the two Commissions will work in parallel in developing the new chapter on management of outbreaks of listed diseases taking into account comments of the Member Countries.

Annex 3 (contd)**iii) Chapter 1.6. Procedure for self-declaration and for official recognition by the OIE**

The Headquarters updated the Commissions on progress towards the revision and harmonisation, when relevant, of the questionnaires for the official recognition of disease status for six diseases (AHS, BSE, CBPP, CSF, FMD, and PPR) and the official control programme for three diseases (CBPP, FMD, PPR) included in Chapter 1.6. It also noted the progress on strengthening of the procedures for self-declaration of disease freedom.

The revised questionnaires have been prepared by the OIE Headquarters, in consultation with each *ad hoc* Group on disease status and the Scientific Commission, and presented to the *Terrestrial Code* Commission for further circulation for Member Countries' comments.

Both Commissions were of the view that these revised questionnaires should be circulated to Member Countries for comment and in addition agreed to seek their views on the removal of the questionnaires from the *Terrestrial Code*. The questionnaires would then only be available on the OIE website and could be revised and updated as necessary.

iv) Chapter 1.4. Animal Health Surveillance

The OIE Headquarters presented a brief update on on-going preparatory activities towards convening an *ad hoc* Group on animal health surveillance, tentatively scheduled to be held in June 2017.

The Code Commission asked the OIE Headquarters to provide it with an opportunity to participate in developing the Terms of Reference (ToR) for the *ad hoc* Group to accurately convey the Member Countries' specific requests for a revision of the chapter. It was agreed that there was a need for participation of representatives of both Commissions in the planned meeting of the *ad hoc* Group.

v) Antimicrobial resistance

The Headquarters gave a brief update to the Commissions on the ongoing discussion about the proposed definitions for 'therapeutic use', 'preventative use' and 'growth promotion' proposed by the *ad hoc* Group on AMR, with a view to update Chapter 6.8.

The Code Commission took note of the report of the *ad hoc* Group on AMR (January 2017), which had been endorsed by the Scientific Commission and its advice on the Member Countries comments on the proposed amendments of Chapter 6.7. The Code Commission also indicated that the revised Chapter 6.7. and the proposed new definitions related to AMR would be circulated for Member Countries' comments. The Code Commission also noted that revision of Chapter 6.8. would be included in its work programme with a view to further discussion at its September 2017 meeting.

b) Disease-specific chapters**i) Chapter 8.15. Infection with rinderpest – proposal for revised definition**

The Commissions considered the amendments proposed by a Member Country and the FAO-OIE Rinderpest Joint Advisory Committee (JAC) on the definition of rinderpest virus (RPV) containing material in Chapter 8.15. and agreed to circulate the revised definition for Member Countries' comments with a view to its adoption in 2018.

ii) Chapter 8.X. Infection with *Mycobacterium tuberculosis* complex

The Scientific Commission noted that it had provided the scientific reference to support the proposed amendments made in the chapter and the Code Commission noted that it anticipated this would go for adoption in 2017.

iii) Chapters on equine and non-equine trypanosomiasis

- a) revised Chapter 12.3. on infection with Trypanozoon in equids (dourine, equine surra), and
- b) the draft new Chapter 8.X. on infection with *Trypanosoma evansi* (non-equine surra).

The Scientific Commission explained that since it had identified some inconsistencies between the two draft chapters proposed by an *ad hoc* Group on equine trypanosomiasis, it decided there was a need to revisit the chapters before forwarding them to the Code Commission for further consideration. The Code Commission noted that in light of its full agenda it would not have an opportunity to review these chapters until its September 2017 meeting.

iv) Chapter 8.8. Infection with foot and mouth disease virus (FMD)

The Scientific Commission advised that the proposed amendments on the FMD chapter had been forwarded to the Code Commission for consideration. It also noted that an *ad hoc* Group was to be convened in order to explore and develop other tools that may allow the introduction of more flexibility in the waiting periods for recovery of free status.

The Code Commission advised that it would take into consideration the comments provided by the Scientific Commission and the report of the *ad hoc* Group on FMD held in June 2016. It was agreed that a representative of the Scientific Commission would participate in the 2nd week of the Code Commission in order to facilitate the discussion on several key articles of the chapter.

v) Chapter 12.10. Infection with *Burkholderia mallei*

The Scientific Commission explained that extensive comments from Member Countries on the amended articles on surveillance were sent to it for advice. It was decided to consult the OIE experts on glanders in order to address these comments and the expert opinion would be considered at its September 2017 meeting.

The Code Commission noted that in light of the need for further expert opinion and that the Biological Standards Commission had proposed a revised *Manual* chapter on glanders for Member Country comments and possible adoption in 2018, it would make a decision on the next step in revising the chapter in the course of its meeting.

The Chair of the joint meeting drew attention to the fact that the revised chapter on glanders had been proposed for adoption in May 2017 in the Code Commission's September 2016 meeting report, and requested the Code Commission to give clear explanation in its report on the decision on this chapter in order to avoid unnecessary confusion.

vi) Chapter 11.11. Infection with lumpy skin disease (LSD)

The Scientific Commission explained that it had proposed amendments to the recovery of free status in response to questions arising from comments from a Member Country. The Code Commission noted that it would undertake the review of the revised chapter in the course of its meeting and anticipated that it would be able to propose it for adoption in May 2017.

Annex 3 (contd)**2. Other business****a) Peste des petits ruminants (PPR) Mongolia – situation**

The Code Commission noted that the recent PPR outbreaks in Mongolia have raised concerns and that there was a need to review the epidemiological role of wildlife in this disease.

The Scientific Commission agreed with the need for further scientific evidence to clarify the role of wildlife in the epidemiology of PPR in Mongolia. It however noted that the current provisions on wildlife in the *Terrestrial Code* are still valid and there is no need for a revision of the chapter at this stage.

b) Updating of Commissions' work programmes - 5 key priorities per commission for 2017

The Chair invited each Commission to present the 5 key priority issues on their work programmes.

The Scientific Commission highlighted the following key priority areas for 2017:

- revision of waiting period for the recovery of FMD free status;
- revision of Chapter 1.4. on surveillance;
- revision of Chapter 4.3. on zoning and compartmentalisation;
- proposed new concepts in FMD chapter;
- revision of 15 questionnaires in Chapter 1.6.

The Code Commission highlighted the following key priority areas for 2017:

- revision and reorganisation of Chapter 1.6.;
- restructure of Section 4 (especially new chapters on outbreak management and vaccination);
- revision of chapters on veterinary public health (especially on Chapters 6.1. and 6.2.);
- revision of Chapter 10.4. on AI;
- revision of Chapter 15.2. on CSF.

3. Information on recent & upcoming *ad hoc* Group meetings

The OIE Headquarters noted there were a number of *ad hoc* Group meetings planned for the coming year and that given budget constraints there may be a need to prioritise them. It also noted that the timing of *ad hoc* Group meetings impacted on the ability of the Commissions to fully consider these reports, particularly where the *ad hoc* Group was proposing significant change to chapters in response to Member Countries' comments.

4. Dates of next meetings

The OIE Headquarters noted that the dates for the September meetings would not allow for a joint meeting; however it was anticipated that this scheduling would allow for greater interaction between the Secretariats of the Commissions and facilitate better exchange of information between the two Commissions.

5. Coordination between the Specialist Commissions

The secretariat updated the Commissions on the progress being made to provide a more harmonised approach to the provision of secretariat functions to the four Commissions including strengthening and clarifying roles and responsibilities of the secretariat, better planning and coordination of agendas.

Noting that the members of Specialist Commissions are in general not Delegates it was agreed to circulate the unofficial reports of both Commissions to Members of the Commissions at the same time as they were uploaded to the Delegate website.

As part of new efforts to improve coordination, the secretariat proposed mechanisms for communication between Commissions in between regular meetings. Two possible scenarios were presented: 1) to create a meeting of the bureaus of the Commissions during the General Session; and 2) to utilise a teleconference with members of the Commissions to follow up on specific topics with the Headquarters between Commission meetings and report back to the respective Commissions.

Both Commissions expressed their full support for the initiative proposed by the secretariat and agreed that there was a need to work more closely between sessions.

GLOSSARY (PART A–AMENDMENTS)

ANIMAL HEALTH STATUS

means the status of a country, ~~or a zone~~ or compartment with respect to an *animal disease* in accordance with the criteria listed in the relevant disease-specific chapter or Chapter 1.4. of the *Terrestrial Code dealing with the disease*.

CAPTIVE WILD [ANIMAL]

means an *animal* that has a phenotype not significantly affected by human selection but that is captive or otherwise lives under direct human supervision or control, including zoo *animals* and pets.

FERAL [ANIMAL]

means an *animal* of a domesticated species that now lives without direct human supervision or control.

INFECTION

means the entry and development or multiplication of an ~~infectious~~ pathogenic agent in the body of humans or *animals*.

INFESTATION

means the external invasion or colonisation of *animals* or their immediate surroundings by arthropods, which may cause ~~disease clinical signs~~ or are potential *vectors* of ~~infectious~~ pathogenic agents.

NOTIFICATION

means the procedure by which:

- a) the *Veterinary Authority* informs the *Headquarters*,
- b) the *Headquarters* inform the *Veterinary Authority*,

of the occurrence ~~of an outbreak of disease,~~ or infection or infestation in accordance with Chapter 1.1.

PATHOGENIC AGENT

~~means an organism that causes or contributes to the development of a disease.~~

WILD [ANIMAL]

means an *animal* that has a phenotype unaffected by human selection and lives independent of direct human supervision or control.

 — Text deleted.

Annex 4 (contd)

GLOSSARY (PART A'–DELETIONS)

~~POST-JOURNEY PERIOD~~

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

~~QUALITY~~

~~is defined by International Standard ISO 8402 as 'the totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs'.~~

~~TRANSPORT/TRANSPORTATION~~

~~means the procedures associated with the carrying of animals for commercial purposes from one location to another by any means.~~

~~TRANSPORTER~~

~~means the person licensed by the Competent Authority to transport animals.~~

~~TRAVEL~~

~~means the movement of a vehicle/vessel or container carrying animals from one location to another.~~

~~ZOOZOSIS~~

~~means any disease or infection which is naturally transmissible from animals to humans.~~

— Text deleted.

GLOSSARY (PART A''-EDITORIAL)

ANIMAL HANDLER

means a person with a knowledge of the behaviour and needs of *animals* who, with appropriate experience and a professional and positive response to an *animal's* needs, can achieve effective management and good *welfare*. Competence should be gained through formal training ~~and/or~~ practical experience.

ANIMAL IDENTIFICATION SYSTEM

means the inclusion and linking of components such as identification of *establishments* ~~or~~ *owners*, the person(s) responsible for the *anima*(s), movements and other records with *animal identification*.

ANIMAL WELFARE

means how an *animal* is coping with the conditions in which it lives. An *animal* is in a good state of *welfare* if (as indicated by scientific evidence) it is healthy, comfortable, well nourished, safe, able to express innate behaviour, and if it is not suffering from unpleasant states such as pain, fear and distress. Good *animal welfare* requires *disease* prevention and veterinary treatment, appropriate shelter, management, nutrition, humane handling and humane *slaughter* and *killing*. *Animal welfare* refers to the state of the *animal*; the treatment that an *animal* receives is covered by other terms such as animal care, animal husbandry, and humane treatment.

FLOCK

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

HERD

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

INCUBATION PERIOD

means the longest period ~~which that~~ elapses between the introduction of the pathogen into the *animal* and the occurrence of the first clinical signs of the *disease*.

INTERNATIONAL VETERINARY CERTIFICATE

means a certificate, issued in accordance with Chapter 5.2., describing the animal health ~~and/or~~ public health requirements ~~which that~~ are fulfilled by the exported *commodities*.

KILLING

means any procedure ~~which that~~ causes the *death* of an *animal*.

OFFICIAL VETERINARIAN

means a *veterinarian* authorised by the *Veterinary Authority* of the country to perform certain designated official tasks associated with animal health ~~and/or~~ public health and inspections of *commodities* and, when appropriate, to certify in accordance with Chapters 5.1. and 5.2.

Annex 4 (contd)**QUARANTINE STATION**

means an *establishment* under the control of the *Veterinary Authority* where *animals* are maintained in isolation with no direct or indirect contact with other *animals*, to ensure that there is no transmission of specified pathogen(s) outside the *establishment* while the *animals* are undergoing observation for a specified length of time and, if appropriate, testing ~~and~~ or treatment.

RESPONSIBLE DOG OWNERSHIP

means the situation whereby a person (~~as defined above~~) accepts and commits to perform various duties in accordance with the legislation in place and focused on the satisfaction of the behavioural, environmental and physical needs of a dog and to the prevention of risks (aggression, *disease* transmission or injuries) that the dog may pose to the community, other *animals* or the environment.

SAFE COMMODITY

means a *commodity* ~~which~~ that can be traded without the need for risk mitigation measures specifically directed against a particular listed *disease*, *infection* or *infestation* and regardless of the status of the country or *zone* of origin for that *disease*, *infection* or *infestation*.

SLAUGHTER

means any procedure ~~which~~ that causes the *death* of an *animal* by bleeding.

STUNNING

means any mechanical, electrical, chemical or other procedure ~~which~~ that 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.

— Text deleted.

CHAPTER 1.2.

**CRITERIA FOR THE INCLUSION OF DISEASES,
INFECTIONS AND INFESTATIONS IN THE OIE LIST**

Article 1.2.1.

Introduction

This chapter describes the criteria for the inclusion of *diseases*, *infections* and *infestations* in Chapter 1.3.

The objective of ~~listing diseases~~ is to support Member Countries by providing information needed to take appropriate action to prevent the transboundary spread of important animal *diseases*, including *zoonoses*. This is achieved by transparent, timely and consistent *notification*.

Each *listed disease* normally has a corresponding chapter that ~~to~~ assists Member Countries in the harmonisation of *disease* detection, prevention and control, and provides standards for safe *international trade* in *animals* and their products.

The requirements for *notification* are detailed in Chapter 1.1.

Principles and methods of validation of diagnostic tests are described in Chapter 1.1.5. of the *Terrestrial Manual*.

[...]

— Text deleted.

CHAPTER 1.3.

**DISEASES, INFECTIONS AND INFESTATIONS
LISTED BY THE OIE**

Preamble

The following *diseases, infections and infestations in this chapter* ~~are~~ have been assessed in accordance with Chapter 1.2. and constitute ~~included in the OIE list of terrestrial animal diseases.~~

In case of modifications of this list adopted by the World Assembly of Delegates, the new list comes into force on 1 January of the following year.

[...]

— Text deleted.

CHAPTER 2.X.

CRITERIA APPLIED BY THE OIE FOR ASSESSING THE SAFETY OF COMMODITIES

Article 2.X.1.

Assessing the safety of animal products from a country or zone not free from a specific listed disease

General provisions

For the purposes of this chapter the word 'safety' is applied only to animal and human health considerations for *listed diseases*.

In many *disease-specific* chapters, Article X.X.2, the second article lists *animal products commodities* that can be traded from a country or zone regardless of its status with respect to not free from the specific *listed disease*. The criteria for their inclusion of *animal products* in the list of *safe commodities* are based on the absence of the pathogenic agent in the traded *animal products commodity*, either due to its absence in the tissues from which the *animal products commodity* are is derived or to its inactivation by the processing or treatment that the *animal products* have undergone.

The assessment of the safety of the *animal products commodities* using the criteria relating to processing or treatment can only be undertaken when processing or treatments are well defined. It may not be necessary to take into account the entire process or treatment, so long as the steps critical for the inactivation of the pathogen pathogenic agent of concern are considered.

It is ~~assumed~~ expected that processing or treatment (i) uses standardised protocols, which include the steps considered critical in the inactivation of the pathogenic agent of concern; (ii) is conducted in accordance with Good Manufacturing Practices; and (iii) that any other steps in the treatment, processing and subsequent handling of the *animal product* do not jeopardise its safety.

Article 2.X.2.

Criteria

For an *animal product* to be considered a *safe commodity* for *international trade*, it should comply with the following criteria:

- 1) There is strong evidence that the pathogenic agent is not present in the tissues from which the *animal product* is derived ~~at a in an amount concentration~~ able to cause *infection* in a human or *animal* by a natural exposure route. This evidence is based on the known distribution of the pathogenic agent in an infected *animal*, whether or not it shows clinical signs of *disease*.

OR

- 2) If the pathogenic agent may be present in, or may contaminate, the tissues from which the *animal product* is derived, the standard processing or treatment normally applied to produce the *animal product commodity* to be traded, while not being specifically directed at this ~~pathogen~~ pathogenic agent, inactivates ~~the pathogen~~ it to the extent that possible *infection* of a human or *animal* is prevented through its action, which is:

- a) physical (e.g. temperature, drying, irradiation);

or

- b) chemical (e.g. iodine, pH, salt, smoke);

Annex 7 (contd)

or

c) biological (e.g. fermentation);

or

d) a combination of a) to c) above.

— Text deleted.

CHAPTER 4.16.

HIGH HEALTH STATUS HORSE SUBPOPULATION

[...]

Article 4.16.3.

Recommendations for the Veterinary Authorities

Organisations that are responsible for ensuring compliance with this chapter should be authorised and supervised by the *Veterinary Authorities*. *Veterinary Authorities* are ~~also~~ encouraged to develop specific protocols for the temporary importation of horses of high health status entering the country for the purpose of competition at equestrian events or for their onward movement to other such events and for their return to their country of usual residence.

Veterinary Authorities are encouraged to recognise the international biosecurity plan developed by the FEI and IFHA on the basis of the *OIE Handbook for the Management of High Health, High Performance Horses*, ~~the relevant OIE biosecurity guidelines (under study)~~.

— Text deleted.

CHAPTER 5.3.

OIE PROCEDURES RELEVANT TO THE AGREEMENT ON THE APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES OF THE WORLD TRADE ORGANIZATION

Article 5.3.1.

The Agreement on the Application of Sanitary and Phytosanitary Measures and role and responsibility of the OIE

The *Agreement on the Application of Sanitary and Phytosanitary Measures* (SPS Agreement) specifically encourages the Members of the World Trade Organization to base their *sanitary measures* on international standards, guidelines and recommendations, where they exist. Members may choose to implement sanitary measures more stringent ~~adopt a higher level of protection than that provided by those in~~ international standards, texts ~~if these are deemed necessary to protect animal or human health and are scientifically justified by a risk analysis~~ ~~there is a scientific justification or if the level of protection provided by the relevant international texts is considered to be inappropriate~~. In such circumstances, Members are ~~subject to obligations relating to risk assessment and to~~ should adopt a consistent approach of to risk management.

~~The SPS Agreement encourages Governments to make a wider use of risk analysis: WTO Members shall undertake an assessment as appropriate to the circumstances of the actual risk involved.~~

To promote transparency, ~~The~~ the SPS Agreement, in Article 7, obliges WTO Members to notify changes in, and provide relevant information on, *sanitary measures* ~~which~~ that may, directly or indirectly, affect international trade.

The SPS Agreement recognises the OIE as the relevant international organisation responsible for the development and promotion of international animal health standards, guidelines, and recommendations affecting trade in live *animals* and animal products.

Article 5.3.2.

Introduction ~~on~~ to the judgement determination of the equivalence of sanitary measures

The importation of *animals* and animal products involves a degree of *risk* ~~to the animal health status and human health status of~~ in an *importing country*. The estimation of that *risk* and the choice of the appropriate *risk management* option(s) are made ~~more~~ difficult by differences among the animal health management systems and animal production and processing systems in Member Countries. However, ~~it is now recognised that~~ significantly different animal health and production systems and measures ~~can provide~~ may achieve equivalent animal and human health protection for the purposes of *international trade*, ~~with benefits to both the importing country and the exporting country.~~

~~These~~ The recommendations in this chapter are intended to assist Member Countries to determine whether *sanitary measures* arising from different animal health and production systems ~~may provide~~ achieve the same level of animal and human health protection. They discuss principles ~~which might~~ that may be utilised in a judgement determination of equivalence, and outline a step-wise process for trading partners to follow ~~in~~ facilitating a judgement of equivalence. These provisions are applicable whether equivalence applies ~~at the level of~~ to specific measures or on a systems-wide basis, and whether equivalence applies to specific areas of trade or *commodities*, or in generally general.

Annex 9 (contd)

Article 5.3.3.

General considerations on the judgement determination of the equivalence of sanitary measures

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

~~International recognition of the legitimacy of different approaches to achieving the importing country's appropriate level of protection (ALOP) has led to the principle of equivalence being included in trade agreements, including the SPS Agreement of the WTO.~~

If trading partners agree that the measures applied achieve the same level of health protection, these measures are considered equivalent. Benefits of applying equivalence may include:

- 1) minimising costs associated with international trade by tailoring allowing sanitary measures to be tailored ~~animal health measures~~ to local circumstances;
- 2) maximising animal health outcomes for a given level of resource input;
- 3) facilitating trade by achieving the required health protection through less trade restrictive *sanitary measures*; and
- 4) decreased reliance on relatively costly commodity testing and isolation procedures ~~in bilateral or multilateral agreements.~~

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

~~It is essential to apply a scientific~~ Member Countries should use *risk analysis* to the extent practicable in establishing the basis for a judgement determination of equivalence.

Article 5.3.4.

Prerequisite considerations ~~in a judgement~~ for the determination of equivalence1) Application of risk assessment

~~Application of the discipline of risk~~ Risk assessment provides a structured basis for judging equivalence among different *sanitary measures* as it allows a comparison ~~close examination to be made~~ of the effect of a measure(s) on a particular step(s) in the importation pathway, ~~and the relative~~ with the effects of a proposed alternative measure(s) ~~on the same or related steps.~~

A judgement determination of equivalence ~~should~~ needs to assess compare the effectiveness of the *sanitary measures* ~~in terms of its effectiveness against~~ regarding the particular *risk* or group of *risks* against which ~~it~~ the measure is they are designed to protect. Such an assessment may include the following elements: the purpose of the measure, the level of protection achieved by the measure and the contribution the measure makes to achieving the ALOP of the importing country.

2) Categorisation of sanitary measures

Proposals for equivalence may ~~be in terms of a measure comprising~~ consider a single component of a measure (e.g. an isolation or sampling procedure, a test or treatment requirement, a certification procedure) or multiple components (e.g. a production system for a commodity) of a measure, or a combination of measures. ~~Multiple components or combinations of measures~~ Measures may be applied consecutively or concurrently.

Annex 9 (contd)

~~Sanitary measures are those described in each the disease-specific chapter of the *Terrestrial Code* which are used for to manage risks reduction and are appropriate for particular posed by that diseases, infection or infestation. Sanitary measures may be applied either alone or in combination and include test requirements, processing requirements, inspection or certification procedures, quarantine confinements, and sampling procedures.~~

For the purposes of ~~judging~~ determining equivalence, *sanitary measures* can be broadly categorised as:

- a) infrastructure: including the legislative base (e.g. animal health law) and administrative systems (e.g. organisation of Veterinary Services national and regional animal health authorities, emergency response organisations);
- b) programme design and implementation: including documentation of systems, performance and decision criteria, *laboratory* capability, and provisions for certification, audit and enforcement;
- c) specific technical requirement: including requirements applicable to the use of secure facilities, treatment (e.g. retorting of cans), specific test (e.g. ELISA) and procedures (e.g. pre-export inspection).

A ~~sanitary~~ Sanitary measure(s) proposed for a judgement determination of equivalence may fall into one or more of these categories, which are not mutually exclusive.

In some cases, such as a method for pathogen inactivation, a comparison of specific technical requirements may suffice. In many instances, however, ~~a judgement as to~~ assessment of whether the same level of protection is likely to will be achieved may only be able to be determined through an evaluation of all relevant components of an *exporting country's animal health management systems* and animal production systems. For example, a judgement of equivalence for a specific sanitary measure at the programme design/implementation level may require a prior examination of infrastructure while a judgement of equivalence for a specific measure at the specific technical requirement level may require that the specific measure be judged in its context through examination of infrastructure and programmes.

