Annex 1

MEETING OF THE OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 18–29 September 2017

List of participants

MEMBERS OF THE CODE COMMISSION

Dr Etienne Bonbon
President
Seconded Veterinary Expert
Crisis Management Centre for Animal Health
FAO/AGAH
Viale delle Terme di Caracalla - 00153 Rome,
ITALY
Tel: +39 06 570 52447
etienne.bonbon@fao.org
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
gmfunes@magyp.gob.ar

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
saleehhammami@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
scmacdiarmid1948@gmail.com

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 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

Annex 2

MEETING OF THE OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 18–29 September 2017

Adopted agenda

1. **Meeting with the Director General (Monday 25 September)**
2. **Adoption of the agenda**
3. **Cooperation with other Specialist Commissions**
4. **Examination of Member Countries' comments at the 85th General Session**
   - 4.1. User's guide
   - 4.2. Criteria applied by the OIE for assessing the safety of commodities (Chapter 2.2.)
   - 4.3. Prevention and control of *Salmonella* in commercial pig production systems (Chapter 6.13.)
   - 4.4. Welfare of working equids (Chapter 7.12.)
   - 4.5. Infection with *Mycobacterium tuberculosis* complex (Chapter 8.11.)
   - 4.6. Infection with avian influenza viruses (Chapter 10.4.)
   - 4.7. Infection with lumpy skin disease (Chapter 11.9.)
   - 4.8. Infection with African swine fever virus (Chapter 15.1.)
5. **Texts circulated for Member Country comments at the February 2017 Code Commission meeting**
   - 5.1. Glossary
   - 5.2. Animal health