Article 5.3.5.

Principles for ~~judgement~~ determination of equivalence

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

- 1) an *importing country* has the right to set the level of protection it deems appropriate (~~its ALOP~~) in relation to human and animal life and health in its territory; this ALOP may be expressed in qualitative or quantitative terms;
- 2) the *importing country* should be able to describe the reason for each *sanitary measure* i.e. the level of protection intended to be achieved by application of the identified measure against a hazard risk;
- 3) an *importing country* should recognise that *sanitary measures* different from the ones it has proposed may be capable of ~~providing~~ achieving the same level of protection, in particular, it should consider the existence of free zones or compartments, and of safe commodities;
- 4) the *importing country* should, upon request, ~~enter into consultations~~ consult with the *exporting country* with the aim of facilitating a judgement determination of equivalence;
- 5) any *sanitary measure* or combination of *sanitary measures* can be proposed for judgement determination of equivalence;
- 6) an interactive process should be followed that applies a defined sequence of steps, and utilises an agreed process for exchange of information, so as to limit data collection to that which is necessary, to minimise administrative burden, and to facilitate resolution of claims;
- 7) the *exporting country* should be able to demonstrate objectively how the alternative *sanitary measure(s)* proposed as equivalent will provide the same level of protection;
- 8) the *exporting country* should present a submission for equivalence in a form that facilitates judgement determination by the *importing country*;

Annex 9 (contd)

- 9) the *importing country* should evaluate submissions for equivalence in a timely, consistent, transparent and objective manner, and in accordance with appropriate *risk assessment* principles;
- 10) the *importing country* should take into account any knowledge of and prior experience with the *Veterinary Authority* or other *Competent Authority* of the *exporting country*;
- 10bis) the *importing country* should take into account any arrangements it has with other *exporting countries* on similar issues;
- 10ter) the *importing country* may also take into account any knowledge of the *exporting country's* arrangements with other *importing countries*;
- 11) the *exporting country* should provide access to enable the procedures or systems ~~which that~~ are the subject of the equivalence ~~judgement~~ determination to be examined and evaluated upon request of the *importing country*;
- 12) the *importing country* should be the sole ~~determinant~~ judge of equivalence, but should provide to the *exporting country* a full explanation for its judgement;
- 13) to facilitate a ~~judgement~~ determination of equivalence, Member Countries should base their *sanitary measures* on relevant OIE standards and guidelines, where these exist. However, they may choose to implement more stringent sanitary measures if these are scientifically justified by a risk analysis;
- 14) to allow the ~~judgement~~ determination of equivalence to be reassessed if necessary, the *importing country* and the *exporting country* should keep each other informed of significant changes to infrastructure, health status or programmes ~~which that~~ may bear on the ~~judgement~~ determination of equivalence; and
- 15) ~~appropriate technical assistance from an importing country, following a should give positive consideration to a request by an exporting developing country, for appropriate technical assistance that would may facilitate the successful completion of a judgement~~ determination of equivalence.

Article 5.3.6.

Sequence of steps to be taken in judgement determination of equivalence

There is no single sequence of steps ~~which that must should~~ be followed in all ~~judgements~~ determinations of equivalence. The steps that trading partners choose will generally depend on the circumstances and their trading experience. ~~Nevertheless, The the~~ interactive sequence of steps described below may be useful for assessing any all sanitary measures irrespective of their categorisation as infrastructure, programme design/ and implementation or specific technical requirement components of an animal health management system or and animal production system.

This sequence assumes that the *importing country* is meeting its obligations under the WTO SPS Agreement and has in place a transparent measure based either on an international standard or a *risk analysis*.

Recommended steps are:

- 1) the *exporting country* identifies the measure(s) for which it wishes to propose an alternative ~~measure(s)~~, and requests from the *importing country* a reason for its *sanitary measure* in terms of the level of protection intended to be achieved against a ~~hazard(s)~~ risk;
- 2) the *importing country* explains the reason for the measure(s), in terms that which would facilitate comparison with an alternative *sanitary measure(s)* and consistent with the principles set out in these provisions;
- 3) the *exporting country* demonstrates the case for equivalence of an alternative *sanitary measure(s)* in a form ~~which that~~ facilitates evaluation analysis by an *importing country*;
- 4) the *exporting country* responds to any technical concerns raised by the *importing country* by providing relevant further information;

- 5) judgement determination of equivalence by the *importing country* should takes into account as appropriate:
- the impact of biological variability and uncertainty;
 - the expected effect of the alternative *sanitary measure(s)* ~~on all relevant hazards;~~
 - OIE standards and guidelines;
 - ~~application of solely qualitative frameworks where it is not possible or reasonable to conduct quantitative the results of a risk assessment;~~
- 6) the *importing country* notifies the *exporting country* of its judgement and its ~~the underlying~~ reasons within a reasonable period of time. The judgement:
- ~~recognition recognises~~ of the equivalence of the *exporting country's* alternative *sanitary measure(s)*; or
 - requests ~~for~~ further information; or
 - ~~rejection rejects~~ of the case for equivalence of the alternative *sanitary measure(s)*;
- 7) an attempt should be made to resolve any differences of opinion over judgement of a case, ~~either interim or final,~~ by using an agreed mechanism such as to reach consensus (e.g. the OIE informal procedure for dispute mediation), ~~or by referral to an agreed expert (Article 5.3.8.);~~
- 8) depending on the category of measures involved, the *importing country* and the *exporting country* may informally acknowledge the equivalence or enter into a formal or informal agreement of equivalence agreement giving effect to the judgement ~~or a less formal acknowledgement of the equivalence of a specific measure(s) may suffice.~~

An *importing country* recognising the equivalence of an *exporting country's* alternative *sanitary measure(s)* ~~needs to~~ should ensure that it acts consistently with regard to applications from third countries for recognition of equivalence applying to the same or a very similar measure(s). Consistent action does not mean however that a specific measure(s) proposed by several *exporting countries* should always be judged as equivalent because ~~as~~ a measure(s) should not be considered in isolation but as part of a system of infrastructure, policies and procedures, in the context of the animal health situation in the exporting country.

Article 5.3.7.

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

The terms 'zone' and 'zoning' in the Terrestrial Code have the same meaning as 'region', 'area' and 'regionalisation' in the SPS Agreement of the WTO.

The establishment ~~There is no single sequence of steps which should be followed in establishing of a disease-free zone or a compartment is described in Chapter 4.3 and should be considered by trading partners when establishing sanitary measures for trade. The steps that the Veterinary Services of the importing country and the exporting country choose and implement will generally depend on the circumstances existing within the countries and at their borders, and their trading history. The recommended Recommended steps are:~~

- For zoning
 - The *exporting country* identifies a geographical area within its territory, which, based on surveillance, it considers to contain an animal *subpopulation* with a distinct health status with respect to a specific ~~disease/specific diseases,~~ infection or infestation, ~~based on surveillance.~~
 - The *exporting country* describes in the *biosecurity plan* for the *zone* the measures ~~which are being, or will be,~~ applied to distinguish such an area epidemiologically from other parts of its territory, in accordance with the recommendations in the *Terrestrial Code*.

Annex 9 (contd)

- c) The *exporting country* provides:
- i) the above information to the *importing country*, with an explanation of why the area can be treated as an epidemiologically separate *zone* for *international trade* purposes;
 - ii) access to enable the procedures or systems that establish the *zone* to be examined and evaluated upon request by the *importing country*.
- d) The *importing country* determines whether it accepts such an area as a *zone* for the importation of *animals and/or* animal products, taking into account:
- i) an evaluation of the *exporting country's Veterinary Services*;
 - ii) the result of a *risk assessment* based on the information provided by the *exporting country* and its own research;
 - iii) its own animal health situation with respect to the *disease(s)* concerned; and
 - iv) other relevant OIE standards or guidelines.
- e) The *importing country* notifies the *exporting country* of its determination judgement and the underlying its reasons, within a reasonable period of time, being:
- i) recognition of the *zone*; or
 - ii) request for further information; or
 - iii) rejection of the area as a *zone* for *international trade* purposes.
- f) An attempt should be made to resolve any differences over recognition of the *zone*, ~~either in the interim or finally~~, by using an agreed mechanism ~~to reach consensus~~ such as the OIE informal procedure for dispute mediation (Article 5.3.8.).
- g) The *Veterinary Authorities* of the *importing* and *exporting countries* should enter into an formal agreement recognising the *zone*.
2. For compartmentalisation
- a) Based on discussions with the relevant industry, the *exporting country* identifies within its territory a *compartment* comprising an animal *subpopulation* contained in one or more *establishments*, ~~or and~~ other premises operating under common management practices and related to biosecurity plan. The *compartment* contains an identifiable animal *subpopulation* with a distinct health status with respect to a specific *disease(s)*. The *exporting country* describes how this status is maintained through a partnership between the relevant industry and the *Veterinary Authority* of the *exporting country*.
- b) The *exporting country* examines the *compartment's biosecurity plan* and confirms through an audit that:
- i) the *compartment* is epidemiologically closed throughout its routine operating procedures as a result of effective implementation of its *biosecurity plan*; and
 - ii) the *surveillance* and monitoring programme in place is appropriate to verify the status of such a *subpopulation* with respect to ~~such the~~ disease(s) in question.
- c) The *exporting country* describes the *compartment*, in accordance with ~~the recommendations in the~~ Terrestrial Code Chapters 4.3. and 4.4.

Annex 9 (contd)

- d) The *exporting country* provides:
- i) the above information to the *importing country*, with an explanation of why such a *subpopulation* can be treated as an epidemiologically separate *compartment* for *international trade* purposes; and
 - ii) access to enable the procedures or systems that establish the *compartment* to be examined and evaluated upon request by the *importing country*.
- e) The *importing country* determines whether it accepts such a *subpopulation* as a *compartment* for the importation of *animals* or ~~and~~ animal products, taking into account:
- i) an evaluation of the *exporting country's Veterinary Services*;
 - ii) the result of a *risk assessment* based on the information provided by the *exporting country* and its own research;
 - iii) its own animal health situation with respect to the disease(s) concerned; and
 - iv) other relevant OIE standards or guidelines.
- f) The *importing country* notifies the *exporting country* of its ~~determination~~ judgement and ~~the underlying~~ its reasons, within a reasonable period of time, being:
- i) recognition of the *compartment*, or
 - ii) request for further information; or
 - iii) rejection of such a *subpopulation* as a *compartment* for *international trade* purposes.
- g) An attempt should be made to resolve any differences over recognition of the *compartment*, ~~either in the interim or finally~~, by using an agreed mechanism ~~to reach consensus~~ such as the OIE informal procedure for dispute mediation (Article 5.3.8.).
- h) The *Veterinary Authorities* of the *importing* and *exporting countries* should enter into an formal ~~formal~~ agreement recognising the *compartment*.
- i) ~~The Veterinary Authority of the exporting country should promptly inform importing countries of any occurrence of a disease in respect of which the compartment was defined.~~

Article 5.3.8.

The OIE informal procedure for dispute mediation

OIE ~~shall maintain~~ maintains ~~its existing~~ a voluntary in-house mechanisms for assisting Member Countries to resolve differences. In-house procedures that ~~which~~ will apply are that:

- 1) Both parties agree to give the OIE a mandate to assist them in resolving their differences.
- 2) If considered appropriate, the Director General of the OIE recommends an expert, or experts, and a chairman, as requested, agreed by both parties.
- 3) Both parties agree on the terms of reference and working programme, and to meet all expenses incurred by the OIE.

Annex 9 (contd)

- 4) The expert or experts are entitled to seek clarification of any of the information and data provided by either country in the assessment or consultation processes, or to request additional information or data from either country.
- 5) The expert or experts ~~shall~~ submit a confidential report to the Director General of the OIE, who ~~will~~ then transmits it to both parties.

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DRAFT CHAPTER 6.X.

PREVENTION AND CONTROL OF *SALMONELLA* IN COMMERCIAL **CATTLE BOVINE** PRODUCTION SYSTEMS

Article 6.X.1.

Introduction

Nontyphoidal salmonellosis is one of the most common **foodborne food-borne** bacterial diseases in the world with *Salmonella* Enteritidis and *S. Typhimurium* (including monophasic variants) being the predominant serotypes identified in humans in most countries. *S. Enteritidis* is primarily associated with poultry while *S. Typhimurium* may be present in many mammalian and avian hosts. In addition, a These serotypes and several others occur at variable prevalence in **cattle bovines** depending on the region. In some countries *S. Dublin* and *S. Newport* may also cause salmonellosis in humans. limited number of other serotypes associated with cattle may cause salmonellosis in humans, for example, *S. Dublin* and *S. Newport*.

~~As is the case in most food producing animals,~~ *Salmonella* infection in **cattle bovines** is mostly subclinical, although clinical *disease* such as enteritis, septicaemia or abortion can may occur. Subclinical *infection*, can be of variable duration including a carrier state, can be of variable duration and can play an important role in the spread of *Salmonella* within and between *herds* and pose a public health *risk*.

Herd size and stocking density may influence the ~~risk~~ likelihood of introduction, dissemination or persistence of *Salmonella*; however, this is also dependent on geographical region, husbandry and other factors such as season and age.

Salmonella serotypes and their *prevalence* in **cattle bovines** may vary considerably within and between farms, countries and regions. It is important for Veterinary Authorities and producers to consider serotypes of *Salmonella*, their occurrence and the *disease* burden in **cattle bovine** and human populations if when they developing and implementing strategies for the prevention and control of *Salmonella* in commercial **cattle bovine** production systems.

Article 6.X.2.

Definitions

For the purposes of this chapter:

Commercial **cattle bovine production systems:** means those systems where in which the purpose of the operation includes some or all of the following: breeding, rearing and management of **cattle bovines** for the production of *meat and meat products* or *milk and milk products*.

Intensive **cattle bovine production systems:** means commercial systems where in which **cattle bovines** are in confinement and are fully dependent on humans to provide for basic animal needs such as food, shelter and water on a daily basis.

Extensive **cattle bovine production systems:** means commercial systems where in which **cattle bovines** have the freedom to roam outdoors, and where the **cattle bovines** have some autonomy over diet selection (through grazing), water consumption and access to shelter.

Feed: means any material (single or multiple), whether processed, semi-processed or raw, which is intended to be fed directly to terrestrial *animals* (except bees).

Feed ingredient: means a component part or constituent of any combination or mixture making up a feed, whether or not it has a nutritional value in the *animals* diet, including feed additives. Ingredients are of plant (including aquatic plants) or terrestrial or aquatic animal origin, or other organic or inorganic substances.

Annex 10 (contd)

Semi-intensive cattle production systems: means commercial systems in which cattle are exposed to any combination of both intensive and extensive husbandry methods, either simultaneously or variably according to changes in climatic conditions or physiological state of the cattle.

Article 6.X.3.

Purpose and scope

The purpose of this chapter is to provide recommendations for the prevention and control of *Salmonella* in commercial cattle bovine production systems in order to reduce the burden of *disease* in cattle bovines and the risk of human illness through foodborne food-borne contamination as well as human *infections* resulting from direct or indirect contact with infected cattle bovines (e.g. via faeces or abortion material).

For the purposes of this chapter a bovine means *Bos taurus*, *B. indicus*, *B. javanicus* and *B. grunniens*, water buffaloes (*Bubalus bubalis*) and bison (*Bison bison* and *B. bonasus*).

This chapter applies to bovines cattle (*Bos taurus*, *B. indicus*, *B. javanicus* and *B. grunniens*), water buffaloes (*Bubalus bubalis*) and wood bison (*Bison bison* and *B. bonasus*) kept in commercial cattle bovine production systems.

This chapter should be read in conjunction with the Codex Alimentarius Code of Hygienic Practice for Meat (CAC/RCP 58-2005), and the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products (CAC/RCP 57-2004), Code of Practice of on Good Animal Feeding (CAC/RCP 54-2004), and the Guidelines for the Control of Nontyphoidal *Salmonella* spp. in Beef and Pork Meat (CAC/GL 87-2016), and the OIE/FAO Guide to Good Farming Practices for Animal Production Food Safety.

Article 6.X.4.

Objectives of prevention and control measures

It is recommended that Prevention prevention and control measures be may focus focused on those serotypes of *Salmonella* of greatest consequence to cattle bovines or and public health. These measures will also contribute to the reduction of other serotypes.

Reduction of *Salmonella* in cattle in primary production may reduce the level of the pathogen:

- 1) entering the slaughterhouse/abattoir and therefore decrease the risk of beef contamination during slaughter and dressing procedures;
- 2) in milk and milk products;
- 3) in the farm environment, thereby reducing the risk of dissemination of *Salmonella* and contact infections in humans.

Prevention and control measures in commercial cattle bovine production systems may:

- 1) reduce the prevalence and amount of *Salmonella* entering the slaughterhouse/abattoir and therefore decrease the challenge to the slaughter and dressing procedures and the likelihood of bovine meat contamination;
- 2) reduce the likelihood of *Salmonella* contamination in milk;
- 3) reduce *Salmonella* contamination of the environment via cattle bovine faecal waste, which in turn will limit infection of animals (including wildlife);
- 4) reduce the likelihood of infections in humans through contact with infected cattle bovines or contaminated materials or water.

While control in the primary production phase can decrease the number of animals carrying or shedding *Salmonella*, controls after primary production are also important to minimise the contamination and cross-contamination of carcasses and meat products.

When appropriate, good-Good farming practices and, when appropriate, the principles of hazard analysis and critical control points (HACCP) should be taken into account when designing prevention and control measures.

Articles 6.X.5. to 6.X.4416. provide recommendations for the prevention and control of *Salmonella* in commercial cattle bovine production systems. These recommendations may also have beneficial effects on the occurrence of contribute to the prevention and control of some other infections and diseases.

Article 6.X.5.

Biosecurity

Biosecurity is intended essential to assist with the prevention prevent and control of *Salmonella*. A biosecurity plan should be developed according to the commercial cattle bovine production system employed. The applicability of the measures, described below, will vary according to the type of commercial cattle bovine production system.

When including *Salmonella* as part of a biosecurity plan the following should be addressed:

- 1) location, design and management of the establishment;
- 2) veterinary supervision of cattle bovine health;
- 3) management of the introduction and mixing of cattle bovines;
- 4) training of personnel in their responsibilities and their role in animal health, human health and food safety;
- 4bis) prevention of contamination of feed and water, including for irrigation;
- 5) maintenance of records including data on cattle bovine health, production, movements, feeding, water supply, medications, vaccination, and mortality, and cleaning and disinfection of farm buildings and equipment;
- 6) availability of test results to the farm operator when *Salmonella* surveillance is conducted;
- 7) removal of unwanted vegetation and debris that could attract or harbour pests around cattle premises for bovines;
- 8) minimising the entry of domestic animals and wild birds into cattle buildings for bovines and feed stores;
- 9) cleaning and disinfection procedures for buildings in which cattle bovines are handled or housed, in accordance with Chapter 4.13.;
- 10) control of pests such as rodents and arthropods and regular assessment of effectiveness;
- 11) control and hygienic procedures for entry and movement of persons and vehicles;
- 12) cleaning and disinfection of equipment and vehicles identified as posing a risk;
- 13) storage and disposal of dead animals, bedding, faeces and other potentially contaminated farm waste in a manner that minimises the likelihood of dissemination of *Salmonella* and prevents the direct or indirect exposure of humans, livestock and wildlife to *Salmonella*. Particular care should be taken when cattle bedding and faeces of bovines are applied to land used for horticultural crops intended for human consumption;
- 14) procedures for prevention of dissemination of *Salmonella* when an animal is suspected or known to be infected.

Annex 10 (contd)

Article 6.X.56.

Location and design of establishments for bovines cattle establishment

When making decisions on the location and design of **cattle establishments for bovines**, it is recommended that ~~mitigation~~ reduction of the ~~risk~~ likelihood of transfer of **pathogens pathogenic agents**, including *Salmonella*, from major sources of contamination be considered. Sources of *Salmonella* may include other livestock establishments or areas of application or disposal of contaminated waste or effluent. ~~Transfer~~ Other sources and vectors of Salmonella between establishments may involve carriage by include vehicles, equipment, water-courses, persons-personnel, domestic animals, wild birds, rodents, flies and other wildlife.

~~It is recommended that the~~ The design of intensive **cattle bovine production** systems should consider the following:

- 1) management of faecal waste to minimise contamination of the establishment;
- 2) adequate drainage for the site and control of run-off water and untreated waste water;
- 3) use of materials for construction that facilitate effective cleaning and disinfection;
- 4) control of the points of entry and movement of vehicles, equipment and persons;
- 5) preventing contamination of feed and water during storage and distribution;
- 6) cattle handling and movements of bovines to minimise stress and spread of Salmonella infection;
- 7) separation of cattle bovines according to likelihood of different infection with, or susceptibility to, Salmonella risk status;
- 8) restriction of entry of domestic animals, wild birds, rodents, flies and other relevant wildlife.

In extensive **cattle bovine** production systems, location and design options may be limited; however, applicable ~~biosecurity measures~~ should be considered.

Article 6.X.6.

Biosecurity management plan

~~Biosecurity measures that include management and physical factors designed to reduce the risk of introduction, establishment and spread of animal diseases, infections or infestations to, from and within an animal population would also be expected to assist with the prevention and control of Salmonella.~~

~~When developing a biosecurity management plan it is recommended that the following be taken into consideration:~~

- ~~1) Veterinary supervision of cattle health.~~
- ~~2) Management of introduction and mixing of cattle.~~
- ~~3) Training of personnel in their responsibilities and their role in animal health, human health and food safety.~~
- ~~4) Maintenance of records including data on cattle health, production, movements, medications, vaccination, and mortality, and cleaning and disinfection of farm buildings and equipment.~~
- ~~5) Availability of test results to the farm operator when Salmonella surveillance is conducted.~~
- ~~6) Removal of unwanted vegetation and debris that could attract or harbour pests around cattle premises.~~

Annex 10 (contd)

- 7) Minimising the entry of wild birds into cattle buildings and feed stores.
- 8) ~~Cleaning and disinfection procedures for buildings in which cattle are handled or housed. For example, the cleaning and disinfection procedures for intensive calf housing, calving areas and sick pens after emptying may include feeders, drinkers, floor, walls, aisles, partitions between pens, and ventilation ducting.~~

When disinfectants are used they should be applied at an effective concentration after a complementary cleaning procedure.
- 9) Control of pests such as rodents and arthropods when required and regular assessment of effectiveness.
- 10) Control of persons and vehicles entering the establishment.
- 11) ~~Cleaning and disinfection of vehicles and equipment identified as a risk.~~
- 12) Storage and disposal of cattle carcasses, bedding, faeces and other potentially contaminated farm waste in a safe manner to minimise the risk of dissemination of *Salmonella* and to prevent the direct or indirect exposure of humans, livestock and wildlife to *Salmonella*. Particular care to be taken when cattle bedding and faeces are used as fertiliser for horticultural crops intended for human consumption.

Article 6.X.7.

Management of cattle introductions of bovines into the establishment

To minimise the risk likelihood of introducing *Salmonella* through cattle introductions of bovines, it is recommended that:

- 1) ~~There be good communication within the cattle bovine industry should be encouraged to raise awareness of the risk likelihood of introducing *Salmonella* through cattle introductions.~~
- 2) ~~The number of separate sources of cattle for breeding or rearing be kept to as few as possible. For example in a closed dairy herd it is possible to introduce new genetic material solely by semen or embryos. consideration should be given to minimising the number of sources of replacement cattle bovines.~~
- 3) ~~the introduction of new genetic material should be introduced through the use of semen and embryos be considered whenever practicable.~~
- 4) ~~if possible, cattle bovines should be sourced directly from herds of origin because live animal markets or other places where cattle bovines from multiple properties are mixed for resale may increase the risk likelihood of spread of *Salmonella* and other ~~infections~~ infectious agents among cattle bovines.~~
- 5) ~~newly introduced cattle bovines should be kept separate from the rest of the herd for a suitable period before mixing with other cattle bovines, e.g. four weeks.~~
- 6) ~~Where appropriate, for example with cattle of unknown status, pooled faecal samples from introduced cattle could be taken to assess their *Salmonella* status.~~
- 6) ~~where when appropriate, testing of animals for *Salmonella* prior to introduction or mixing with other cattle bovines should be considered to inform subsequent control measures, for example, when introducing cattle bovines of unknown status.~~

Article 6.X.8.

On farm cattle Mmanagement of bovines on farm

To minimise reduce the risk likelihood of transferring *Salmonella* among cattle bovines, it is recommended that:

- 1) cattle bovines with suspected salmonellosis or otherwise sick should be separated from healthy cattle bovines.

Annex 10 (contd)

- 2) care of healthy cattle bovines should be carried out prior to care of cattle bovines with suspected salmonellosis;
- 3) priority should be given to the hygienic management of calving areas, for example keeping perinatal cattle bovines separated from sick cattle bovines and maintaining a clean environment;
- 4) cattle bovines should be segregated according to age;
- 5) when possible, the 'all-in-all-out' principle for production cohorts should be used. In particular, the unnecessary mixing of different age groups during rearing, especially of calves, should be avoided;
- 6) consideration should be given to the potential for between-herd transmission of *Salmonella* via breeding, rearing and grazing of cattle bovines from multiple sources on a single site, for example shared pasture, and heifer rearing, or sharing of bulls;
- 7) consideration should be given to the potential for between-herd transmission of *Salmonella* through direct contact between cattle bovines across boundary lines or indirectly, for example through contamination of water courses.

Article 6.X.9.

~~Feed and water~~ Feed and feed ingredients1- Compound feed ~~Feed and feed ingredients~~

~~Compound feed~~ Feed and feed ingredients can be sources of *Salmonella* infection for cattle bovines. For the effective control of *Salmonella* ~~it is recommended that~~:

- 1a) ~~Where~~ when appropriate, ~~compound~~ feed and feed ingredients should be produced, handled, stored, transported and distributed according to Good Manufacturing Practices, considering Hazard Analysis Critical Control Points (HACCP) principles and recommendations in accordance with Chapter 6.3.
- 2b) ~~Compound~~ where practical, feed Feed and feed ingredients should be transported, and stored and fed in a hygienic manner that minimises contamination by manure faecal waste and, where practicable, minimises access by domestic animals, wild birds, rodents and other wildlife.

2- Water

~~Where there is reason to be concerned about infection of cattle with Salmonella from contaminated water, measures be taken to evaluate and minimise the risk. For example sediment in water troughs may act as a reservoir for contamination.~~

Article 6.X.10.

Water

Drinking water Water for drinking should be of an appropriate quality. When there is reason to be concerned about infection of cattle bovines with Salmonella from contaminated water, measures should be taken to evaluate and minimise the risk. For example sediment in water troughs may act as a reservoir for contamination. Where practicable, untreated surface water should be avoided as a water source.

Article 6.X.1011.

~~Prevention, treatment and control~~ Additional prevention and control measures

- 1) The immune status of calves is important and therefore care should be taken to ensure that newborn calves consume adequate amounts of high quality colostrum in accordance with Article 7.9.5. (point 3c)) and Article 7.X.5. Raw milk from infected cows should not be fed to calves.

Annex 10 (contd)

- 1) ~~Antimicrobial agents may modify normal flora in the gut and increase the likelihood of colonisation by *Salmonella*. If antimicrobial agents are used, they should be used in accordance with Chapter 6.9. Antimicrobial agents should not be used to control subclinical infection with *Salmonella* in cattle because the effectiveness of the treatment is limited, they may increase the risk of *Salmonella* colonisation, and their use can contribute to the development of antimicrobial resistance.~~
- 2) Vaccination may be used considered as part of a *Salmonella* control programme. Vaccine production and use should be in accordance with Chapter 1.1.6. of the *Terrestrial Manual*. The protective effect of vaccines is generally serotype-specific and few licensed vaccines are available for cattle and is influenced by factors such as timing of vaccination in relation to exposure.
- 3) ~~Use of probiotics may reduce colonisation of cattle by *Salmonella* and shedding of *Salmonella*; however, efficacy is variable.~~
- 34) ~~Because conditions such as A number of conditions, for example liver fluke and infection with bovine viral diarrhoea virus, may increase the susceptibility of cattle bovines to *Salmonella*; therefore, control of these such conditions is recommended.~~
- 5) ~~The immune status of calves is important and therefore care should be taken to ensure that new born calves consume adequate amounts of high quality colostrum.~~
- 4) Stress may increase the susceptibility of cattle bovines to *Salmonella*. Management of potentially stressful situations, such as mixing of groups of cattle bovines, may reduce the likelihood of clinical disease or shedding of *Salmonella*.
- 5) Antimicrobial agents may modify normal flora in the gut and increase the likelihood of colonisation by *Salmonella*. In circumstances when antimicrobial agents are considered necessary for the treatment of clinical enteric salmonellosis, they should be used in accordance with Chapter 6.9. Furthermore, antimicrobial agents should not be used to control subclinical infection with *Salmonella* in cattle bovines because the effectiveness of the treatment is limited, they may increase the risk of *Salmonella* colonisation, and their use can contribute to the development of antimicrobial resistance.

Article 6.X.41~~12~~.

Transportation

~~Hygienic maintenance of vehicles is recommended. Vehicles should be properly cleaned and disinfected after transportation of animals, in accordance with Chapter 4.13.~~

~~When transporting animals from multiple establishments, it is recommended that the *Salmonella* status of the establishments should be considered to avoid cross-contamination of cattle bovines.~~

~~In addition, the relevant recommendations in Chapters 7.2., 7.3. and 7.4. apply.~~

~~When transporting animals from multiple establishments, it is recommended that the *Salmonella* status of the establishments be considered to avoid cross-contamination of cattle.~~

Article 6.X.42~~13~~.

Lairage

Relevant aspects of lairage management include consideration of effective cleaning and disinfection between groups, minimising mixing of separate groups animals that have not continuously been kept together and managing stress.

In addition, the relevant recommendations in Articles 7.5.1., 7.5.3. and 7.5.4. apply.

Annex 10 (contd)Article 6.X.14.**Cleanliness of hides**

Cleanliness of hides can be achieved by applying suitable practices during housing (for example additional clean bedding), transport and lairage. Dirty hides increase the risk of microbial contamination of carcasses during the slaughter process. Contamination can be reduced by hide washing of the live animal or of the slaughtered animal before hide removal.

Article 6.X.15.**Surveillance in ~~cattle~~ for *Salmonella* in commercial ~~cattle~~ **cattle bovine** production systems**

Surveillance data provide information to assist the *Competent Authorities* in their decision making regarding the requirement for, and design of, control programmes and in setting and verifying performance objectives. ~~Sampling and testing methods, frequency and type of samples required should be determined by the Veterinary Services.~~

Standards for diagnostic tests are described in the *Terrestrial Manual*. In addition, other sampling and testing methodologies such as testing of bulk milk or serum samples by ELISA may provide useful information on *herd* or individual animal status. Boot swab samples from communal areas in **cattle** housing **for bovines**, slurry samples, ~~or caecal~~ or lymph nodes ~~samples~~ collected post-mortem can also be useful for microbiological testing. Some **sero**types of *Salmonella* such as *S. Dublin* can be difficult to detect ~~through~~ using microbiological methods.

~~If vaccination is used, if serology is used as the surveillance method, it may not be possible to distinguish between vaccinated and infected cattle bovines by means of serological testing.~~

Article 6.X.16.**Prevention and control in low prevalence regions**

In regions where *Salmonella* infection of **cattle bovines** is uncommon, it may be possible to maintain low prevalence status or eliminate *infection* from *herds* through a combination of good farming practices, herd surveillance, individual testing, movement controls, ~~and possible or and~~ removal of persistent carriers.

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DRAFT CHAPTER 6.Y.

PREVENTION AND CONTROL OF *SALMONELLA* IN COMMERCIAL PIG PRODUCTION SYSTEMS PIG HERDS

Article 6.Y.1.

Introduction

Nontyphoidal salmonellosis is one of the most common foodborne bacterial diseases in the world with *Salmonella* Enteritidis and *S. Typhimurium* (including monophasic variants) being the predominant serotypes identified in most countries. humans in most countries. *S. Enteritidis* is primarily associated with poultry while *S. Typhimurium* may be present in many mammalian and avian hosts. These serotypes and several others occur at variable prevalence in pigs depending on the region. In some countries *S. Infantis* and *S. Choleraesuis* may cause salmonellosis in humans.

Salmonella infection in pigs is mostly subclinical, although clinical disease such as enteritis and septicaemia in weaned pigs may occur. Subclinical infection, including a carrier state, can be of variable duration and can play an important role in the spread of *Salmonella* within and between herds and pose a public health risk.

As is the case in most food producing animals, *Salmonella* infection in pigs is mostly subclinical and of variable duration. Pigs with subclinical infection play an important role in the spread of *Salmonella* between herds and pose a public health risk.

Salmonella serotypes and their prevalence in pigs may vary considerably within and between farms, regions and countries and regions. It is important for Veterinary Authorities and producers to consider the types serotypes of *Salmonella*, their occurrence and the disease burden and their prevalence in pig and human populations when they developing and implementing strategies for the prevention and control of *Salmonella* in commercial pig production systems. *Salmonella* reduction strategies.

Article 6.Y.2.

Definitions

For the purpose of this chapter:

Commercial pig production systems: means those systems in which the purpose of the operation includes some or all of the following: breeding, rearing and management of pigs for the production of meat.

Feed: means any material (single or multiple), whether processed, semi-processed or raw, which is intended to be fed directly to terrestrial animals (except bees).

Feed ingredient: means a component part or constituent of any combination or mixture making up a feed, whether or not it has a nutritional value in the animal's diet, including feed additives. Ingredients are of plant (including aquatic plants) or terrestrial or aquatic animal origin, or other organic or inorganic substances.

Article 6.Y.23.

Purpose and scope

This chapter provides recommendations for the prevention and control of *Salmonella* in commercial pig production systems in order to reduce the burden of infection in pigs and the risk of human illness through foodborne food-borne contamination as well as human infections resulting from direct or indirect contact with infected pigs.

Annex 11 (contd)

To combat the occurrence of food borne salmonellosis, a pre harvest pathogen reduction strategy can assist in reducing the presence of *Salmonella* in pig meat.

This chapter provides recommendations on the prevention and control of *Salmonella* in domestic pigs kept for commercial breeding and production from farm to slaughter. It should be read in conjunction with the Codex Alimentarius Code of Hygienic Practice for Meat (CAC/RCP 58-2005), Code of Good Animal Feeding (CAC/RCP 54-2004), and the Guidelines for the Control of Nontyphoidal *Salmonella* spp. in Beef and Pork Meat (CAC/GL 87-2016) and the Codex Alimentarius Code of Hygienic Practice for Meat (CAC/RCP 58-2005), and the OIE/FAO Guide to Good Farming Practices for Animal Production Food Safety.

Article 6.Y.3.

Surveillance in pig herds for *Salmonella*

Where justified by risk assessment, surveillance should be carried out to identify the occurrence and distribution of *Salmonella* in pig herds. Surveillance data will provide information to assist the Competent Authorities in their decision making regarding the requirement for, and design of, control programmes. Sampling and testing methods, frequency and type of samples required should be determined by the Veterinary Services based on the risk assessment.

Serological testing, usually using 'meat juice' at slaughter, is a common method for assessing exposure to *Salmonella* in pig herds. Benefits of serological testing include low cost per test, high throughput capability and the potential for automation of tests. Collection of samples at the slaughterhouse/abattoir enables centralised sampling of multiple herds. Serological testing does not detect exposure to all serotypes and does not provide information on the serotypes present.

Microbiological testing identifies serotypes present in pig herds and can provide epidemiological information on likely sources of *Salmonella* and on the presence of strains with higher public health risk, including those with enhanced virulence or resistance to antimicrobial agents. Bacteriological sampling of individual pigs has low sensitivity but this can be overcome by repeated sampling, by pooling of samples (such as individual faecal samples or mesenteric lymph nodes) or sampling naturally pooled material (such as sampling of faeces from the floor of pig pens).

Communication of the results of post mortem *Salmonella* testing that are relevant to the *Salmonella* status of pigs at herd level to the herd manager or veterinarian is an important element of a *Salmonella* control programme.

Article 6.Y.4.

Definitions

Food: means any material (single or multiple), whether processed, semi-processed or raw, which is intended to be fed directly to terrestrial animals (except bees).

Feed ingredient: means a component part or constituent of any combination or mixture making up a feed, whether or not it has a nutritional value in the animals' diet, including feed additives. Ingredients are of plant (including aquatic plants) or terrestrial or aquatic animal origin, or other organic or inorganic substances.

Article 6.Y.5.

Prevention Objectives of prevention and control measures

Prevention and control measures may focus on those serotypes of *Salmonella* of greatest consequence to pigs and public health. These measures will also contribute to the reduction of other serotypes.

Prevention and control measures in commercial pig production systems may:

- 1) reduce the prevalence and amount of *Salmonella* entering the slaughterhouse/abattoir and therefore decrease the challenge to the slaughter and dressing procedures and the likelihood of pig meat contamination;

Annex 11 (contd)

- 2) reduce *Salmonella* contamination of the environment via pig faecal waste manure, which in turn will limit infection of animals (including wildlife);
- 3) reduce the likelihood of infections in humans through contact with infected pigs or contaminated materials or water.

While control in the primary production phase can decrease the number of animals carrying or shedding *Salmonella*, controls after primary production are also important to minimise the contamination and cross-contamination of carcasses and meat products.

When appropriate, good Good farming practices and, when appropriate, the principles of hazard analysis and critical control points (HACCP) should be taken into account when designing prevention and control measures.

Articles 6.Y.65. to 6.Y.1414. provide recommendations for the prevention and control of *Salmonella* at herd level in commercial pig production systems. Contamination of pig meat can be reduced by measures taken during the slaughter process. Reduction of *Salmonella* in pigs entering the slaughterhouse/abattoir enhances the effectiveness of such measures. These recommendations will may also contribute to the prevention and control of some have beneficial effects on the occurrence of other infections and diseases.

Article 6.Y.65.

Biosecurity measures

It is important to have biosecurity measures in place to reduce the risk of introduction of *Salmonella* or the entry of new strains of *Salmonella* into pig herds, the spread of these strains across the herd, as well as to minimise prevalence of existing strains.

Biosecurity is intended essential to assist with the prevention prevent and control of *Salmonella*. A biosecurity plan should be developed according to the commercial pig production system employed. The choice of specific measures will vary according to the type of commercial pig production system.

When including *Salmonella* as part of a biosecurity plan the following should be addressed:

It is recommended that biosecurity measures include the following:

- 1) location, design and management of the establishment. Development and implementation of a biosecurity plan including management strategies for the prevention and control of *Salmonella*.
- 2) veterinary supervision of pig health;
- 3) management of the introduction and mixing of pigs;
- 4) training of personnel regarding in their responsibilities and the significance of their role in improving animal health, human health, and and food safety;
- 4bis) prevention of contamination of feed and water, including for irrigation;
- 5) maintenance of records including data on pig health, production, movements, feeding, water supply, medications, vaccination, mortality, surveillance, and cleaning and disinfection of farm buildings and equipment;
- 6) availability of test results to the farm operator when *Salmonella* surveillance is conducted;
- 4) veterinary supervision of pig health and *Salmonella* control.
- 7) removal of unwanted vegetation and debris that could attract or harbour pests around pig housing;
- 8) prevention of minimising the entry of domestic animals and wild birds into pig houses and buildings and feed stores;

Annex 11 (contd)

- 97) cleaning and disinfection procedures for buildings in which pigs are handled or housed in accordance with Chapter 4.13. ~~Cleaning and disinfection procedures for pig housing, general equipment, transportation equipment and animal walkways. The cleaning and disinfection procedures for pig housing after emptying should include at least feeders, drinkers, floor, walls, aisles, partitions between pens, and ventilation ducting. All visible organic material should be removed before disinfection with a suitable disinfectant at an effective concentration. Disinfectants should be used in accordance with Chapter 4.13.~~
- 108) control of pests such as rodents and arthropods, and regular assessment of effectiveness. ~~Procedures for the control of vermin such as rodents and arthropods should be in place and regular checks should be carried out to assess effectiveness. When the presence of vermin is detected timely control actions should be taken to prevent the development of unmanageable populations; for example, the placement of baits for rodents where they are nesting.~~
- 119) Controlled access of persons and vehicles entering the establishment. ~~control and hygienic procedures for entry and movement of persons and vehicles;~~
- 1240) biosecurity measures applied to all personnel and visitors entering the establishment. ~~This~~ As a minimum, this should include hand washing and changing into clean clothes and footwear provided by the establishment. Similar precautions are recommended when ~~moving~~ they move between separate epidemiological units on large farms;
- ~~14) vehicles and equipment identified as a risk in the biosecurity plan should be cleaned and disinfected before entering the establishment.~~
- 13) cleaning and disinfection of equipment and vehicles identified as posing a risk;
- 142) pig carcasses, storage and disposal of dead animals, bedding, faeces and other potentially contaminated farm waste should be stored and disposed of in a safe manner to that minimises the risk-likelihood of dissemination of Salmonella and to prevents the direct or indirect exposure of humans, livestock and wildlife to Salmonella. ~~Particular care should be taken when pig bedding and faeces are applied to land used to fertilise for horticultural crops intended for human consumption;~~
- 15) procedures for prevention of dissemination of Salmonella when an animal animals are is suspected or known to be infected.

Article 6.Y.76.

Facility Location and design of pig establishments

When making decisions on the location and design of pig establishments, reduction of the likelihood of transfer of pathogens pathogenic agents, including Salmonella, from major sources of contamination should be considered. Sources of Salmonella may include other livestock establishments or areas of application or disposal of contaminated waste or effluent. Other sources and vectors of Salmonella include vehicles, equipment, water-courses, personnel, domestic animals, birds, rodents, flies and wildlife.

The design of commercial pig production systems should consider the following:

~~Good design of pig units facilitates the management and control of pathogens.~~

~~It is recommended that facility design consider the following:~~

- 1) location proximity of other livestock establishments, in relation to and wild bird and rodent populations;
- 2) management of faecal waste to minimise contamination of the establishment;
- 32) adequate drainage for the site and control of run-off water and untreated waste water;
- 43) use of smooth impervious materials for construction of pig houses to enable effective cleaning and disinfection;

Annex 11 (contd)

- 54) ~~surrounding paving the area immediately surrounding indoor pig houses or indoor establishments with concrete or other impervious material, to~~ This will facilitate rodent control and minimise recontamination after facilitate cleaning and disinfection;
- 65) ~~a controlled of entry and movement of vehicles, equipment and persons, point to prevent the entry of unwanted animals and people; for example, locate delivery and collection points away from pig housing or feed storage;~~
- 7) preventing contamination of feed and water during storage and distribution;
- 6) ~~a sign indicating restricted entry at the entrance to the establishment;~~
- 87) pig flow handling and movements to minimise stress and spread of Salmonella infection;
- 98) ~~prevention of entry of wild birds, rodents and feral animals; restriction of entry of domestic animals, wild birds, rodents, flies and other relevant wildlife.~~
- 9) ~~location of delivery and collection points away from pig housing or feed storage.~~

Article 6.Y.7.**Management of new pig introductions into the establishment**

Introduction of pigs into a herd is an important a risk factor, especially in moderate and high prevalence regions. To minimise the likelihood of introducing Salmonella by replacement pigs:

- 1) good communication along the pig production chain should be encouraged to raise awareness of the risk of introducing Salmonella through pig introductions;
- 2) consideration should be given to minimising the number of sources for both replacement breeding stock and rearing pigs, and matching Salmonella herd status in terms of Salmonella freedom or occurrence of priority serotypes such as S. Typhimurium;
- 3) new genetic material should be introduced through the use of semen whenever practicable;
- 4) if possible, pigs should be sourced directly from herds of origin because live animal markets or other places where pigs from multiple properties are mixed for resale may increase the likelihood of spread of Salmonella and other infectious agents among pigs;
- 5) newly introduced pigs should be kept separate from the rest of the herd for a suitable period before mixing with other pigs, e.g. four weeks;
- 6) when appropriate, testing of pigs for Salmonella prior to introduction or mixing with other pigs should be considered to inform subsequent control measures, for example, when introducing pigs of unknown status.

Article 6.Y.8.**Moving and mixing of pigs**

The moving and mixing of pigs increases the likelihood of spread of Salmonella. To minimise the spread of Salmonella:

- 1) the number of pig movements and mixing of pigs should be minimised;
- 2) if possible, the 'all-in-all-out' system with a single age group of pigs should be used. In particular, the addition to younger groups of pigs held back from older groups should be avoided;
- 3) sick pigs should be segregated from healthy ones.

Annex 11 (contd)

Article 6.Y.89.

Feed and feed composition1. Feed and feed ingredients

Feed and feed ingredients can be sources of *Salmonella* for pigs. This is especially important in herds, countries or regions of low prevalence. To minimise the spread of *Salmonella* through feed:

- a) feed and feed ingredients should be produced, handled, stored, transported and distributed in accordance with Chapter 6.3.;
- b) ~~when practicable,~~ feed and feed ingredients should be transported, stored and fed in a ~~hygienic~~ manner that minimises contamination by ~~manure faecal waste~~ and, ~~where practicable,~~ minimises access by domestic animals, birds, rodents and ~~wildlife~~;
- c) ~~when practicable,~~ feeds feed should be treated with heat, or with approved bactericidal or bacteriostatic treatments such as ~~organic acids~~.

~~*Salmonella* contaminated feed and feed ingredients are known to be important sources of infection for pigs. Therefore, feed and feed ingredients should be produced, handled, stored, transported and distributed according to Good Manufacturing Practices, considering Hazard Analysis Critical Control Points (HACCP) principles and recommendations in accordance with Chapter 6.3.~~

~~For the effective control of *Salmonella* it is recommended that:~~

- ~~1) Feed and feed ingredients should come from monitored sources.~~
- ~~2) Heat treated feeds are used and may also include the addition of bactericidal or bacteriostatic treatments, e.g. organic acids. Where heat treatment is not possible, the use of bacteriostatic or bactericidal treatments or processes should be considered.~~
- ~~3) Cooling systems and dust control in feed ingredient processing plants and compound feed mills should be managed to avoid recontamination of feed and feed ingredients with *Salmonella*.~~
- ~~4) Feed should be stored and transported in a hygienic manner that prevents exposure to possible residual *Salmonella* contamination.~~
- ~~5) Access to feed by wild birds and rodents should be prevented.~~
- ~~6) Spilled feed should be cleaned up immediately to remove attractants for ~~wild~~ birds, rodents and other pests.~~

2. Feed composition

When *Salmonella* is present in a pig herd, the composition of feed may influence the occurrence of *Salmonella* in individual pigs.

For the control of *Salmonella* the following be considered:

- a) liquid feed that is fermented or containing *milk products* has a protective effect due to the presence of beneficial bacteria and lowered pH;
- b) coarsely ground feed may reduce the occurrence of *Salmonella* by slowing gastric transit (thereby increasing exposure to gastric acid) and reducing dysbacteriosis. Coarsely ground feed ingredients may be fed alongside pelleted feed;
- c) fine grinding needed to produce heat treated pellets may result in dysbacteriosis which favours the colonisation and multiplication of *Salmonella* in the intestine. Therefore, heat treated pellets are more appropriate for situations in which *Salmonella* is uncommon;
- d) when wheat is the predominant feed ingredient, reducing the proportion of this ingredient may reduce the occurrence of *Salmonella* because the rapid fermentation of wheat promotes dysbacteriosis.

Article 6.Y.9.10.

Water

~~For the effective control of *Salmonella* through water, it is recommended that:~~

- 1) ~~the drinking water supply should be monitored and controlled to maintain it free from *Salmonella* contamination;~~
- 2) ~~water holding tanks should be enclosed;~~
- 3) ~~water supply and delivery systems should not be accessible to birds, rodents, or wildlife;~~
- 4) ~~the water delivery system should be regularly cleaned and disinfected. For example in an 'all-in-all-out' system this would occur before restocking.~~

Article 6.Y.10.

Feed composition

~~For the control of *Salmonella* it is recommended that the following be considered when determining feed composition:~~

- 1) ~~slower gastric transit time of ingested feed increases exposure of *Salmonella* to stomach acid resulting in decreased survival.~~
- 2) ~~modified fermentation conditions in the gastrointestinal tract may enhance colonisation by protective bacteria and thereby suppress the colonisation and multiplication of *Salmonella*.~~
- 3) ~~liquid feed that is fermented has a protective effect due to the presence of beneficial bacteria and low pH levels; for example, the inclusion of fermented milk products.~~

~~Where *Salmonella* is present in a pig herd, the composition of feed may influence the occurrence of *Salmonella* in individual pigs. For the effective control of *Salmonella* it is recommended that:~~

- 4) ~~feed should be coarsely ground.~~
- 5) ~~where feed is wheat based, reducing the proportion of wheat may reduce the occurrence of *Salmonella* in pigs.~~
- 6) ~~coarsely ground material may be added to pelleted feed.~~

Article 6.Y.11.

Pig flow management

~~The movement and mixing of pigs increase the risk of spread of *Salmonella*. For the effective control of *Salmonella* it is recommended that:~~

- 1) ~~The number of pig movements and mixing of pigs between weaning and dispatch for slaughter should be minimised.~~
- 2) ~~If possible, the 'all in all out' single age group principle should be used. In particular, the addition to younger groups of pigs held back from older groups should be avoided.~~

Article 6.Y.12.

Management of new pig introductions

~~To minimise the risk of new introductions of *Salmonella* in replacement pigs in a herd, it is recommended that:~~

- 1) ~~There is good communication along the pig production chain to ensure that steps are taken to minimise the introduction and dissemination of *Salmonella*.~~
- 2) ~~A closed herd policy is applied with the introduction of new genetic material by semen only.~~

Annex 11 (contd)

- 3) ~~The number of separate sources for both replacement breeding stock and rearing pigs are as few as possible.~~
- 4) ~~Newly introduced pigs are kept separate from the rest of the herd for a suitable period before incorporating with other pigs, e.g. four weeks.~~
- 5) ~~Replacement breeding pigs are of a similar Salmonella status to that of the herd, for example a Salmonella free herd should source replacements from Salmonella free herds; or herds that are free of specific Salmonella serotypes such as S. Typhimurium should avoid introducing pigs from breeding herds infected with such serotypes.~~
- 6) ~~Where appropriate, pooled faecal samples from introduced pigs are taken to assess their Salmonella status.~~

Article 6.Y.13.

Stress reduction

~~Given that stress may increase the multiplication and shedding of Salmonella by pigs and their susceptibility to infection, it is important to consider management measures that reduce stress.~~

Article 6.Y.411.

Pig treatments-Additional prevention and control measures

- 1) Vaccination may be considered as part of a Salmonella control programme. Vaccine production and use should be in accordance with Chapter 1.1.6. of the Terrestrial Manual. The protective effect of vaccines is generally serotype-specific and is influenced by factors such as timing of vaccination in relation to exposure.
- 2) Antimicrobial agents may modify normal flora in the gut and increase the likelihood of colonisation by Salmonella. In circumstances when antimicrobial agents are considered necessary for the treatment of clinical enteric salmonellosis, they should be used in accordance with Chapter 6.9. Furthermore, antimicrobial agents should not be used to control subclinical infection with Salmonella in pigs because the effectiveness of the treatment is limited, they may increase the risk of Salmonella colonisation, and their use can contribute to the development of antimicrobial resistance.

~~Antimicrobial agents may modify normal flora in the gut and increase the likelihood of colonisation by Salmonella. If antimicrobial agents are used for the control of clinical infections in pigs, they should be used in accordance with Chapters 6.7., 6.8., 6.9. and 6.10.~~

~~Antimicrobial agents should not be used to control subclinical infection with Salmonella in pigs because the effectiveness of the treatment is limited and can contribute to the development of antimicrobial resistance.~~

- 2) ~~Vaccination may be used as part a Salmonella control programme. Vaccine production and use should be in accordance with Chapter 2.9.9. of the Terrestrial Manual.~~

~~Vaccines for Salmonella in pigs may increase the threshold for infection and reduce the level of excretion of the organism. The protective effect of vaccines is serotype specific and few licensed vaccines are available for pigs.~~

~~If serology is used as the surveillance method, it may not be possible to distinguish between vaccination and infection with a field strain.~~

~~If live vaccines are used:~~

- a) ~~it is important that field and vaccine strains be easily differentiated in the laboratory;~~
 - b) ~~the vaccine strain should not be present at the time of slaughter.~~
- 3) Where approved by the Competent Authority, Organic organic acids, probiotics and prebiotics may be added to feed or water to reduce shedding of Salmonella by pigs. However, efficacy is variable.

Article 6.Y.4512.

Transportation

Vehicles should be properly cleaned and disinfected after transportation of animals, in accordance with Chapter 4.13.

When transporting animals from multiple establishments, the Salmonella status of the establishments should be considered to avoid cross-contamination of pigs.

In addition, the relevant recommendations in Chapters 7.2., 7.3. and 7.4. apply.

Article 6.Y.4613.

Lairage

Lairage can may be used at various stages in pig production, for example accumulation of weaned pigs before movement to nursery herds, holding finisher pigs before transport to slaughter and holding pigs at the slaughterhouse/abattoir before slaughter. Important aspects of lairage management include effective cleaning and disinfection between groups, minimising mixing of separate groups and managing stress.

Relevant aspects of lairage management include consideration of effective cleaning and disinfection between groups, minimising mixing of animals that have not continually been kept together and managing stress.

In addition, the relevant recommendations in Articles 7.5.1., 7.5.3. and 7.5.4. apply.

Article 6.Y.14.

Surveillance for Salmonella in commercial pig production systems

Surveillance data provide information to assist the Competent Authorities in their decision making regarding the requirement for, and design of, control programmes and in setting and verifying performance objectives. Harmonised surveillance systems to determine the occurrence of Salmonella at herd level are in place in some countries. Communication between slaughterhouses/abattoirs, Veterinary Services and the herd manager or veterinarian of the results of Salmonella surveillance systems is an important element of a Salmonella control programme.

Standards for diagnostic tests are described in the Terrestrial Manual. Serological testing, usually using 'meat juice' at slaughter, is one method for assessing exposure to Salmonella in pig herds. Benefits of serological testing include low cost per test, high throughput capability and the potential for automation of tests. Collection of samples at the slaughterhouse/abattoir enables centralised sampling of multiple herds. While serology is a useful tool for risk ranking of herds, serological testing does not detect exposure to all serotypes or differentiate between different serotypes within the serogroups included in the antigenic range of the test or the level of Salmonella in pigs at slaughter. If serology is used as the surveillance method, it may not be possible to distinguish between vaccinated and infected pigs.

Serological testing gives no indication of excretion of Salmonella in the herd and does not reflect how infectious is the tested group.

Microbiological testing, with additional phenotyping or genotyping, identifies serotypes of Salmonella present in pig herds and can provide epidemiological information on likely sources of Salmonella and on the presence of strains with enhanced virulence or resistance to antimicrobial agents. Bacteriological sampling of individual pigs has low sensitivity but this can be overcome by sampling at herd level or repeated sampling of individual animals. Pooling of samples (such as individual faecal samples or mesenteric lymph nodes) or sampling naturally pooled material (such as sampling of faeces from the floor of pig pens) will decrease the costs. Some serotypes of Salmonella such as S. Choleraesuis can be difficult to detect using microbiological methods.

Annex 11 (contd)Article 6.Y.14~~15~~.**Prevention and control in low prevalence regions**

In regions where *Salmonella* infection of pigs is uncommon, it may be possible to maintain low prevalence status or eliminate infection from herds through a combination of good farming practices, herd surveillance, individual testing, movement controls, and removal of persistent carriers.

~~In regions where *Salmonella* infection of pigs is uncommon it may be possible to eliminate infection from individual herds by means of a test and removal policy. This can be accomplished by placing movement controls on the herd, repeated bacteriological sampling of groups of pigs and culling of persistently infected pigs. Movement controls can be lifted after two rounds of negative tests and confirmation of implementation of effective prevention and control measures as described in Articles 6.Y.5. to 6.Y.14.~~

~~It may be possible to attempt this approach in individual herds, for example in valuable breeding herds, in higher prevalence regions. However, the risk of reintroduction of infection must be low to achieve success with this approach. In individual herds, for example valuable breeding herds, in higher prevalence regions, the success of this approach is dependent upon a low likelihood of reintroduction of infection.~~

Article 6.Y.14~~16~~.**Outdoor pig production**

~~As far as possible~~ Where practicable, the prevention and control measures described in Articles 6.Y.5. to 6.Y.14~~15~~. should also be applied to outdoor pigs in commercial pig production systems to reduce *Salmonella* infection in pigs. In addition, ~~it~~ it is recommended that:

- 1) field rotation programmes be used to minimise *Salmonella* contamination and accumulation in soil and surface water and therefore ingestion by pigs;
- 2) systems used to provide feed, and where possible water, be provided using troughs or bird proof hoppers be designed to minimise attraction of, or access by, of wild birds;
- 3) the location of other outdoor pig herds and the concentration and behaviour of *wild* birds in the area be considered ~~when establishing outdoor pig herds.~~

Article 6.Y.19.

Live animal markets

~~Live animal markets pose a significant risk of spreading *Salmonella* and other infections and diseases among pigs. If possible, sourcing replacement pigs from live animal markets should be avoided. Precautions should be taken to prevent the spread of *Salmonella* from markets to pig herds by personnel or vehicles.~~

 — Text deleted.

CHAPTER 7.11.

**ANIMAL WELFARE AND DAIRY CATTLE
PRODUCTION SYSTEMS**

[..]

Article 7.11.6.

Recommendations on system design and management including physical environment

1. [...]
2. [...]
3. [...]
4. [...]
5. Flooring, bedding, resting surfaces and outdoor areas

In all production systems cattle need a well-drained and comfortable place to rest. All cattle in a group should have sufficient space to lie down and rest at the same time.

Particular attention should be given to the provisions for areas used for calving. The environment in such areas (e.g. floors, bedding, temperature, calving pen and hygiene) should be appropriate to ensure the welfare of calving cows and new born calves.

In housed systems calving areas should be thoroughly cleaned and provided with fresh bedding between each calving. Group pens for calving should be managed based on the principle 'all in - all out'. The group calving pen should be thoroughly cleaned and provided with fresh bedding between each animal group. The time interval between first and last calving of cows kept in the same group calving pen should be minimised.

Outdoor calving pens and fields should be selected to provide the cow with a clean and comfortable environment.

Floor management in housed production systems can have a significant impact on cattle welfare. Areas that compromise welfare and are not suitable for resting (e.g. places with excessive faecal accumulation, or wet bedding) should not be included in the determination of the area available for cattle to lie down.

Slopes of the pens should allow water to drain away from feed troughs and not pool the pens.

Flooring, bedding, resting surfaces and outdoor yards should be cleaned as conditions warrant, to ensure good hygiene, comfort and minimise risk of diseases and injuries.

In pasture systems, stock should be rotated between fields to ensure good hygiene and minimise risk of diseases and injuries.

Annex 12 (contd)

Bedding should be provided to all animals housed on concrete. In straw, sand or other bedding systems such as rubber mats, crumbled-rubber-filled mattresses and waterbeds, the bedding should be suitable (e.g. hygienic, non-toxic) and maintained to provide cattle with a clean, dry and comfortable place ~~in~~ on which to lie.

The design of a standing, or cubicle, or free stall, should be such that the animals can stand and lie comfortably on a solid surface (e.g. length, width and height should be appropriate for the size of the largest animal). There should be sufficient room for the animal to rest and to rise adopting normal postures, to move its head freely as it stands up, and to groom itself without difficulty. Where housing design provides only individual spaces ~~are provided~~ for cows to rest, there should be at least one space per cow.

Alleys and gates should be designed and operated to allow free movement of cattle. Floors should be designed to minimise slipping and falling, promote foot health, and reduce the risk of claw injuries.

If a housing system includes areas of slatted floor, cattle, including replacement stock, should have access to a solid lying area. The slat and gap widths should be appropriate to the hoof size of the cattle to prevent injuries.

If cattle have to be tethered whether indoors or outdoors, they should, as a minimum, be able to lie down, stand up, maintain normal body posture and groom themselves unimpeded. Cows kept in tie stall housing should be allowed sufficient untethered exercise to prevent welfare problems. When tethered outdoors they should be able to walk. *Animal handlers* should be aware of the higher risks of welfare problems where cattle are tethered.

Where breeding bulls are in housing systems, care should be taken to ensure that they have sight of other cattle with sufficient space for resting and exercise. If used for natural mating, the floor should not be slatted or slippery.

Outcome-based measurables: morbidity rates, especially lameness and injuries (e.g. hock and knee injuries and skin lesions), behaviour (e.g. altered locomotion and posture, altered lying time, grooming and not using the intended lying areas), changes in weight and body condition, physical appearance (e.g. hair loss, cleanliness score), growth rate.

[...]

— Text deleted.

CHAPTER 7.12.

WELFARE OF WORKING EQUIDS

Article 7.12.1.

Introduction

In many countries, working equids, used for transport and traction, contribute directly and indirectly to households' livelihoods and benefit communities as a whole. Working equids may be of direct or indirect use in production and commercial activities.

Specifically, they contribute to agricultural production and food security by transporting, for instance, water and fodder for other livestock, firewood and other daily needs to the homestead and agricultural products to the market. They provide draught power for agricultural work and transport. They may supply manure, *milk*, *meat* and hides for household use or income.

The welfare of these working equids is often poor because their owners lack sufficient resources to meet their needs or have insufficient knowledge of the appropriate care of equids. Certain working contexts, such as working in construction industries or in harsh environments, may present a particular risk to their welfare.

Article 7.12.2.

Scope

This chapter applies to horses, donkeys and mules that are destined, used for or retired from traction, transport and generation of income. Equids used in sports or competitions, leisure activities, research or kept solely for the production of *meat* or biopharmaceuticals, or research are excluded.

For the purposes of this chapter, harness means all parts of the driving harness, saddle, bridle and bit that are used to control the working equid, act as a braking system when pulling a cart, hold loads in place and transfer power to attached carts or agricultural implements.

Article 7.12.3.

Responsibilities

All organisations with defined responsibilities as outlined below should have personnel with the requisite knowledge and skill to perform their duties.

1. Veterinary Authority

The *Veterinary Authority* is responsible for implementation of animal health and welfare policies, legislations, ~~policies~~ and programmes. However, in the case of working equids, the responsibility may be shared with other government agencies, institutions and relevant stakeholders.

2. Other government agencies

The responsibilities of other government agencies ~~will~~ depend on the range of working equid uses and contexts.

For example those agencies responsible for regulating industrial and construction activities, whether for environmental or labour compliance, may also have a responsibility for the working equids involved in the industry.

Particularly in urban areas, the transport or other responsible agency may have legislative authority in dealing with traffic circulation and have a role to play in ensuring a safe environment for working equids as well as other road users.

Annex 13 (contd)

Environmental protection agencies may regulate and enforce measures to prevent working equids from accessing sources of contamination.

The agency responsible for public health may have legislative authority in dealing with *zoonoses*.

Education authorities have a responsibility in schools and agricultural, *veterinary paraprofessional* and veterinary training institutions. A component on welfare of working equids should be included in animal health and production curricula. ~~Appropriate education and training will prevent many welfare problems.~~

3. Local government authorities

Local government authorities are responsible for many services and programmes that relate to health, safety and public good within their jurisdiction. In many countries the legislative framework gives authority to local government agencies with regard to aspects of transport, agriculture, public health, environmental health and inspection, and compliance activities including those in relation to animal health measures and responsibility for abandoned and stray animals.

In many countries local government agencies are responsible for the development and enforcement of legislation relating to equine drawn carts and carried loads in traffic, *animal identification* (registration), licensing and disposal of dead animals.

4. Private veterinarians

Private *veterinarians* are responsible for providing services and advice to working equid owners or handlers and play an important role in *disease surveillance* because they may be the first to see an equid suffering from a *notifiable disease*. They may also play a role (often in liaison with the police or other local authorities) in dealing with cases of neglect that can lead to welfare problems.

Two-way communication between the private *veterinarians* and *Veterinary Authority*, often via the medium of a veterinary professional organisation, is important and the *Veterinary Authority* is responsible for setting up appropriate mechanisms for this interaction.

Private *veterinarians* may also have a responsibility in supervising and coordination of *veterinary paraprofessionals* involved in delivering animal health services.

5. Non-governmental organisations

Relevant non-governmental organisations (NGOs) and intergovernmental organisations should understand the role of working equids and may help to collect and provide information to support policy formulation, to advocate and promote health and welfare of working equids.

Local NGOs are potential partners of the *Veterinary Services* in the development and implementation of working equid health and welfare programmes.

NGOs may also contribute, together with *veterinarians* and *Competent Authorities*, in educating the public in the importance of *animal welfare* of working equids.

6. Working equid owners and users

Owners and users are ultimately responsible for the welfare of their working equids by ensuring their animals' "five freedoms" (Article 7.1.2).

Article 7.12.4.

Criteria or measurables for the welfare of working equids

The following outcome-based measurables can be useful indicators of *animal welfare*. The use of these indicators and the appropriate thresholds should be adapted to the different situations where working equids are used.

1. Behaviour

Presence or absence of certain equine behaviours could indicate an *animal welfare* problem, including fear, depression or pain. Behaviours differ between horses, donkeys and mules and a good understanding of normal behaviour of each species is required.

Some behaviours may not be uniquely indicative of one type of problem; they may be exhibited for a variety of causes. Depression, apathy, dullness and lethargy in equids that are normally active and alert ~~can be~~ are indicative of a welfare problem. Changes in eating or drinking patterns may indicate a welfare problem, especially a decreased feed intake. This might also be an indicator of dental problems, poor feed quality or even feed contamination.

Behaviours indicating discomfort or pain:

- head pressing, teeth grinding, grunting, food dropping, and inability to eat normally. Such behaviours may indicate disease or pain;
- depression, circling, foot pawing, flank watching, inability to stand up, rolling. Such behaviour may indicate abdominal or other discomfort;
- disturbance of ground or bedding. Such behaviours may indicate disease, abdominal pain, or malnutrition;
- weight shifting, foot pawing, reluctance to move or abnormal movement. Such behaviours may indicate leg, foot, spinal or abdominal pain;
- head shaking or avoidance of head contact. Such behaviours may indicate head, ear or ocular discomfort;
- itching, rubbing, self-inflicted abrasions. Such behaviours may indicate skin problems or parasites;
- restlessness, agitation and anxiety, rigid stance and reluctance to move, lowered head carriage, fixed stare and dilated nostrils, clenched jaw, aggression and reluctance to be handled, may indicate non-specific pain in horses. In donkeys, these behaviours are more subtle and may not be recognised;
- vocalisation, rolling, kicking at abdomen, flank watching and stretching may indicate abdominal pain in horses. In donkeys, dullness and depression;
- weight-shifting, limb guarding, abnormal weight distribution, pointing, hanging and rotating limbs, abnormal movement and reluctance to move may indicate limb and foot pain in horses. These signs are more subtle in donkeys, although repeated episodes of lying down are reportedly more indicative;
- headshaking, abnormal bit behaviour, altered eating, anorexia and quidding may indicate head and dental pain.

Behaviours indicating fear or anxiety:

- unusual avoidance of humans, especially when handlers or objects associated with their handling come close;
- a reluctance by the working equids to engage in their use for traction or transport or even a cessation and aggressive behaviour, especially when fitting equipment or loading is undertaken.

Behaviours indicating stress:

- oral stereotypies: crib biting, aerophagia (“wind sucking”);
- locomotive stereotypies: stable walking, weaving;
- abnormal vocalisation, agitation and or defaecation.

2. Morbidity

Morbidity, including incidence of *disease*, lameness, injuries or post-procedural complications, may be a direct or indirect indicator of the *animal welfare* status.

Annex 13 (contd)

Understanding the aetiology of the *disease* or syndrome is important for detecting potential *animal welfare* problems. Scoring systems, such as those used to score lameness and body condition, ~~can~~ provide additional information.

3. Mortality

Mortality, like morbidity, may be a direct or indirect indicator of the *animal welfare* status. Depending on the context, causes of mortality should be investigated as well as temporal and spatial patterns of mortality and possible relationship with husbandry and handling practices. Necropsy is useful in establishing the cause of *death*.

4. Body condition and physical appearance

Poor or changing body condition or physical appearance may be an indicator of compromised animal welfare and health and scoring systems help to provide objectivity.

Observation of physical appearance often provides an indication of animal welfare and health. Attributes of physical appearance that may indicate compromised welfare include:

- feet or limb abnormalities,
- wounds or injuries,
- dehydration or signs of heat stress,
- abnormal discharges,
- presence of parasites,
- abnormal coat or hair loss,
- excessive soiling with faeces, mud or dirt,
- emaciation.

5. Handling responses

Poor human-animal interactions can lead to or be caused by improper handling. This may include bad driving and inappropriate restraint methods, or the misuse of whips and sticks, and can result in fear and distress.

Indicators include:

- aversive or apathetic responses to fitting of equipment and loads,
- defensive responses from the equid to the owner or user such as threatening facial expressions, kicking, biting and avoiding human contact.

6. Complications due to management practices

Some management practices, such as castration and hoof care, are commonly performed in working equids to facilitate handling and improve human safety and *animal welfare*.

Working equids are shod for two main reasons; to prevent hoof wear and to improve performance. Many equids cope well without shoes and, if they are coping well, are best unshod. However, poor hoof care and farriery predispose the working equid to injury and infection, and can result in changes to the size, shape and function of the hoof. Untreated abnormalities of the foot can create long-term problems in other parts of the leg and body due to change in gait and weight bearing.

If management practices such as these are not performed properly, *animal welfare* may be compromised.

Indicators of such problems include:

- post-procedure *infection* and swelling;
- post-procedure lameness;
- myiasis;
- behaviour indicating pain or fear;
- mortality.

It is important to note that some practices are not based on evidence and are inherently bad for welfare. Evidence of firing, nasal slitting, lampas cutting and harmful substances applied to wounds should be identified as indicators of poor welfare.

7. Lameness

Traditionally, lameness has been defined as any alteration of the horse's gait. In addition, lameness can manifest in such ways as a change in attitude or performance. These abnormalities can be caused by pain in the neck, withers, shoulders, back, loin, hips, legs or feet. Identifying the source of the problem is essential for proper treatment. Lameness or gait abnormalities are the most common signs of working equids seen by *veterinarians*. Various scoring systems are available to assess the degree of lameness.

Indicators of such problems include:

- hoof conformation abnormalities;
- unequal weight bearing;
- hoof and pastern axis and angles;

8. Fitness to work

Fitness to work is the state or condition of being physically sound and healthy, especially as a result of exercise and proper nutrition, to perform work well. Various factors such as the animal's age, breed or physiological state (e.g. pregnancy) may influence its fitness to work.

Indicators of an equid's inability to carry out the work demanded of it include the presence of heat stress, lameness, poor body condition or weight loss, harness related wounds and aversive behavioural responses to, for example, harness or equipment fitting.

Article 7.12.5.

Recommendations

Articles 7.12.7. to 7.12.13. provide recommendations for measures applied to working equids.

Each recommendation includes a list of relevant outcome-based measurables derived from Article 7.12.4. This does not exclude other measures being used when appropriate.

Article 7.12.6.

Feeding and provision of water

1. Feeding

Equids are natural grazers that eat small ~~quantities amounts~~ but eat often. Their natural diet is mainly grasses, which have a high roughage content. Horses in particular should be fed frequently with a predominantly fibre-based diet: ~~either~~ grass, hay or a suitable and safe alternative in order to mimic their natural feeding pattern as closely as possible.

Energy, fibre, protein, mineral (including trace minerals) and vitamin contents in the diet of working equids, their balance, safety, digestibility and availability are major factors determining the power of the animals, their growth and overall productivity and their health and welfare.

Working equids should be provided with access to an appropriate quantity of balanced and safe feed, of adequate quality to meet their specific physiological and working needs. In case of feed shortages, the *animal handler* should ensure that the period of reduced feeding is as short as possible and that mitigation strategies are implemented if welfare and health are at risk of being compromised.

Annex 13 (contd)

If supplementary feed is not available, steps should be taken to avoid starvation, including *slaughter*, sale or relocation of the animals, or humane *killing*.

Owners and handlers should allow working equids to forage whenever possible and allow for an adequate number of working breaks to allow the animals to eat. Long fibre forage is important for digestion. Cut green forage should be provided when grazing is not possible. Dry long fibre forage ~~is important and should be~~ provided when adequate green forage is not available.

Inadequate diets and feeding systems may contribute to *diseases*, stress, discomfort or to abnormal behaviour in working equids and should be avoided. *Animal handlers* should be aware of the animals' nutritional needs and consult an expert for advice on ration formulation and feeding programmes when needed.

2. Provision of water

The most important nutrient for the welfare of working equids is water. Working equids need regular and adequate access to palatable, safe water that meets their physiological and work requirements which may vary.

Outcome-based measurables: behaviour, morbidity, mortality, body condition and physical appearance, and fitness to work.

Article 7.12.7.

Shelter

Effective shelter should be provided for working equids both in the resting and working environments. Shelter should provide protection against adverse weather conditions and against predators and injury as well as good ventilation and the ability to rest comfortably. Resting space should be dry, clean and large enough for the equid to lie down, get up and turn around easily.

1. Heat stress

Heat stress is a common condition in working equids in hot, humid environments and *animal handlers* should be aware of the risk that heat stress poses. Equid owners and handlers should be aware of how to prevent it through provision of appropriate shade or shelter along with sufficient drinking water and avoiding work at extreme high temperatures. Owners may also be trained in effective treatment of hyperthermia as timely veterinary assistance may not be available.

Behaviours which indicate heat stress include increased respiratory rate and effort; flared nostrils; increased head movement and lack of response to the environment.

Outcome-based measurables: behaviour, morbidity, mortality, body condition and physical appearance and fitness to work.

2. Cold

Protection from extreme cold weather conditions should be provided when these are likely to create a serious risk to the welfare of equids, particularly of neonates and young animals and others that are physiologically compromised. Such a protection could be provided by extra bedding, blankets or shelter. Care should be taken that, in an attempt to protect against the cold, ventilation and air quality are not compromised

Behaviour which indicates suffering from cold stress includes shivering and huddling together.

Outcome-based measurables: behaviour, mortality and body condition and physical appearance.

3. Protection from predators and injury

Working equids should be kept safe from predators and from road accidents, which are common occurrences if equids are left free to roam. If working equids are housed alongside horned cattle, care should be taken to protect them from injury. Enclosures used should be structurally sound and free of sharp edges, protrusions and other features that could cause injury.

Outcome based measurables: behaviour, morbidity, mortality, body condition and physical appearance and lameness.

Article 7.12.8.

Management1. Biosecurity

Biosecurity plans should be designed, commensurate with the desired health status of the equid population or *herd* and current disease risk. These *biosecurity plans* should be promoted with stakeholders for effective implementation and should address the control of the major sources and pathways for spread of pathogens by:

- a) equids,
- b) other *animals* and *vectors*,
- c) people,
- d) equipment
- e) *vehicles*,
- f) air,
- g) water supply,
- h) feed.

Outcome-based measurables: morbidity, mortality, changes in body condition and physical appearance.

2. Animal health management

Effective national programmes for the prevention and treatment of working equid *diseases* and conditions require clear roles and responsibilities to be defined for official and private animal health service personnel as well as for owners.

Owners and handlers of working equids should be aware of signs of ill-health, *disease*, distress and injuries. If they suspect the presence of disease and are not able to manage it, they should seek advice from *veterinarians* or other qualified persons.

Non-ambulatory working equids should have access to feed and water at all times. They should not be transported or moved unless absolutely necessary for treatment or diagnosis. Such movements should be done carefully using methods that avoid dragging or excessive lifting.

When treatment is attempted, equids that are unable to stand unaided and refuse to eat or drink should be euthanised in accordance with Chapter 7.6., as soon as recovery is deemed unlikely.

Outcome-based measurables: morbidity, mortality, behaviour, body condition and physical appearance.

Article 7.12.9.

Handling and management practices

Management practices should be accomplished expertly and with the proper equipment and pain relief if appropriate. Painful husbandry procedures should be performed under the recommendation or supervision of a *veterinarian*.

Drivers and handlers should be trained to acquire good management skills.

Poor management practices include bad handling, inappropriate restraint such as too tight tethering or hobbling, the working of animals that are unfit or immature, poor housing that does not protect the equids from adverse weather conditions, inadequate handling equipment, excessive number of working hours, underfeeding, lack of access to water, lack of resting periods, working under heat stress, overloading, beating or whipping and some traditional practices.

Annex 13 (contd)

Competent Authorities and *veterinarians* should educate owners and handlers of working equids to cease unsafe, ineffective and inhumane practices and also encourage good management and handling skills.

Working equids should not be kept confined indoors for long periods.

Working equids should not be tethered or hobbled continuously. In situations where temporary hobbling is necessary, the *animal handlers* should ensure sufficient distance between the two hobbled legs to allow the equid to stand naturally and move without risk of injury.

When temporary tethering is necessary working equids should be able to lie down, and if tethered outdoors, turn around and walk. The tethering site should be free from obstructions that may entangle the tether. Adequate water, feed and supervision should be provided; if necessary, action should be taken by moving the animals to areas providing shade or shelter.

Mares in season should not be tethered near stallions; mares about to foal or with a foal should not be tethered.

Equipment used to hobble should be designed for that purpose. The parts of the hobbles which are in contact with the skin should not be made from material that causes pain or injury.

Owners and users of working equids should be discouraged from using whips and harmful goads such as sticks. Instead humane training practices for equids should be promoted which focus on developing good driving practices.

Outcome based measurables: behaviour, morbidity, mortality, body condition and physical appearance, lameness and fitness to work.

Article 7.12.10.

Behaviour

Animal handlers should be familiar with normal and abnormal behaviour of each type of working equid in order to interpret the welfare implications of what is being observed.

~~Good~~ Human-animal interaction should be positive in order not to compromise the welfare of the working equid.

Different natural behaviours and social interactions between horses, mules and donkeys should be taken into account.

Outcome-based measurables: behaviour, body condition and physical appearance, and fitness to work.

Article 7.12.11.

End of working life

Consideration should be given to end of life issues.

Abandonment of equids should be discouraged. The *Competent Authorities* should develop and implement guidance or legislation to prevent abandonment while taking steps to make provision for abandoned animals to ensure their welfare.

When working equids need to be *slaughtered or killed*, recommendations in Chapters 7.5 and 7.6 should be followed to avoid the equid suffering a prolonged and painful *death* by abandonment, neglect or disease or acute, painful death such as being eaten by *wild animals*, or hit by a road vehicle.

Article 7.12.12.

Appropriate workloads

Equids continue to develop until over the age of five years so consideration should be given, according to workload, as to when working life commences. In general this should be three years of age or more but never less than two years of age. Animals that are subjected to excessive work too young in life will usually suffer from leg and back injuries in later life, resulting in a much-reduced working life.

Annex 13 (contd)

Consideration should be given to the animal's overall condition, and other factors such as climate, and the work load should be adjusted accordingly. In particular, special considerations should be given to old animals and to mares three months before and after foaling, in order to not jeopardise pregnancy and allow the foal sufficient suckling access and resting time.

~~Mares should not be ridden or worked three months before and after foaling.~~

~~Special considerations should be given to old animals.~~

In general, animals should work a maximum of six hours per day and should be given at least one, preferably two, full day's rest in every seven-day period. ~~Consideration should be given to the animal's physical condition and age and the work load should be adjusted accordingly.~~

Consideration should be given to the weather conditions (work should be reduced in very hot weather). Breaks should be given at least every two hours and drinkable water should be provided.

All animals should receive sufficient good quality feed corresponding to their individual requirements. Drinkable water and roughage should be available to aid digestion.

Sick or injured animals should not be worked. Any animal that has been under veterinary treatment should not be returned to work until advised by the *veterinarian*.

Outcome based measurables: behaviour, body condition and physical appearance, handling response lameness and fitness to work.

Article 7.12.13.

Farriery and harnessing

1. Farriery

Owners and handlers should routinely clean and check the hooves of the working equid before and after work.

Hoof trimming and shoeing of working equids should only be performed by persons with the necessary knowledge and skills.

Outcome based measurables: behaviour, body condition and physical appearance, lameness and fitness to work.

2. Harnessing

A properly designed, well-fitted and comfortable harness allows the working equid to pull the equipment to the best of its ability, efficiently and without risk of pain or injuries. Harness injury should be prevented by using properly fitted and adjusted harness which is checked daily for damage and repaired promptly as necessary. Equids should be **appropriately groomed before harnessing and** checked after work for signs of rubbing and hair loss and the source of any problems should be removed through maintenance and padding where required.

Harness should not have sharp edges which could cause injury; should fit well so that it does not cause wounds or chafing caused by excess movement; should be smoothly shaped or padded so that loads imposed on the working equids' bodies are spread over a large area; and should not impede the animal's movement or normal breathing or restrict blood supply.

Carts should be maintained to ensure accurate balancing and appropriate tyre pressure. For draught equids the use of swingletrees is recommended so as to balance the pull and thus as a result reduce the risk of sores from the harness.

Owners should ensure effective harnessing and good riding and driving practices.

Annex 13 (contd)

Bits should be of a simple type (such as a straight bar snaffle), depending on work, but should always be smooth, appropriately sized for the equid and kept clean. Inappropriate materials such as thin cord or wire should never be used as bits or to repair bits.

Outcome based measurables: Behaviour, body condition and physical appearance, lameness and fitness to work.

— Text deleted.

DRAFT CHAPTER 8.X.

INFECTION WITH *MYCOBACTERIUM TUBERCULOSIS* COMPLEX

Article 8.X.1.

General provisions

The recommendations in this chapter are intended to manage the human and animal health risks associated with *infection* of animals with a member of the *Mycobacterium tuberculosis* (*M. tuberculosis*) complex.

For the purposes of ~~this chapter~~ the *Terrestrial Code*, *M. tuberculosis* complex comprises *M. bovis*, *M. caprae* and *M. tuberculosis*, but excludes vaccine strains.

Many different domestic and *wild animal* species belonging to diverse mammalian taxa are known to be susceptible to *infection* with *M. tuberculosis* complex. Their epidemiological significance depends on the degree of susceptibility, the husbandry system, the density, spatial distribution and ecology of populations as well as the pathogenesis and transmission pathways. In some geographical regions, certain *wild animal* species can act as reservoirs.

For the purposes of this chapter, 'animals' means domestic and *captive wild* animal populations of the following categories:

- 1) Bovids: this term means **cattle bovines** (*Bos taurus*, *B. indicus*, *B. frontalis*, *B. javanicus* and *B. grunniens*), water buffaloes (*Bubalus bubalis*), and bison (*Bison bison* and *B. bonasus*);₂
- 2) Cervids: this term means red deer (*Cervus elaphus elaphus*), wapiti/elk (*C. elaphus canadensis*), sika (*C. nippon*), samba (*C. unicolor unicolor*), rusa (*C. timorensis*), roe deer (*Capreolus capreolus*), fallow deer (*Dama dama*), white-tailed, black-tailed and mule deer (*Odocoileus* spp.) and reindeer/caribou (*Rangifer tarandus*);₂
- 3) Goats (*Capra hircus*);₂
- 4) ~~New World Camelids (under study).~~
- 4) New World camelids: this term means alpacas (*Lama guanicoe pacos*) and **domestic** llamas (*Lama guanicoe glama*).

The chapter deals not only with the occurrence of clinical signs caused by *infection* with *M. tuberculosis* complex, but also with the presence of *infection* with *M. tuberculosis* complex in the absence of clinical signs.

For the purposes of the *Terrestrial Code*, the following defines the occurrence of *infection* with *M. tuberculosis* complex:

- A member of *M. tuberculosis* complex has been identified in a sample from an animal or a product derived from that animal;

OR

- positive results to a diagnostic test have been obtained and there is an epidemiological link to a case of *infection* with *M. tuberculosis* complex or there is other reason to suspect *infection* with *M. tuberculosis* complex.

When authorising import or transit of *commodities* listed in this chapter, with the exception of those listed in Article 8.X.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the *M. tuberculosis* complex *infection* status of the animal population of the country, *zone* or *herd* of origin.

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

Annex 14 (contd)

Article 8.X.2.

Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any *M. tuberculosis* complex-related conditions, regardless of the *M. tuberculosis* complex *infection* status of the animal populations of the country, *zone* or *herd* of origin:

- 1) *fresh meat* and *meat products* originating from animals that have been subjected to ante- and post-mortem inspections as described in Chapter 6.2.;
- 2) cured hides, skins and trophies;
- 3) gelatine, collagen, tallow and *meat-and-bone meal*.

Article 8.X.3.

Country or zone historically free from infection with *M. tuberculosis* complex in specified animal categories

A country or *zone* may be considered historically free from *infection* with *M. tuberculosis* complex in specified animal categories when the ~~conditions~~ requirements of point 1 a) of Article 1.4.6. have been met for the relevant animal categories.

Article 8.X.4.

Country or zone free from infection with *M. tuberculosis* complex in bovids

- 1) To qualify as free from *infection* with *M. tuberculosis* complex in bovids, a country or *zone* should satisfy the following requirements:
 - a) *infection* in animals is a *notifiable disease* in the entire country;
 - b) a surveillance programme based on regular testing of all *herds* has been in place for at least three years and for the past three years this testing has demonstrated that *infection* with *M. tuberculosis* complex was not present in at least 99.8% of the *herds* representing at least 99.9% of the bovids in the country or *zone*;
 - c) a *surveillance* programme in accordance with Chapter 1.4. is in place to detect *infection* with *M. tuberculosis* complex in the country or *zone* through ante- and post-mortem inspections of bovids as described in Chapter 6.2.;
 - d) regulatory measures have been implemented for the early detection of *infection* with *M. tuberculosis* complex in bovids;
 - e) bovids and their germplasm introduced into the country or *zone* comply with the recommendations in Articles 8.X.7., 8.X.10. and 8.X.12.
- 2) To maintain the status as free from *infection* with *M. tuberculosis* complex in bovids, a country or *zone* should satisfy the following requirements:
 - a) the requirements in points 1 a), 1 c), 1 d) and 1 e) above are met;
 - b) a *surveillance* programme based on regular testing of bovids is in place in the country or *zone* to detect *infection* with *M. tuberculosis* complex in accordance with Article 1.4.4.;
 - c) once the *surveillance* programme described in point b) has demonstrated that *infection* with *M. tuberculosis* complex has not been present in at least 99.8% of the *herds* representing 99.9% of the bovids in the country or *zone* for two consecutive years, *surveillance* may be maintained through ante- and post-mortem inspections as described in Chapter 6.2.;

Annex 14 (contd)

- 3) The country or *zone* status of free from *infection* with *M. tuberculosis* complex in bovids is not affected by the occurrence of *infection* with *M. tuberculosis* complex in other animal categories or *feral* or *wild animals* provided that measures ~~have been implemented~~ intended to prevent transmission of *infection* with *M. tuberculosis* complex to bovids have been implemented and are periodically reassessed.

Article 8.X.5.

Country or zone free from infection with *M. tuberculosis* complex in cervids

- 1) To qualify as free from *infection* with *M. tuberculosis* complex in cervids, a country or *zone* should satisfy the following requirements:
- a) *infection* with *M. tuberculosis* complex in animals is a *notifiable disease* in the entire country;
 - b) regular testing of all cervid *herds* has been in place for at least three years and for the past three years this testing has demonstrated that *infection* with *M. tuberculosis* complex was not present in at least 99.8% of the *herds* representing at least 99.9% of the cervids in the country or *zone*;
 - c) a *surveillance* programme is in place to detect *infection* with *M. tuberculosis* complex in the country or *zone* through ante- and post-mortem inspections as described in Chapter 6.2.;
 - d) regulatory measures have been implemented for the early detection of *infection* with *M. tuberculosis* complex in cervids;
 - e) cervids and their germplasm introduced into the country or *zone* comply with the recommendations in Articles 8.X.7., 8.X.11. and 8.X.12.
- 2) To maintain the status as free from *infection* with *M. tuberculosis* complex in cervids, a country or *zone* should satisfy the following requirements:
- a) the requirements in points 1 a), 1 c), 1 d) and 1 e) above are met;
 - b) a *surveillance* programme based on regular testing of cervids is in place in the country or *zone* to detect *infection* with *M. tuberculosis* complex in accordance with Article 1.4.4.;
 - c) once the *surveillance* programme described in point b) has demonstrated that *infection* with *M. tuberculosis* complex has not been present in at least 99.8% of the *herds* representing 99.9% of the cervids in the country or *zone* for two consecutive years, *surveillance* may be maintained through ante- and post-mortem inspections as described in Chapter 6.2.
- 3) The country or *zone* status free from *infection* with *M. tuberculosis* complex in cervids is not affected by the occurrence of *infection* with *M. tuberculosis* complex in other animal categories or *feral* or *wild animals* provided that measures ~~have been implemented~~ intended to prevent transmission of *infection* with *M. tuberculosis* complex to cervids have been implemented and are periodically reassessed.

Article 8.X.6.

Herd free from infection with *M. tuberculosis* complex in bovids or cervids

- 1) To qualify as free from *infection* with *M. tuberculosis* complex, a *herd* of bovids or cervids should satisfy the following requirements:
- a) the *herd* is in a country or *zone* free from *infection* with *M. tuberculosis* complex in bovids or in cervids and is certified free by the *Veterinary Authority*;

OR

Annex 14 (contd)

- b) the ~~herd meets~~ satisfies the following ~~conditions~~ requirements:
- i) *infection with M. tuberculosis complex in animals is a notifiable disease in the entire country;*
 - ii) no evidence occurrence of *infection with M. tuberculosis complex* has been detected in the *herd* for at least the past 12 months;
 - iii) *bovids or cervids in the herd have shown no clinical signs of infection with M. tuberculosis complex or lesions at ante- or post-mortem inspections for at least the past 12 months;*
 - iv) *two tests have been performed with negative results at a minimum interval of six months on all bovids or cervids over six weeks of age present in the herd at the time of testing. The first test was performed at least six months after the removal of the last case;*
 - v) *bovids or cervids and their germplasm introduced into the herd comply with Articles 8.X.7., 8.X.10., 8.X.11. and 8.X.12.;*
 - vi) *for at least the past 12 months, there has been no evidence occurrence of infection with M. tuberculosis complex in other herds of the same establishments or measures have been implemented to prevent any transmission of infection with M. tuberculosis complex from these other herds;*

2) to maintain the free status, either:

- a) the requirements in point 1 a) are met;

OR

- b) the requirements in points 1 b) i) to iii), v) and vi) are met and bovids or cervids in the *herd*:

- i) *showed a negative result to an annual test to ensure the continuing absence of infection with M. tuberculosis complex;*

OR

- ii) *showed a negative result to a test every two years to ensure the continuing absence of infection with M. tuberculosis complex if it has been confirmed that the annual percentage of herds infected with M. tuberculosis complex is not more than 1% of all herds in the country or zone during the past two years;*

OR

- iii) *showed a negative result to a test every three years to ensure the continuing absence of infection with M. tuberculosis complex if it has been confirmed that the annual percentage of herds infected with M. tuberculosis complex is not more than 0.2% of all herds in the country or zone during the past four years;*

OR

- iv) *showed a negative result to a test every four years to ensure the continuing absence of infection with M. tuberculosis complex if it has been confirmed that the annual percentage of herds infected with M. tuberculosis complex is not more than 0.1% of all herds in the country or zone during the past six years;*

OR

- c) ~~When there is a known wildlife reservoir of M. tuberculosis complex, all herds in the country or zone are covered by a surveillance programme in accordance with point 1c) of Articles 8.X.4. and 8.X.5 and all herds identified as being at risk of infection with M. tuberculosis complex, based on; the requirements in points 1 b) i) to iii), v) and vi) are met; and~~

- i) the risk of transmission of infection with M. tuberculosis complex from known wildlife reservoirs has been assessed through active surveillance;

Annex 14 (contd)

- ii)* all herds identified as being at risk are subjected to a testing programme commensurate with the assessed epidemiological risk of infection with *M. tuberculosis* complex. In identifying herds at risk, the following should be considered:
- i)* == a location associated with suspected or confirmed infection with *M. tuberculosis* complex in wildlife; or
 - ii)* == a history of infection with *M. tuberculosis* complex within last five years; or
 - iii)* == an epidemiological link with herds in either of the two points above; ~~are subjected to a testing programme commensurate with the assessed epidemiological risk of infection with *M. tuberculosis* complex.~~

Article 8.X.7.

Recommendations for the importation of bovids ~~and~~ or cervids for breeding or rearing

Veterinary Authorities of importing countries should require the presentation of an international veterinary certificate attesting that the bovids ~~and~~ or cervids:

- 1) showed no clinical signs of infection with *M. tuberculosis* complex on the day of shipment;
- 2)
 - a) originate from a herd free from infection with *M. tuberculosis* complex that is in a country or zone free from infection with *M. tuberculosis* complex; or
 - b) originate from a herd free from infection with *M. tuberculosis* complex and have been tested for infection with *M. tuberculosis* complex with negative results within 30 days prior to shipment; or
 - c) have been isolated for at least ~~90 days~~ six months prior to shipment including protection from contact with ~~animal~~ any reservoirs of *M. tuberculosis* complex and all isolated animals showed negative results to at least two consecutive tests carried out at a six-month interval, with the second test performed within 30 days prior to shipment.

Article 8.X.8.

Recommendations for the importation of goats for breeding or rearing

Veterinary Authorities of importing countries should require the presentation of an international veterinary certificate attesting that:

- 1) infection with *M. tuberculosis* complex in animals is a notifiable disease in the entire country;
- 2) the goats showed no clinical signs of infection with *M. tuberculosis* complex on the day of shipment;
- 3) either:
 - a) the goats were have been kept since birth in herds in which no case of infection with *M. tuberculosis* complex has been detected for the past three years; or
 - b) have been isolated for at least six months prior to shipment including protection from contact with any reservoir of *M. tuberculosis* complex and all isolated animals showed negative results to at least two consecutive tests carried out at a six-month interval, with the second test performed within 30 days prior to shipment.

Article 8.X.9.

Recommendations for the importation of bovids ~~and~~ or cervids for slaughter

Veterinary Authorities of importing countries should require the presentation of an international veterinary certificate attesting that the bovids ~~and~~ or cervids:

Annex 14 (contd)

- 1) showed no clinical signs of *infection* with *M. tuberculosis* complex on the day of shipment;
- 2) either:
 - a) originate from a country, *zone* or *herd* free from *infection* with *M. tuberculosis* complex;

or

 - b) are *not* being culled as part of an eradication programme against *infection* with *M. tuberculosis* complex and were tested for *infection* with *M. tuberculosis* complex with negative results within 30 days prior to shipment.

Article 8.X.10.

Recommendations for the importation of semen of bovids

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that:

- 1) the donor males showed no clinical signs of *infection* with *M. tuberculosis* complex on the day of collection of the semen;
- 2) the donor males ~~either~~:
 - a) were kept in an *artificial insemination centre* complying with the provisions of Chapter 4.5. and complied with Article 4.6.2.; or
 - b) were kept in a herd free from infection with *M. tuberculosis* complex that is in a country or zone free from infection with *M. tuberculosis* complex; or
 - c) were kept in a *herd* free from *infection* with *M. tuberculosis* complex and showed negative results to a tests performed within 30 days prior to collection of the semen, carried out annually and the semen which was collected, processed and stored in conformity accordance with the provisions of Articles 4.5.34. to 4.5.5. and Articles 4.6.5. to 4.6.7.

Article 8.X.11.

Recommendations for the importation of semen of cervids

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that:

- 1) the donor males showed no clinical signs of *infection* with *M. tuberculosis* complex on the day of collection of the semen;
- 2) the donor males either:
 - a) were kept in a *herd* free from *infection* with *M. tuberculosis* complex in a country or *zone* free from *infection* with *M. tuberculosis* complex ~~and which only accepts cervids from free herds in a free country, or zone~~; or
 - b) were kept in a *herd* free from *infection* with *M. tuberculosis* complex and showed negative results to a tests performed within 30 days prior to collection of the semen, carried out annually and the semen which was collected, processed and stored in conformity accordance with the provisions of Articles 4.5.34. to 4.5.5. and Articles 4.6.5. to 4.6.7.

Article 8.X.12.

Recommendations for the importation of embryos of bovids ~~and~~ or cervids

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that:

- 1) the donor females either:
 - a) originated from a *herd* free from *infection* with *M. tuberculosis* complex in a country or *zone* free from *infection* with *M. tuberculosis* complex; or
 - b) were kept in a *herd* free from *infection* with *M. tuberculosis* complex, and were subjected to a test for *infection* with *M. tuberculosis* complex with negative results during an isolation period of 30 days in the *establishment* of origin prior to collection;
- 2) the semen used for embryo production complied with Article 8.X.10. or 8.X.11.:
- 3) the embryos were collected, processed and stored in accordance with the relevant provisions of Chapters 4.7. to 4.9.

Article 8.X.13.

Recommendations for the importation of milk and milk products of bovids

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that the *milk* or *milk products*:

- 1) have been derived from bovids in a *herd* free from *infection* with *M. tuberculosis* complex; or
- 2) were subjected to pasteurisation or any combination of control measures with equivalent performance as described in the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products.

Article 8.X.14.

Recommendations for the importation of milk and milk products of goats

~~*Veterinary Authorities of importing countries* should require the presentation of an *international veterinary certificate* attesting that:~~

- 1) ~~*infection* with *M. tuberculosis* complex in animals is a *notifiable disease* in the entire country and the *milk* or *milk products* have been derived from goats kept in *herds* in which no case of *infection* with *M. tuberculosis* complex has been detected for the past three years;~~

OR

- 2) ~~the *milk* or *milk products* were subjected to pasteurisation or any combination of control measures with equivalent performance as described in the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products.~~

— Text deleted.

CHAPTER 10.4.

INFECTION WITH AVIAN INFLUENZA VIRUSES

[...]

Article 10.4.25.

Procedures for the inactivation of avian influenza viruses in eggs and egg products

The following times for industry standard temperatures are suitable for the inactivation of avian influenza viruses present in eggs and egg products:

	Core temperature (°C)	Time
Whole egg	60	188 seconds
Whole egg blends	60	188 seconds
Whole egg blends	61.1	94 seconds
Liquid egg white	55.6	870 seconds
Liquid egg white	56.7	232 seconds
<u>Plain or pure egg yolk</u>	<u>60</u>	<u>288 seconds</u>
10% salted yolk	62.2	138 seconds
Dried egg white	67	20 hours
Dried egg white	54.4	543 <u>50.4</u> hours
<u>Dried egg white</u>	<u>51.7</u>	<u>73.2</u> hours

The listed temperatures are indicative of a range that achieves a 7-log kill of avian influenza virus. These are listed as examples in a variety of egg products, but where when scientifically documented, variances from these times and temperatures and for additional egg products may also be suitable when they achieve ~~the~~ equivalent inactivation of the virus.

[...]

— Text deleted.

CHAPTER 11.11.

INFECTION WITH LUMPY SKIN DISEASE VIRUS

Article 11.11.1.

General provisions

Lumpy skin disease (LSD) susceptible animals are **cattle bovines** (*Bos indicus* and *B. taurus*) and water buffaloes (*Bubalus bubalis*) and occasionally certain wild ruminants.

For the purpose of the *Terrestrial Code*, LSD is defined as an infection of **cattle bovines** (~~*Bos indicus* and *B. taurus*~~) and water buffaloes (~~*Bubalus bubalis*~~) with lumpy skin disease virus (LSDV).

The following defines **the occurrence of** infection with LSDV:

- 1) LSDV has been isolated from a sample from **cattle a bovine or a water buffaloes**; or
- 2) antigen or nucleic acid specific to LSDV, excluding vaccine strains, has been identified in a sample from **cattle a bovine** or **a water buffaloes** showing clinical signs consistent with LSD, or epidemiologically linked to a suspected or confirmed case, or giving cause for suspicion of previous association or contact with LSDV; or
- 3) antibodies specific to LSDV, **which are not a consequence of vaccination**, have been identified in a sample from **cattle a bovine** or **a water buffaloes** that either shows clinical signs consistent with LSD, or **are is** epidemiologically linked to a suspected or confirmed case.

For the purposes of the *Terrestrial Code*, the *incubation period* for LSD shall be 28 days.

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

Article 11.11.2.

Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any LSD related conditions regardless of the status of the animal population of the *exporting country*.

- 1) skeletal muscle *meat*;
- 2) **casings**;
- 3) gelatine and collagen;
- 4) tallow;
- 5) hooves and horns;
- 6) ~~horns~~.

Article 11.11.3.

Country or zone free from LSD

A country or a *zone* may be considered free from LSD when *infection* with LSDV is notifiable in the entire country, importation of **cattle bovines** and water buffaloes and their *commodities* is carried out in accordance with this chapter, and either:

Annex 16 (contd)

- 1) the country or *zone* is historically free as described in point 1 a) of Article 1.4.6.; or
- 2) for at least three years, the country or zone vaccination has been prohibited in the country or zone vaccination, has not reported any case of infection with LSDV and a clinical surveillance programme in accordance with Article 11.11.14. has demonstrated no evidence occurrence of infection with LSDV in the country or zone for at least three years; or
- 3) for at least two years, the country or zone vaccination has been prohibited in the country or zone vaccination, has not reported any case of infection with LSDV and a clinical, virological and serological surveillance programme in accordance with Article 11.11.14. has demonstrated no evidence occurrence of infection with LSDV in the country or zone for at least two years.

A country or *zone* free from LSD that is adjacent to an infected area country or zone should include a *zone* in which *surveillance* is conducted in accordance with Article 11.11.14.

A country or *zone* free from LSD will not lose its status as a result of introduction of seropositive or vaccinated cattle bovines or water buffaloes or their *commodities*, provided they were introduced in accordance with this chapter.

Article 11.11.3bis.**Recovery of free status**

- 1) When a case of LSD occurs in a country or zone previously free from LSD, one of the following waiting periods is applicable to regain free status:
 - a) when a stamping-out policy has been applied:
 - = 14 months after the slaughter or killing of the last case, or after the last vaccination if emergency vaccination has been used, whichever occurred last, a stamping-out policy has been applied and during which period clinical, virological and serological surveillance has been conducted in accordance with Article 11.11.14.;
 - b) = 26 months after the slaughter or killing of the last case, or after the last vaccination if emergency vaccination has been used, whichever occurred last, a stamping-out policy has been applied and during which period clinical surveillance alone has been conducted in accordance with Article 11.11.14.;
 - be) when a stamping-out policy is not applied, Article 11.11.3. applies.
- 2) When preventive vaccination is conducted in a country or zone free from LSD, in response to a threat but without the occurrence of a case of LSD, free status may be regained eight months after the last vaccination when clinical, virological and serological surveillance has been conducted in accordance with Article 11.11.14.

Article 11.11.4.**Recommendations for importation from countries or zones free from LSD**

For domestic cattle bovines and water buffaloes

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

- 1) showed no clinical sign of LSD on the day of shipment;
- 2) come from a country or *zone* free from LSD.

Article 11.11.5.

Recommendations for importation from countries or zones not free from LSD

For domestic cattle bovines and water buffaloes

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

- 1) showed no clinical sign of LSD on the day of shipment;
- 2) were kept since birth, or for the past 60 days prior to shipment, in an *epidemiological unit* where no case of LSD occurred during that period;
- 3) were vaccinated against LSD according to manufacturer's instructions at least between 60 days and one year prior to shipment;
- 4) were demonstrated to have antibodies at least 30 days after *vaccination*;
- 5) were kept in a *quarantine station* for the 28 days prior to shipment during which time they were subjected to an agent identification test with negative results.

Article 11.11.6.

Recommendations for importation from countries or zones free from LSD

For semen of cattle bovines and water buffaloes

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

- 1) the donor males:
 - a) showed no clinical sign of LSD on the day of collection;
 - b) were kept in a free country or *zone* for at least 28 days prior to collection;
- 2) the semen was collected, processed and stored in accordance with Chapters 4.5. and 4.6.

Article 11.11.7.

Recommendations for importation from countries or zones not free from LSD

For semen of cattle bovines and water buffaloes

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

- 1) the donor males:
 - a) showed no clinical sign of LSD on the day of collection and the following 28 days;
 - b) were kept for the ~~past~~ 60 days prior to collection, in an *artificial insemination centre* where no case of LSD occurred during that period;
 - c) and EITHER:
 - i) were ~~regularly~~ vaccinated regularly against LSD according to manufacturer's instructions, the first *vaccination* being administrated at least 60 days prior to the first semen collection; and
 - ii) were demonstrated to have antibodies against LSDV at least 30 days after *vaccination*;

Annex 16 (contd)

OR

- iii) were subjected to a serological test to detect antibodies specific to LSDV, with negative results, at least every **44 28** days throughout the collection period and one test **44 21** days after the final collection for this consignment; and
 - iv) were subjected to agent detection by PCR conducted on blood samples collected at commencement and conclusion of, and at least every **44 28** days during, semen collection for this consignment, with negative results; **and**
 - dw)** the semen to be exported was subjected to agent detection by PCR;
- 2) the semen was collected, processed and stored in accordance with Chapters 4.5. and 4.6.

Article 11.11.8.

Recommendations for importation from countries or zones free from LSDFor embryos of **cattle bovines** and water buffaloes*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) the donor females:
 - a) showed no clinical sign of LSD on the day of collection of the embryos;
 - b) kept for at least 28 days prior to collection in a free country or *zone*;
- 2) the embryos were collected, processed and stored in accordance with Chapters 4.7., 4.8. and 4.9., as relevant;
- 3) the semen used for the production of the embryos complied with Article 11.11.6. or 11.11.7., as relevant.

Article 11.11.9.

Recommendations for importation from countries or zones not free from LSDFor embryos of **cattle bovines** and water buffaloes*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) the donor females:
 - a) showed no clinical sign of LSD on the day of collection and the following 28 days;
 - b) were kept in an *establishment* where no *case* of LSD occurred during the 60 days prior to collection;
 - c) **and** EITHER:
 - i) were ~~regularly~~ vaccinated regularly against LSD according to manufacturer's instructions, the first *vaccination* being administrated at least 60 days prior to the first collection; and
 - ii) were demonstrated to have antibodies against LSDV at least 30 days after *vaccination*;

OR

- iii) were subjected to a serological test to detect antibodies specific to LSDV, with negative results, on the day of collection and at least 21 days after collection; **and**
- dw)** were subjected to agent detection by PCR with negative results on a blood sample on the day of collection;

Annex 16 (contd)

- 2) the semen used for the production of the embryos complied with Article 11.11.6. or 11.11.7., as relevant;
- 3) the embryos were collected, processed and stored in accordance with Chapters 4.7., 4.8. and 4.9.

Article 11.11.10.

Recommendations for the importation of milk and milk products

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that the *milk* or the *milk products*:

- 1) have been derived from animals in a country or *zone* free from LSD;

OR

- 2) were subjected to pasteurisation or any combination of control measures with equivalent performance as described in the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products.

~~Article 11.11.11.~~

~~Recommendations for importation of products of animal origin from cattle and water buffaloes intended for agricultural or industrial use~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:~~

- ~~1) these products have been derived from animals that have been kept in a country or zone free from LSD since birth or for at least the past 28 days; or~~
- ~~2) these products have been processed to ensure the destruction of the LSDV.~~

Article 11.11.11+2.

Recommendations for importation of meal and flour from blood, meat other than skeletal muscle, or bones from cattle bovines and water buffaloes

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

- 1) these products have been were derived from animals in a country or *zone* free from LSD; or
- 2) a) the products were processed using heat treatment to a minimum internal temperature of 65°C for at least 30 minutes;
- b) the necessary precautions were taken after processing to avoid contact of the *commodities* with any potential source of LSDV.

Article 11.11.12+3.

Recommendations for importation of hides of cattle bovines and water buffaloes

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

- 1) these products have been were derived from *animals* that have had been kept in a country or *zone* free from LSD since birth or for at least the past 28 days; or

OR

Annex 16 (contd)

- 2) these products had have been were; processed to ensure the destruction of LSDV, in premises controlled and approved by the Veterinary Authority of the exporting country.
- a) derived from animals which have had undergone ante- and post-mortem inspection in accordance with Chapter 6.2. with favourable results; and
 - b) dry-salted or wet-salted for a period of at least 14 days prior to dispatch; or
 - c) treated for a period of at least seven days in salt (NaCl) with the addition of 2% sodium carbonate (Na₂CO₃); or
 - d) dried for a period of at least 42 days at a temperature of at least 20°C; and
- 3) the necessary precautions were taken after processing to avoid contact of the commodities with any potential source of LSDV.

Article 11.11.13.Recommendations for importation of other products of animal origin from bovines and water buffaloes

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

- 1) these products were derived from animals that have been kept in a country or zone free from LSD since birth or for at least the past 28 days; or
- 2) these products were processed to ensure the destruction of the LSDV and the necessary precautions were taken after processing to avoid contact of the commodities with any potential source of LSDV.

Article 11.11.14.

Surveillance1. General principles of surveillance

A Member Country should justify the *surveillance* strategy chosen as being adequate to detect the presence of *infection* with LSDV even in the absence of clinical signs, given the prevailing epidemiological situation in accordance with Chapter 1.4. and Chapter 1.5. under the responsibility of the *Veterinary Authority*.

The ~~Veterinary Authority~~ *Veterinary Services* should implement programmes to raise awareness among farmers and workers who have day-to-day contact with livestock, as well as *veterinary paraprofessionals*, *veterinarians* and diagnosticians, who should report promptly any suspicion of LSD.

In particular Member Countries should have in place:

- a) a formal and ongoing system for detecting and investigating cases outbreaks of disease;
 - b) a procedure for the rapid collection and transport of samples from suspected cases of infection with LSDV to a *laboratory* for diagnosis;
 - c) a system for recording, managing and analysing diagnostic and *surveillance* data.
2. Clinical surveillance

Clinical surveillance is essential for detecting cases of infection with LSDV and requires the physical examination of susceptible animals.

Surveillance based on clinical inspection provides a high level of confidence of detection of *disease* if a sufficient number of clinically susceptible animals is examined regularly at an appropriate frequency and investigations are recorded and quantified. Clinical examination and diagnostic laboratory testing should be pre-planned and applied using appropriate types of samples to clarify the status of suspected cases.

3. Virological and serological surveillance

An active programme of surveillance programme of susceptible populations to detect evidence of *infection* with LSDV is useful to establish the status of a country or *zone*. Serological and molecular testing of cattle bovines and water buffaloes may be used to detect presence of *infection* with LSDV in naturally infected animals.

The study population used for a serological survey should be representative of the population at risk in the country or *zone* and should include be restricted to susceptible unvaccinated animals. Identification of vaccinated animals may minimise interference with serological surveillance and assist with recovery of free status.

4. Surveillance in high-risk areas

Disease-specific enhanced surveillance in a free country or *zone* should be carried out over an appropriate distance from the border with an infected country or *zone*, based upon geography, climate, history of *infection* and other relevant factors. The *surveillance* should be carried out over a distance of at least 20 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 LSDV. A country or *zone* free from LSD may be protected from an adjacent infected country or *zone* by a *protection zone*.

— Text deleted.

CHAPTER 15.1.

INFECTION WITH AFRICAN SWINE FEVER VIRUS

Article 15.1.1.

General provisions

The ~~Suids pig and its close relatives~~ are the only natural non-arthropod hosts for African swine fever virus (ASFV). These include all varieties of *Sus scrofa* (pig), both domestic and *wild*, and African *wild* suid species including warthogs (*Phacochoerus* spp.), bushpigs (*Potamochoerus* spp.) and the giant forest hog (*Hylochoerus meinertzhageni*).

For the purposes of this chapter, a distinction is made among ~~between~~ domestic pigs (permanently captive and farmed free range pigs) and wild pigs (including feral pigs and wild boar) as well as between *Sus scrofa* and African pig species.

= domestic and captive wild pigs, permanently captive or farmed free range, used for the production of meat, or other commercial products or use, or for breeding;

= wild and feral pigs;

= African wild suid species.

All varieties of *Sus scrofa* are susceptible to the pathogenic effects of ASFV, while the African wild suids ~~pigs~~ are not and may act as reservoirs of the virus infection. Ticks of the genus *Ornithodoros* are the only known natural arthropod hosts of the virus and act as reservoirs and biological vectors ~~of the infection~~.

For the purposes of the Terrestrial Code, African swine fever (ASF) is defined as an infection of suids with ASFV.

The following defines the occurrence of infection with ASFV:

1) ASFV has been isolated from samples from a suid;

OR

2) antigen or nucleic acid specific to ASFV has been detected in samples from a suid showing clinical signs or pathological lesions suggestive of ASF or epidemiologically linked to a suspected or confirmed case of ASF, or from a suid giving cause for suspicion of previous association or contact with ASFV, whether or not clinical signs or pathological lesions consistent with ASF are present;

OR

3) antibodies specific to ASFV have been identified in samples from a suid showing clinical signs or pathological lesions consistent with ASF, or epidemiologically linked to a suspected or confirmed case of ASF, or giving cause for suspicion of previous association or contact with ASFV.

For the purposes of the Terrestrial Code, the *incubation period* in *Sus scrofa* ~~is~~ shall be 15 19 days.

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

Annex 17 (contd)

Article 15.1.2.

General criteria for the determination of the ASF status of a country, zone or compartment

The African swine fever (ASF) status of a country, zone or compartment can only be determined after considering the following criteria in domestic and wild pigs, as applicable:

- 1) ASF ~~should be~~ is a notifiable disease in the ~~entire whole~~ country, and all suids showing clinical signs suggestive of ASF are subjected to appropriate field and *laboratory* investigations;
- 2) an ongoing awareness programme is in place to encourage reporting of all ~~cases~~ suids showing signs suggestive of ASF;
- 3) the *Veterinary Authority* has current knowledge of, and authority over, all domestic and captive wild pig herds in the country, zone or compartment;
- 4) the *Veterinary Authority* has current knowledge ~~of about~~ the species of wild and feral pigs and African wild suids present, their distribution population and habitat ~~of wild pigs~~ in the country or zone;
- 5) for domestic and captive wild pigs, an appropriate surveillance programme in accordance with Articles 15.1.22. to 15.1.25. and 15.1.27. is in place;
- 6) for wild and feral pigs, and for African wild suids, if present in the country or zone, a surveillance programme is in place in accordance with Article 15.1.26., considering the presence of natural and artificial boundaries, the ecology of the wild and feral pig and African wild suid populations and an assessment of the likelihood of ASF spread including taking into account the presence of *Ornithodoros* ticks where relevant;
- 7) the domestic and captive wild pig populations are separated by appropriate biosecurity, effectively implemented and supervised, from the wild and feral pig and African wild suid populations, based on the assessed likelihood of spread within the wild and feral pig and African wild suid populations, and surveillance in accordance with Article 15.1.26.; the domestic and captive wild pig population should be separated by appropriate biosecurity, effectively implemented and supervised, from the wild and feral pig and African wild suid populations and they are also protected from *Ornithodoros* ticks where relevant.

Commodities of domestic or captive wild pigs can be traded safely in accordance with the relevant articles of this chapter from countries complying with the provisions of this article, even if they notify infection with ASFV in wild or feral pigs or African wild suids.

Article 15.1.3.

Country or zone free from ASF free country, zone or compartment1. Historically free status-Historical freedom

A country or zone may be considered free from ASF without ~~formally applying a~~ pathogen-specific surveillance programme if the provisions of point 1 a) of Article 1.4.6. are complied with.

2. Free status as a result of an eradication programme-Freedom in all suids

A country or zone which does not meet the conditions of point 1 above may be considered free from ASF when it complies with all the criteria of Article 15.1.2. and when:

- a) surveillance in accordance with Articles 15.1.22. to 15.1.27. has been in place for the past three years;
- b) there has been no case of infection with ASFV during the past three years; this period can be reduced to 12 months when the surveillance has demonstrated no evidence of presence or involvement of *Ornithodoros* ticks;
- c) pig commodities are imported in accordance with Articles 15.1.5. to 15.1.17.

3. Freedom in domestic and captive wild pigs

A country or zone which does not meet the conditions of point 1 or 2 above ~~or a compartment~~ may be considered free from ASF in domestic and captive wild pigs when it complies with all the criteria of Article 15.1.2. and when:

- a) surveillance in accordance with Articles 15.1.22. to 15.1.27. has been in place for the past three years;
- ba) there has been no outbreak case of infection with ASFV in domestic or captive wild pigs during the past three years; this period can be reduced to 12 months when the surveillance has demonstrated no evidence of presence or involvement of Ornithodoros ticks;
- b) no evidence of ASFV infection has been found during the past 12 months;
- c) surveillance has been in place in domestic pigs for the past 12 months;
- cd) imported domestic pigs and pig commodities are imported in accordance with the requirements of in Articles 15.1.5. or to Article 15.1.617.

AND

~~Based on surveillance, ASF infection has been demonstrated not to be present in any wild pig population in the country or zone, and:~~

- ~~e) there has been no clinical evidence, nor virological evidence of ASF in wild pigs during the past 12 months;~~
- ~~f) no seropositive wild pigs have been detected in the age class 6–12 months during the past 12 months;~~
- ~~g) imported wild pigs comply with the requirements in Article 15.1.7.~~

Article 15.1.3bis.

Compartment free from ASF

The establishment of compartment free from ASF should follow the relevant requirements of this chapter and the principles in Chapters 4.3. and 4.4.

Article 15.1.3ter.

Establishment of a containment zone within a country or zone free from ASF

In the event of limited outbreaks of ASF within a country or zone previously free from ASF, including within a protection zone, a containment zone, which includes all outbreaks, may be established for the purposes of minimising the impact on the entire country or zone.

In addition to the requirements for the establishment of a containment zone outlined in point 3 of Article 4.3.3., the surveillance programme should take into account the presence and potential role of Ornithodoros ticks and of wild and feral pigs and African wild suids and any measures in place to avoid their dispersion.

The free status of the areas outside the containment zone is suspended while the containment zone is being established. The free status of these areas outside the containment zone may be reinstated irrespective of the provisions of Article 15.1.4., once the containment zone is clearly established. It should be demonstrated that commodities for international trade either have originated outside the containment zone unless these commodities or comply with the provisions in Articles 15.1.6., 15.1.9., 15.1.11. and Articles 15.1.13. to 15.1.17.

The recovery of the free status of the containment zone should follow the provisions of Article 15.1.4.

Annex 17 (contd)

Article 15.1.4.

Recovery of free status

Should an ASF *outbreak of ASF* occur in a previously free country, or zone or compartment, ~~the free its status~~ may be restored three months after the disinfection of the last infected establishment, provided that:

~~where surveillance has been carried out with negative results, either:~~

- 1) ~~three months after the last case where a stamping-out policy is has been implemented practised and in the case where ticks are suspected to be involved in the epidemiology of the infection, and, in the case where ticks are suspected or known to be involved in the epidemiology of the infection, has been followed by acaricide treatment and the use of sentinel pigs in the infected establishments for two months; or~~
- 2) surveillance in accordance with Article 15.1.25. has been carried out with negative results.
- 2) ~~where a stamping-out policy is not practised~~ Otherwise, the provisions of point 2 of Article 15.1.3. apply should be followed.

AND

~~Based on surveillance, ASF infection has been demonstrated not to be present in any wild pig population in the country or zone.~~

Article 15.1.5.

Recommendations for importation from ASF free countries, zones or compartments free from ASF

For domestic and captive wild pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that ~~the animals:~~

- 1) the animals showed no clinical sign of ASF on the day of shipment;
- 2) the animals were kept in an ASF free country, zone or compartment free from ASF since birth or for at least the past ~~40 days~~ three months;
- 3) if the animals are exported from a free zone or compartment within an infected country or zone, necessary precautions were taken to avoid contact with any source of ASFV until shipment.

Article 15.1.6.

Recommendations for importation from countries or zones ~~considered infected with~~ not free from ASF

For domestic and captive wild pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

- 1) showed no clinical sign of ASF on the day of shipment;
- 2) and either:
 - a) were kept since birth or for the past ~~40 days~~ three months in an ASF free compartment free from ASF; or
 - b) were kept in a quarantine station, isolated for 30 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 15.1.7.

Recommendations for importation from ASF free countries or zonesFor wild pigs

~~Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the animals:~~

- 1) showed no clinical sign of ASF on the day of shipment;
- 2) have been captured in an ASF free country or zone;

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

- 3) 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 201 days after entry into the quarantine station, with negative results.

Article 15.1.8.

Recommendations for importation from ASF free countries, zones or compartments free from ASFFor semen of domestic and captive wild pigs

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

- 1) the donor ~~animals~~ males:
 - a) were kept in an ASF free country, zone or compartment free from ASF since birth or for at least 40 days three months prior to collection;
 - b) showed no clinical sign of ASF on the day of collection of the semen;
- 2) the semen was collected, processed and stored in ~~conformity~~ accordance with the provisions of Chapters 4.5. and 4.6.

Article 15.1.9.

Recommendations for importation from countries or zones ~~considered infected with~~ not free from ASFFor semen of domestic and captive wild pigs

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

- 1) the donor ~~animals~~ males:
 - a) were kept in an ASF free ~~compartment~~ since birth or for at least 40 days three months prior to collection in an establishment, in which surveillance in accordance with Articles 15.1.22. to 15.1.24. demonstrates that no case of ASF has occurred in the past three years; this period can be reduced to 12 months when the surveillance demonstrates that there is no evidence of tick involvement in the epidemiology of the infection;
 - b) showed no clinical sign of ASF on the day of collection of the semen ~~and for the following 40 days;~~
- 2) the semen was collected, processed and stored in ~~conformity~~ accordance with the provisions of Chapters 4.5. and 4.6.

Annex 17 (contd)

Article 15.1.10.

Recommendations for importation from ASF free countries, zones or compartments free from ASFFor in vivo derived embryos of domestic pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

- 1) the donor females:
 - a) ~~were kept in an ASF free country, zone or compartment since birth or for at least 40 days prior to collection;~~
 - a) were kept in a country, zone or compartment free from ASF since birth or for at least three months prior to collection;
 - b) showed no clinical sign of ASF on the day of collection of the embryos;
- 2) the semen used to fertilise the oocytes complied with fertilisation was achieved with semen meeting the conditions referred to in Articles 15.1.7. or 15.1.8., as relevant;
- 3) ~~the embryos were collected, processed and stored in conformity~~ accordance with the relevant provisions of Chapters 4.7. and 4.9., ~~as relevant.~~

Article 15.1.11.

Recommendations for importation from countries or zones ~~considered infected with~~ not free from ASFFor in vivo derived embryos of domestic pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

- 1) the donor females:
 - a) ~~were kept in an ASF free compartment since birth or for at least 40 days~~ three months prior to collection in an establishment, in which surveillance in accordance with Articles 15.1.22. to 15.1.24. demonstrates that no case of ASF has occurred in the past three years; this period can be reduced to 12 months when the surveillance demonstrates that there is no evidence of tick involvement in the epidemiology of the infection;
 - b) showed no clinical sign of ASF on the day of collection of the embryos ~~and for the following 40 days;~~
 - c) were subjected to a serological test performed at least 21 days after collection, with negative results;
- 2) the semen used to fertilise the oocytes complied with fertilisation was achieved with semen meeting the conditions referred to in Articles 15.1.7. or 15.1.8., as relevant;
- 3) ~~the embryos were collected, processed and stored in conformity~~ accordance with the relevant provisions of Chapters 4.7. and 4.9., ~~as relevant.~~

Article 15.1.12.

Recommendations for importation from ASF free countries, zones or compartments free from ASFFor fresh meat of domestic and captive wild pigs

Annex 17 (contd)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *fresh meat* comes from animals which:

- 1) have been kept in an ~~ASF free~~ country, zone or compartment free from ASF since birth ~~or for at least the past 40 days, or which~~ have been imported or introduced in accordance with Article 15.1.5. or Article 15.1.6.;
- 2) have been slaughtered in an approved slaughterhouse/abattoir, where they have been subjected with favourable results to ante- and post-mortem inspections in accordance with Chapter 6.2., ~~and have been found free of any sign suggestive of ASF.~~

Article 15.1.12bis.

Recommendations for importation from countries or zones not free from ASF

For fresh meat of domestic and captive wild pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

- 1) the entire consignment of fresh meat comes from animals which originated from herds in which surveillance in accordance with Articles 15.1.22. to 15.1.24. demonstrates that no case of ASF has occurred in the past three years. This period can be reduced to 12 months when the surveillance demonstrates that there is no evidence of tick involvement in the epidemiology of the infection. In addition, samples from a statistically representative number of animals were tested for ASF, with negative results;
- 2) the entire consignment of fresh meat comes from animals which have been slaughtered in an approved slaughterhouse/abattoir, have been subjected with favourable results to ante- and post-mortem inspections in accordance with Chapter 6.2.;
- 3) necessary precautions have been taken after slaughter to avoid contact of the fresh meat with any source of ASFV.

Article 15.1.13.

Recommendations for importation from ~~ASF free countries or zones~~ of fresh meat of wild and feral pigs

For fresh meat of wild pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

- 4) the entire consignment of *fresh meat* comes from animals which:
 - 1a) have been killed in an ASF free country or zone ~~have been killed in a country or zone free from ASF in accordance with point 1) or 2) of Article 15.1.3.;~~
 - 2b) have been subjected with favourable results to a post-mortem inspection in accordance with Chapter 6.2. in an approved examination centre ~~facility approved by the Veterinary Authority for export purposes, and have been found free of any sign suggestive of ASF;~~

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

- 2) ~~samples has been collected from every animal killed and has been subjected to a virological test and a serological test for ASF, with negative results.~~

Annex 17 (contd)

Article 15.1.14.

Recommendations for the importation of 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

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the products:

- 1) have been prepared:
 - a) exclusively from *fresh meat* meeting the relevant conditions ~~laid down~~ in Articles 15.1.12., 15.1.12bis. or and 15.1.13., as relevant;
 - b) in a processing establishment facility:
 - i) approved by the *Veterinary Authority* for export purposes;
 - ii) processing only *meat* meeting the relevant conditions ~~laid down~~ in Article 15.1.12. or Article 15.1.13., ~~as relevant~~;

OR

- 2) have been processed in an establishment facility approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the ASFV in accordance with Article 15.1.19., and that the necessary precautions were taken after processing to avoid contact of the product with any source of ASFV.

~~Article 15.1.15.~~

~~Recommendations for the importation of pig products of animal origin (from pigs, but not derived from fresh meat) intended for use in animal feeding and for agricultural or industrial use~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that these products:~~

- ~~1) have been prepared:~~
 - ~~a) exclusively from *fresh meat* meeting the conditions laid down in Articles 15.1.12. or 15.1.13., as relevant;~~
 - ~~b) in a processing establishment:~~
 - ~~i) approved by the *Veterinary Authority* for export purposes;~~
 - ~~ii) processing only *meat* meeting the conditions laid down in Articles 15.1.12. or 15.1.13., as relevant;~~

~~OR~~

- ~~2) have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the ASFV, and that the necessary precautions were taken after processing to avoid contact of the product with any source of ASFV.~~

Article 15.1.16.

Recommendations for the importation of bristles (from pigs)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that ~~these products~~ bristles:

- 1) originated from domestic or captive wild pigs in come from an ASF free a country, zone or compartment free from ASF and have been processed in a facility approved by the *Veterinary Authority* for export purposes; or

Annex 17 (contd)

- 2) have been processed in a facility approved by the Veterinary Authority for export purposes so as to ensure the destruction of the ASFV in accordance with one of the processes listed in Article 15.1.21bis., and that the necessary precautions were taken after processing to avoid contact of the product with any source of ASFV.

Article 15.1.17.

Recommendations for the importation of litter and manure (from pigs)

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that these products:

- 1) come from an ASF free country, zone or compartment, or
- 2) have been processed in an establishment approved by the Veterinary Authority for export purposes so as to ensure the destruction of the ASFV, and that the necessary precautions were taken after processing to avoid contact of the product with any source of ASFV.

Article 15.1.17.(Reinstated)

Recommendations for the importation of litter and manure from pigs

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that these products:

- 1) originated from domestic or captive wild pigs in a country, zone or compartment free from ASF; or
- 2) have been processed in a facility approved by the Veterinary Authority for export purposes so as to ensure the destruction of the ASFV in accordance with one of the processes listed in Article 15.1.21ter., and that the necessary precautions were taken after processing to avoid contact of the product with any source of ASFV.

Article 15.1.17bis.

Recommendations for the importation of skins and trophies from suids

Veterinary Authorities of importing countries should require the presentation of an international veterinary certificate attesting that the products:

- 1) originated from suids in a country or zone free from ASF in accordance with point 1 or point 2 of Article 15.1.3. and have been processed in a facility approved by the Veterinary Authority for export purposes; or
- 2) originated from domestic or captive wild pigs in a country, zone or compartment free from ASF and have been processed in a facility approved by the Veterinary Authority for export purposes; or
- 3) have been processed in a facility approved by the Veterinary Authority for export purposes so as to ensure the destruction of ASFV in accordance with one of the procedures referred to in Article 15.1.21., and that the necessary precautions were taken after processing to avoid contact of the product with any source of ASFV.

Article 15.1.17ter.

Recommendations for the importation of other pig products

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that these products:

- 1) originated from domestic or captive wild pigs in a country, zone or compartment free from ASF and have been prepared in a processing facility approved by the Veterinary Authority for export purposes;

Annex 17 (contd)OR

- 2) have been processed in a facility approved by the Veterinary Authority for export purposes so as to ensure the destruction of ASFV, and that the necessary precautions were taken after processing to avoid contact of the product with any source of ASFV.

Article 15.1.18.

Procedures for the inactivation of ASFV in swill

For the inactivation of ASFV in swill, one of the following procedures should be used:

- 1) the swill is maintained at a temperature of at least 90°C for at least 60 minutes, with continuous stirring; or
- 2) the swill is maintained at a temperature of at least 121°C for at least 10 minutes at an absolute pressure of 3 bar; or
- 3) the swill is subjected to an equivalent treatment that has been demonstrated to inactivate ASFV.

Article 15.1.19.

Procedures for the inactivation of ASFV in meat

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

1. Heat treatment

Meat should be subjected to one of the following:

- a) heat treatment in a hermetically sealed container with a Fo value of 3.00 or more; or
- b) heat treatment for at least 30 minutes at a minimum temperature of 70°C, which should be reached throughout the meat.

2. Dry cured pig meat

Meat should be cured with salt and dried for a minimum of six months.

Article 15.1.20.

Procedures for the inactivation of ASFV in casings of pigs

For the inactivation of ASFV present in casings of pigs, the following procedures should be used: treating for at least 30 days either with dry salt (NaCl) or with saturated brine ($A_w < 0.80$), or with phosphate supplemented dry salt containing 86.5% NaCl, 10.7% Na_2HPO_4 and 2.8% Na_3PO_4 (weight/weight/weight), and kept at a temperature of greater than 12°C or above during this entire period.

Article 15.1.21.

Procedures for the inactivation of ASFV in skins and trophies

For the inactivation of ASFV in skins and trophies, one of the following procedures should be used:

- 1) boiling in water for an appropriate time so as to ensure that any matter other than bone, tusks or teeth is removed; or
- 2) soaking, with agitation, in a 4% (w/v) solution of washing soda (sodium carbonate- Na_2CO_3) maintained at pH 11.5 or above for at least 48 hours; or
- 3) soaking, with agitation, in a formic acid solution (100 kg salt [NaCl] and 12 kg formic acid per 1,000 litres water) maintained at below pH 3.0 for at least 48 hours; wetting and dressing agents may be added; or

Annex 17 (contd)

- 4) in the case of raw hides, treating for at least 28 days with salt (NaCl) containing 2% washing soda (sodium carbonate–Na₂CO₃); or
- 5) treatment with 1% formalin for a minimum of six days.

Article 15.1.21bis.

Procedures for the inactivation of ASFV in bristles

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

- 1) boiling for at least 30 minutes;
- 2) immersion for at least 24 hours in a 1% solution of formaldehyde.

Article 15.1.21ter.

Procedures for the inactivation of ASFV in litter and manure from pigs

For the inactivation of ASFV present in litter and manure of pigs, one of the following procedures should be used:

- 1) moist heat treatment for at least one hour at a minimum temperature of 55°C;
- 2) moist heat treatment for at least 30 minutes at a minimum temperature of 70°C.

Article 15.1.22.

Introduction to surveillance

Articles 15.1.22. to 15.1.27. provide recommendations for surveillance for ASF, and are complementary to Chapters 1.4. and 1.5. The impact and epidemiology of ASF may vary in different regions of the world, as does the routine biosecurity in different production systems. The surveillance strategies employed for determining ASF status should be adapted to the situation. The approach used should take into account the presence of wild or feral pigs or African wild suids, the presence of *Ornithodoros* ticks, and the presence of ASF in adjacent countries or zones.

Surveillance for ASF should be in the form of an ongoing programme designed to establish that susceptible populations in a country, zone or compartment are free from infection with ASFV or to detect the introduction of ASFV into a free population. Consideration should be given to the specific characteristics of ASF epidemiology which include:

- = the role of swill feeding;
- = the impact of different systems of production of domestic and captive wild pigs;
- = the role of wild and feral pigs and African wild suids on the maintenance and spread of the disease;
- = whether *Ornithodoros* ticks are present and the role they may play in the maintenance and spread of the disease;
- = the lack of pathognomonic gross lesions and clinical signs;
- = the occurrence of carriers;
- = the genotypic variability of ASFV.

Annex 17 (contd)Article 15.1.23.General conditions and methods for surveillance

- 1) A surveillance system in accordance with Chapter 1.4. and under the responsibility of the Veterinary Authority should address the following:
 - a) a formal and ongoing system for detecting and investigating cases of ASF;
 - b) a procedure for the rapid collection and transport of samples from suspected cases to a laboratory;
 - c) appropriate laboratory testing capability for ASF diagnosis;
 - d) a system for recording, managing and analysing diagnostic and surveillance data.
- 2) The ASF surveillance programme should:
 - a) include an early detection system throughout the production, marketing and processing chain for reporting suspected cases. Diagnosticians and those with regular contact with pigs should report promptly any suspicion of ASF to the Veterinary Authority. The reporting system under the Veterinary Authority should be supported directly or indirectly (e.g. through private veterinarians or veterinary paraprofessionals) by government or private sector awareness programmes targeted to all relevant stakeholders. Personnel responsible for surveillance should be able to seek expertise in ASF diagnosis, epidemiological evaluation and control;
 - b) conduct, when relevant, regular and frequent clinical inspections and laboratory testing of high-risk groups (for example, where swill feeding is practised), or those adjacent to an ASF infected country or zone (for example, bordering areas where infected wild and feral pigs or African wild suids are present).

Article 15.1.24.Surveillance strategies1. Introduction

The population covered by surveillance aimed at detecting disease and infection should include domestic, captive wild, wild and feral suid populations within the country or zone. Surveillance should be composed of random and non-random approaches using clinical, virological and serological methods appropriate for the infection status of the country or zone.

The strategy employed to establish the prevalence or absence of infection with ASFV may be based on randomised or non-randomised clinical investigation or sampling at an acceptable level of statistical confidence. If an increased likelihood of infection in particular localities or subpopulations can be identified, targeted sampling may be an appropriate strategy. This may include:

- a) specific high-risk wild and feral suid populations and their proximity;
- b) farms which feed swill;
- c) pigs reared outdoors.

Risk factors may include, for example, temporal and spatial distribution of past outbreaks, and pig movements and demographics.

Member Countries should review their surveillance strategies whenever an increase in the risk of incursion of ASFV is perceived. Such changes include but are not limited to:

- = an emergence or an increase in the prevalence of ASF in countries or zones from which live pigs or products are imported;
- = an increase in the prevalence of ASF in wild or feral suids in the country or zone;
- = an increase in the prevalence of ASF in adjacent countries or zones;
- = an increased entry of, or exposure to, infected wild or feral suid populations from adjacent countries or zones;
- = evidence of involvement of ticks in the epidemiology of ASF as demonstrated by surveillance implemented in accordance with Chapter 1.5.

2. Clinical surveillance

Clinical surveillance is the most effective tool for detecting ASF due to severe clinical signs and pathology associated with infection with ASFV. However, due to the clinical similarity with other diseases such as classical swine fever, porcine reproductive and respiratory syndrome and erysipelas, and those associated with porcine circovirus 2 infection, clinical surveillance should be supplemented, as appropriate, by serological and virological surveillance.

Clinical signs and pathological findings are useful for early detection; in particular, any cases where clinical signs or lesions suggestive of ASF are accompanied by high mortality should be investigated without delay.

Wild and feral suids rarely present the opportunity for clinical observation, but should form part of any surveillance scheme and should, ideally, be monitored for virus as well as antibodies.

3. Virological surveillance

Virological surveillance is important for early detection, differential diagnosis and for systematic sampling of target populations. It should be conducted:

- a) to investigate clinically suspected cases;
- b) to monitor at risk populations;
- c) to follow up positive serological results;
- d) to investigate increased mortality when ASF cannot be ruled out;
- e) to confirm eradication after a stamping-out policy has been applied.

Molecular detection methods can be applied to large-scale screening for the presence of virus. If targeted at high-risk groups, they provide an opportunity for early detection that can considerably reduce the subsequent spread of ASFV. Epidemiological understanding of the pathways of spread of ASFV can be greatly enhanced by molecular analyses of viruses in endemic areas and those involved in outbreaks in areas previously free from ASF. Therefore, ASFV isolates should be sent to an OIE Reference Laboratory for further characterisation.

4. Serological surveillance

Serology is an effective and efficient surveillance tool. Serological surveillance aims at detecting antibodies against ASFV. Positive ASFV antibody test results can indicate an ongoing or past outbreaks, since some animals may recover and remain seropositive for a significant period, possibly life. This may include carrier animals. However, ASF serology is not suitable for early detection.

It may be possible to use sera collected for other survey purposes for ASF surveillance. However, the principles of survey design and the requirement for statistical validity should not be compromised.

Annex 17 (contd)Article 15.1.25.**Surveillance procedures for recovery of free status**

In addition to the general conditions described in Articles 15.1.3. and 15.1.4., a Member Country seeking recovery of free status for the entire country or a zone, including for a containment zone, should show evidence of an active surveillance programme to demonstrate no evidence of infection with ASFV.

The domestic and captive wild pig populations should undergo regular clinical and pathological examinations and virological and serological testing, planned and implemented according to the general conditions and methods described in this chapter.

This surveillance programme should include:

- 1) establishments in the proximity of the outbreaks;
- 2) establishments epidemiologically linked to the outbreaks;
- 3) animals moved from or used as sentinels or to repopulate affected establishments;
- 4) all establishments where contiguous culling has been carried out;
- 5) wild and feral suid populations in the area of the outbreaks.

Article 15.1.26.**Surveillance for ASFV in wild and feral pigs and African wild suids**

- 1) The objective of a surveillance programme is either to demonstrate that infection with ASFV is not present in wild and feral suids or, if known to be present, to estimate the geographical distribution of the infection.

Surveillance in wild and feral suids presents additional challenges including:

- a) determination of the distribution, size and movement patterns of the wild and feral suid population;
- b) relevance and practicality of assessing the possible presence of infection with ASFV in the population;
- c) determination of the practicability of establishing a zone taking into account the degree of interaction with domestic and captive wild pigs within the proposed zone.

The geographic distribution and estimated size of wild and feral suid populations should be assessed as a prerequisite for designing a population monitoring system following Chapter 1.4.

- 2) For implementation of the surveillance programme, the limits of the area over which wild and feral pigs range should be defined. Subpopulations of wild and feral suids may be separated from each other by natural or artificial barriers.
- 3) The surveillance programme may include animals found dead, road kills, animals showing abnormal behaviour and hunted animals, and may also include awareness campaigns targeted at hunters and farmers.
- 4) There may be situations where a more targeted surveillance programme can provide additional assurance. The criteria to define high risk areas for targeted surveillance include:
 - a) areas with past history of ASF;
 - b) subregions with large populations of wild or feral pigs or African wild suids;
 - c) border regions with ASF affected countries or zones;

- d) interface between wild and feral pig populations, and domestic and captive wild pig populations;
- e) areas with farms with free-ranging and outdoor pigs;
- f) areas with a high level of hunting activity, where animal dispersion and feeding as well as inappropriate disposal of waste can occur;
- g) other risk areas determined by the Veterinary Authority such as ports, airports, garbage dumps and picnic and camping areas.

Article 15.1.27.

Surveillance for arthropod vectors

Vector surveillance aims at defining the type and distribution of ticks of the genus *Ornithodoros*. Any species of *Ornithodoros* should be considered to be a potential vector or reservoir of ASFV. The virus is generally transmitted transstadially. Transovarial transmission has been observed only in ticks of the *Ornithodoros moubata* complex.

The Competent Veterinary Authority should have knowledge of the presence, distribution and identity of *Ornithodoros*, taking into account climatic or habitat changes that may affect distribution.

When vector surveillance is considered necessary, a sampling plan in accordance with Chapter 1.5. should take into account the biology and ecology of species present and, in particular, the favoured habitat of these species in burrows and structures associated with pig production. The plan should also take into account the distribution and density of pigs in the country or zone.

Sampling methods include CO₂ trapping and flagging, and vacuuming of burrows or structures.

— Text deleted.

CHAPTER 15.X.

INFECTION WITH PORCINE REPRODUCTIVE AND RESPIRATORY SYNDROME VIRUS

Article 15.X.1.

General provisions

The pig is the only natural host for porcine reproductive and respiratory syndrome virus (PRRSV).

For the purposes of the *Terrestrial Code*, porcine reproductive and respiratory syndrome (PRRS) is defined as an *infection* of domestic and *captive wild pigs* with PRRSV.

The following defines the occurrence of *infection* with PRRSV:

- 1) a strain of PRRSV, excluding vaccine strains, has been isolated from a samples from a domestic or *captive wild pig*;

OR

- 2) ~~viral antigen has been identified, or viral ribonucleic acid specific to PRRSV, which is not a consequence of vaccination, has been demonstrated to be present~~ detected in a samples from a domestic or *captive wild pig* epidemiologically linked to a confirmed or suspected outbreak case of PRRS, or giving cause for suspicion of previous association or contact with PRRSV, with or without clinical signs consistent with PRRS;

OR

- 3) a live PRRSV vaccine strain has been isolated or antigen or ribonucleic acid specific to a live PRRSV vaccine strain has been detected in a samples from a domestic or *captive wild pig* that is unvaccinated, or has been vaccinated with an inactivated vaccine, or with a different vaccine strain, showing clinical signs suggestive of PRRS, or epidemiologically linked to a suspected or confirmed case;

OR

- ~~4) virus specific antibodies specific against to PRRSV, that are not unless they are demonstrated to be a consequence of vaccination or maternally derived immunity, have been identified in samples from a domestic or captive wild pig in a herd showing clinical signs consistent with PRRS, or epidemiologically linked to a confirmed or suspected outbreak of PRRS, or giving cause for suspicion of previous association or contact with PRRSV.~~

OR

- 4) ~~the detection of a vaccinal or vaccine like virus in a non vaccinated domestic or captive wild pig.~~

For the purposes of the *Terrestrial Code*, the *incubation period* for or PRRS is shall be 14 days. ~~Pigs are usually infective between days 3 three and 40 days post *infection*, but can remain so for several months.~~

Commodities of domestic or captive wild pigs can be traded safely in accordance with the relevant articles of this chapter, even if exporting countries inform the OIE of the presence of *infection* with PRRSV in wild or feral pigs.-A Member Country should not impose bans on the trade in commodities of domestic and captive wild pigs in response to information on the presence of *infection* with PRRSV in wild or feral pigs.

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

Annex 18 (contd)

Article 15.X.2.

Safe commodities

When authorising import or transit of the following *commodities* and any products made from these *commodities* and containing no other tissues from pigs, *Veterinary Authorities* should not require any PRRS related conditions, regardless of the PRRS status of the *exporting country, zone or compartment*:

- 1) hides, skins and trophies;
- 2) bristles;
- 3) ~~meat and~~ meat products ~~from pigs that have passed ante- and post mortem inspections;~~
- 4) ~~meat-and-bone meal;~~
- 5) ~~blood by-products;~~
- 6) ~~casings;~~
- 7) ~~gelatine.~~

Article 15.X.3.

Country, zone or compartment free from PRRS

A country, *zone* or *compartment* may be considered free from PRRS when following conditions are met:

- 1) PRRS is a *notifiable disease* in the entire country;
- 2) an *early detection system* is in place;
- 3) *surveillance* in accordance with Articles 15.X.13-15 to 15.X.16-18. has been in place for at least 12 months; ~~capable of detecting the presence of infection with PRRSV even in the absence of clinical signs;~~
- 4) there has been no evidence of occurrence of *infection* with PRRSV has been found in domestic and *captive wild* pigs during the past 12 months;
- 5) no *vaccination* against PRRS with inactivated vaccines has been carried out during the past 12 months;
- 6) no vaccination against PRRS with modified live vaccines has been carried out during the past 24 months;
- 6) ~~measures are in place to prevent the introduction of PRRSV;~~
- 7) ~~imported~~ pigs and pig *commodities* are imported or introduced in accordance with ~~comply with the requirements in Articles 15.X.5. to 15.X.12-14.~~

Article 15.X.4.

Recovery of free status

Should a PRRS *outbreak* occur in a previously free country, *zone* or *compartment*, the free status may be restored three months after the disposal or slaughter of the last case, provided that:

- ≡ by means of a stamping-out policy or the slaughter of all susceptible animals in the infected herds followed by cleaning and disinfection of the farm establishments, has been implemented; ~~a modified stamping-out policy with or without emergency vaccination. Free status can be regained three months after the culling of the last case or vaccinated pig provided.~~

Annex 18 (contd)

= ~~surveillance is~~ has been carried out in accordance with Articles 15.X.13~~45~~ to 15.X.16~~48~~ with negative results.

Where a stamping-out policy or depopulation by means of slaughter ~~modified stamping-out policy is~~ are not practised, ~~the provisions of~~ Article 15.X.3. applies.

Article 15.X.5.

Recommendations for importation from countries, zones or compartments free from PRRSFor domestic and captive wild pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

- 1) showed no clinical sign of PRRS on the day of shipment;
- 2) were kept in a country, *zone* or *compartment* free from PRRS since birth or for at least the past three months.

Article 15.X.6.

Recommendations for importation from countries or zones not free from PRRSFor domestic and captive wild pigs for breeding or rearing

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the ~~animals~~ pigs:

- 1) were kept, since birth or for at least three months prior to isolation, in an establishment in which no infection with PRRSV was detected within that period;
- 2) showed no clinical sign of PRRS on the day of shipment;
- 3) have not been vaccinated against PRRS nor are they the progeny of vaccinated sows;
- 4) were isolated for 28 days by application of biosecurity and subjected to a serological test for infection with PRRSV, with negative results, on two occasions, at an interval of not less than 21 days, the second test being performed within 15 days prior to shipment.

Article 15.X.7.

Recommendations for importation from countries or zones not free from PRRSFor domestic and captive wild pigs for slaughter

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals showed no clinical sign of PRRS on the day of shipment.

The pigs should be transported directly with appropriate biosecurity from the *place of shipment* to the *slaughterhouse/abattoir* for immediate *slaughter*.

Article 15.X.8.

Recommendations for importation of wild and feral pigs

~~Regardless of the PRRS status of the country of origin, Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the animals:~~

Annex 18 (contd)

- 1) ~~showed no clinical sign of PRRS on the day of shipment;~~
- 2) ~~were isolated in a *quarantine station*, and were subjected to a serological test for PRRS, with negative results, on two occasions, at an interval of not less than 21 days, the second test being performed within 15 days prior to shipment;~~
- 3) ~~have not been vaccinated against PRRS.~~

Article 15.X.89.

Recommendations for importation from countries, zones or compartments free from PRRSFor semen of domestic and captive wild pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

- 1) the donor ~~animals~~ males:
 - a) were kept in a country, *zone* or *compartment* free from PRRS since birth or for at least three months prior to collection;
 - b) showed no clinical sign of PRRS on the day of collection of the semen;
- 2) the semen was collected, processed and stored in ~~conformity with the provisions of~~ accordance with Chapters 4.5. and 4.6.

Article 15.X.9+0.

Recommendations for importation from countries or zones not free from PRRSFor semen of domestic and captive wild pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

- 1) the donor ~~animals~~ males have not been vaccinated against PRRS; and:
 - a) ~~and either~~:
 - a*i*) were kept, since birth or for at least three months prior to entry into the pre-entry isolation facility in an establishment in which no pigs have been vaccinated against PRRS and no infection with PRRSV was detected within that period without any evidence of PRRS;
 - b*ii*) showed no clinical sign of PRRS on the day of entry into the pre-entry isolation facility and were ~~serologically tested~~ subjected to a serological test with negative results on samples collected on the same day the day of entry into the pre-entry isolation facility;
 - c*iii*) were kept in the pre-entry isolation facility for at least 28 days and were subjected to a serological test with negative results on samples collected at least no less than 21 days after entry;
 - d*iv*) either:
 - i) have been kept in an artificial insemination centre where, at least every month, serum samples from a statistically representative sample number of all donor males is are subjected are all ~~boars are subjected~~, at least every month, to an serological appropriate test for infection with PRRSV with negative results, at least every month. The sampling scheme should be designed to ensure that all donor males are tested every 12 months and at least once during their stay;

OR

- ~~ii)~~ or have been kept in an artificial insemination centre where all donor males;
- ~~i)~~ have been kept in an artificial insemination centre where all boars were subjected to serological and virological examinations for infection with PRRSV, with negative results, on serum samples taken seronegative for PRRS on the day of collection;
- ~~ii)~~ a sample of semen from each collection for export has been tested for PRRSV nucleic acid with negative results;

OR

- 2) ~~the semen was collected, processed and stored in conformity with the provisions of~~ accordance with the relevant articles in Chapters 4.5. and 4.6.

Article 15.X.1044.

Recommendations for importation of *in vivo* derived embryos of domestic and captive wild pigs from countries, zones or compartments free from PRRS

~~Regardless of the PRRS status of the country of origin,~~ Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

- 1) the donor females were kept in a country, zone or compartment free from PRRS since birth or for at least three months prior to collection;
- 2) the donor females showed no clinical sign of PRRS on the day of collection of the embryos;
- 3) the embryos were collected, processed and stored in conformity with the relevant provisions of in accordance with Chapters 4.7. and or 4.9., as relevant;
- 4) the semen used for the production of embryos complied with the provisions of Article 15.X.8. or 15.X.9.

Article 15.X.1142.

Recommendations for importation of *in vivo* derived embryos of domestic and captive wild pigs from countries or zones not free from PRRS

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

- 1) the donor females:
 - a) showed no clinical sign of PRRS on the day of collection;
 - b) were subjected to a serological test for infection with PRRSV, with negative results, on two occasions, at an interval of not less than 21 days, the second test being performed within 15 days prior to embryo collection;
- 2) the embryos were collected, processed and stored in accordance with Chapters 4.7. or 4.9., as relevant;
- 3) the semen used for the production of embryos complied with the provisions of Article 15.X.8. or 15.X.9.

Annex 18 (contd)

Article 15.X.12.**Recommendations for importation of fresh meat of domestic and captive wild pigs**

Regardless of the PRRS status of the country of origin, Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the entire consignment of fresh meat comes from pigs that have been slaughtered in an approved slaughterhouse/abattoir and have been subjected with favourable results to ante- and post-mortem inspections in accordance with Chapter 6.2.

Article 15.X.12.

Recommendations for importation of fresh meat of domestic and captive wild pigs

Regardless of the PRRS status of the country of origin, Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the entire consignment of fresh meat:

- 1) either:
 - a) comes from pigs that were kept in a country, zone or compartment free from PRRS since birth or for at least the past three months; or
 - b) does not contain:
 - = tonsils;
 - = thymus;
 - = lymph nodes of the head, neck, or thoracic or abdominal viscera;
- 2) comes from pigs that have been slaughtered in a slaughterhouse/abattoir and have been subjected to ante- and post-mortem inspections in accordance with Chapter 6.2. with favourable results.

~~does not contain lymphoid tissues of the head and neck, and thoracic and abdominal viscera; and~~

- 2) ~~comes from animals which:~~
 - a) ~~showed no clinical signs suggestive of PRRS within 24 hours before slaughter;~~
 - b) ~~have been slaughtered in a slaughterhouse/abattoir and have been subjected to ante- and post-mortem inspections in accordance with Chapter 6.2.~~

Article 15.X.13.

Recommendations for importation of fresh meat of wild and feral pigs

Regardless of the PRRS status of the country of origin, Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the entire consignment of fresh meat;

- 1) ~~does not contain lymphoid tissues of the head and neck, and thoracic and abdominal viscera; and~~
- 2) ~~comes from animals which:~~
 - a) ~~have been subjected to a post-mortem inspection in accordance with Chapter 6.2. in an approved examination centre;~~
 - b) ~~have been found free from any sign suggestive of PRRS.~~

Article 15.X.14.

Recommendations for importation of offal

~~Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the entire consignment of offal or products containing offal comes from pigs coming from establishments located in a PRRS free country, zone or compartment.~~

Article 15.X.13+5.

Introduction to surveillance

The following defines the principles and provides a guide to the *surveillance* for PRRS, complementary to Chapter 1.4. This may be for the entire country, a *zone* or a *compartment*. Guidance is also provided for Member Countries seeking recovery of PRRS status for the entire country, for a *zone* or for a *compartment*, following an *outbreak* and for the maintenance of PRRS status.

Surveillance should be capable of detecting the presence of infection with PRRSV even in the absence of clinical signs. *Surveillance* for PRRS should be in the form of a continuing programme designed to establish that domestic and *captive wild* pig populations in a country, *zone* or *compartment* are free from *infection* with PRRSV or to detect the introduction of PRRSV into a population already defined as free. Consideration should be given to the specific characteristics of PRRS epidemiology that include:

- the role of pig-to-pig contact;
- the role of semen in transmission of the virus;
- ~~the existence~~ possible occurrence of aerosol transmission ~~over short distances;~~
- the existence of two distinct genotypes of PRRSV, also with antigenic and virulence variability among strains of both genotypes;
- the frequency of clinically inapparent *infections*, particularly in older ~~animals~~ pigs;
- the possible occurrence of long-term virus-shedding even in the presence of antibodies;
- the lack of a differentiating test for vaccinal antibodies and the inherent risks associated with the use of modified live vaccines for PRRS.

Veterinary Authorities may have information on the genotype prevailing in the country but it should not be assumed that the absence of the other genotype should not be assumed is absent. Therefore, molecular virological and serological tests used for *surveillance* should be able to detect both genotypes and antibodies to both genotypes with similar sensitivity.

Article 15.X.14+6.

General conditions and methods for surveillance

- 1) A *surveillance* system in accordance with Chapter 1.4. and under the responsibility of the *Veterinary Authority* should be in place and including include the following aspects elements:
 - a) formal and ongoing system for detecting and investigating *outbreaks* of PRRS;
 - b) a system for recording, managing and analysing diagnostic and *surveillance* data.

Annex 18 (contd)

- 2) ~~The~~ Any PRRS *surveillance* programme should:
- a) include ~~a system for the~~ reporting and investigation of suspected cases. Diagnosticians and those with regular contact with pigs should report promptly any suspicion of PRRS to the *Veterinary Authority*;
 - b) implement, when relevant, regular and frequent clinical inspections and *laboratory* testing of populations at high-risk of contracting or spreading *disease*, such as *artificial insemination centres* and nucleus *herds*, *establishments* in high pig density areas or with ~~low~~ lax *biosecurity measures*.

Article 15.X. 1517.

Surveillance strategies1. Introduction

The objective of *surveillance* is to estimate the prevalence of infection, demonstrate freedom ~~from infection~~ or to detect introduction of PRRSV as soon as possible.

~~Serology in unvaccinated populations is often the most effective and efficient *surveillance* methodology. In some *animals*, antibodies against PRRSV can disappear after approximately three to six months in the absence of further exposure and this should be considered when interpreting serological *surveillance* results.~~

~~In some circumstances such as clinical *disease* investigations and in high risk populations, virological *surveillance* may provide advantage through earlier detection.~~

The *surveillance* strategy chosen should be justified as adequate to detect the presence of *infection* with PRRSV in accordance with Chapter 1.4. and the epidemiological situation. Cumulative results of targeted and general *surveillance* will increase the level of confidence in the *surveillance* strategy.

2. Clinical surveillance

Clinical signs and pathological findings are useful for early detection. Episodes of high morbidity or mortality in young piglets and reproductive disorders in sows should also be investigated. Highly pathogenic strains may affect pigs of all ages and can include severe respiratory signs. In PRRSV *infections* involving low virulence strains, clinical signs may not be present or are seen only in young *animals*. Therefore, clinical *surveillance* should be supplemented by serological and virological *surveillance*.

3. Virological surveillance

In some circumstances such as clinical disease investigations and in high-risk populations, virological surveillance may provide an advantage through earlier detection.

Virological *surveillance* should be conducted:

- a) to monitor high-risk populations;
- b) to investigate clinically suspected cases;
- c) to follow up positive serological results.

Molecular detection methods are most commonly used for virological *surveillance* and can be also applied to large-scale screening. If targeted at high-risk populations, they provide an opportunity for early detection that can considerably reduce the subsequent spread of *disease*. Molecular analysis can provide valuable information on genotype circulating in the country and enhance epidemiological understanding of the pathways of spread in endemic areas and those involved in *outbreaks* in *disease* free areas.

4. Serological surveillance

Serology in unvaccinated populations is often the most effective and efficient surveillance methodology. In some pigs, antibodies against PRRSV can disappear after approximately three to six months in the absence of further exposure and this should be considered when interpreting serological surveillance results.

In the absence of a test differentiating infected from vaccinated animals (DIVA), serology in vaccinated populations is less useful.

Maternal antibodies are generally detectable until four to eight weeks of age. The collection of samples should therefore take account of the type of *herd* and the age structure of the pigs, with an emphasis on older pigs. However, in countries or *zones* where *vaccination* has been recently discontinued, targeted serological *surveillance* of young unvaccinated ~~animals~~ pigs older than eight weeks can indicate the presence of *infection*.

Article 15.X.16+18.

Additional surveillance requirements for recovery of free status

In addition to the general conditions described in this chapter, a Member Country declaring the recovery of country, *zone* or *compartment* PRRS free status should provide evidence of an active *surveillance* programme to demonstrate absence of *infection* with PRRSV.

This *surveillance* programme should cover:

- 1) *establishments* in the proximity of the *outbreaks*;
- 2) *establishments* epidemiologically linked to the *outbreaks*;
- 3) ~~animals~~ pigs moved from or used to repopulate affected *establishments*.

The pig *herds* should undergo regular clinical, pathological, virological and serological examinations, planned and implemented according to the general conditions and methods described in these recommendations. ~~To regain PRRS free status, the surveillance approach should provide at least the same level of confidence as within the original declaration of freedom.~~

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CHAPTER 4.11.

SOMATIC CELL NUCLEAR TRANSFER IN
PRODUCTION LIVESTOCK AND HORSES

[Article 4.11.1.]

[...]

Article 4.11.4.

Background: risk analysis—general principles

- 1) *Risk analysis* in general includes *hazard* identification, *risk assessment*, *risk management* and *risk communication*. The *risk assessment* is the component of the analysis that estimates the *risks* associated with a *hazard* (see Chapter 2.1.). These principles are routinely used by regulators in making decisions about experimental or commercial releases. These analyses can then be used to determine whether the outcomes require management or regulation. *Risk management* is the process by which *risk* managers evaluate alternative actions or policies in response to the result(s) of the *risk assessment* taking into consideration the various social, economic, and legal considerations that form the environment in which such activities occur.
- 2) For animal *diseases*, particularly those listed in the *Terrestrial Code*, there is broad agreement concerning the likely *risks* and *risks assessments* can be qualitative or quantitative (see Chapter 2.1.). In *disease* scenarios it is more likely that a *qualitative risk assessment, in which the outputs on the likelihood of the outcome or the magnitude of the consequences are expressed in qualitative terms such as 'high', 'medium', 'low' or 'negligible'*, is all that is required. *Qualitative assessments* do not require mathematical modelling to carry out routine decision-making. *Quantitative risk assessments or semi-quantitative risk assessments* assign magnitudes to the *risks* in numerical terms (e.g. 1/1,000,000) ~~or descriptive (high/medium/low) terms.~~
- 3) In the context of animal cloning, two broad categories of *risk assessments* are considered: absolute *risk assessment* and comparative *risk assessments*. Absolute *risk assessments* characterise *risk* independent of a comparator (e.g. the likelihood of an animal transmitting a specific livestock *disease*). A comparative *risk assessment* (or relative *risk assessment*) puts the *risk* in the context of a comparator. For example the degree to which an animal produced by one reproductive technology can transmit a particular *disease* to another animal of the same species compared with the degree to which a similar animal produced by another reproductive technology transmits the same *disease* to another animal of same species.
- 4) Regardless of the methodology used, *hazard* identification is an early step in all science-based *risk assessments*. In the context of assessing the *risks* associated with animal cloning (SCNT) and starting with the embryo and moving on through animal clone development and subsequent progeny, it is important to be clear at this juncture that only a comparative ~~semi-quantitative~~ *risk assessment* can be completed. A systematic, absolute, *quantitative risk assessment* of potential *risks* is difficult, due to the relative newness of the technology, and the variability in outcomes among laboratories and species cloned. Furthermore, with the technology of SCNT there is no introduced *hazard* from the insertion of novel genes (which may potentially happen in transgenesis). Thus, to analyse what factors contribute to animal health *risks*, the existing baseline must be analysed.
- 5) In short, the specific points where the *risk assessment* needs to be focused need to be identified. As illustrated in the accompanying diagram – the focus is to look at the basics of creating an embryo – using current terminology, starting from the selection of donor of oocyte and the cells to the creation of an embryo by the cloning methodology. The second phase will focus on the recipient of the embryo clone and the animal health and care considerations for the animals. The actual embryo clone that is born as an offspring is the third part of the paradigm that needs clear recommendations for assessment, and the next generation, either the progeny of the animal clone (which is a result of normal sexual reproduction) or animals produced by recloning (clones of clones) is the fourth and final stage.

[Article 4.11.5.]

[...]

— Text deleted.

CHAPTER 2.1.

IMPORT RISK ANALYSIS

Article 2.1.1.

Introduction

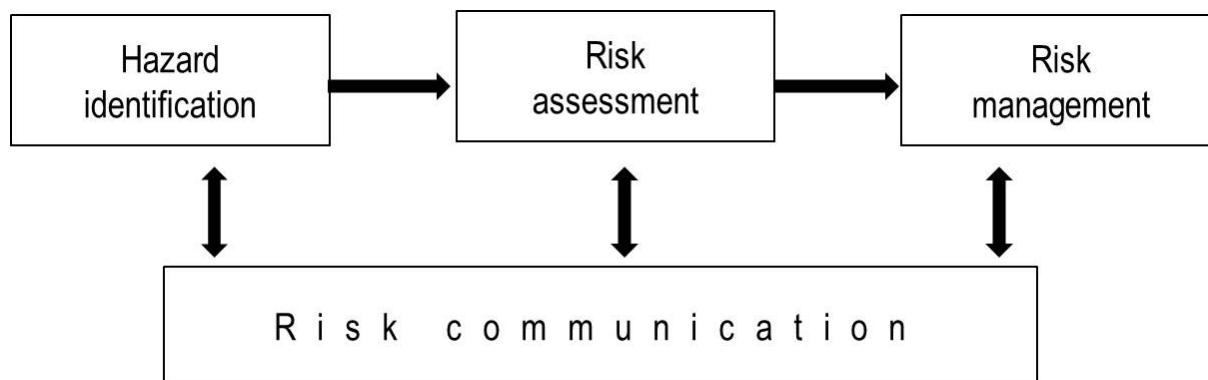
The importation of *animals* and animal products involves a degree of *disease risk* to the *importing country*. This *risk* may be represented by one or several *diseases* or *infections*.

The principal aim of import *risk analysis* is to provide *importing countries* with an objective and defensible method of assessing the *disease risks* associated with the importation of *animals*, animal products, animal genetic material, feedstuffs, biological products and *pathological material*. The analysis should be transparent. This is necessary so that the *exporting country* is provided with clear reasons for the imposition of import conditions or refusal to import.

Transparency is also essential because data are often uncertain or incomplete and, without full documentation, the distinction between facts and the analyst's value judgements may blur.

This chapter provides recommendations and principles for conducting transparent, objective and defensible *risk analyses* for *international trade*. The components of *risk analysis* are *hazard identification*, *risk assessment*, *risk management* and *risk communication* (Figure 1).

Fig. 1. The four components of risk analysis



The *risk assessment* is the component of the analysis which estimates the *risks* associated with a *hazard*. *Risk assessments* may be qualitative or quantitative. For many *diseases*, particularly for those *diseases* listed in this *Terrestrial Code* where there are well developed internationally agreed standards, there is broad agreement concerning the likely *risks*. In such cases it is more likely that a qualitative assessment is all that is required. Qualitative assessment does not require mathematical modelling skills to carry out and so is often the type of assessment used for routine decision making. No single method of import *risk assessment* has proven applicable in all situations, and different methods may be appropriate in different circumstances.

The process of import *risk analysis* usually needs to take into consideration the results of an evaluation of *Veterinary Services*, zoning, compartmentalisation and *surveillance* systems in place for monitoring of animal health in the *exporting country*. These are described in separate chapters in the *Terrestrial Code*.

[Article 2.1.2.]

[...]

Annex 20 (contd)

Article 2.1.3.

Principles of risk assessment

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

[...]

— Text deleted.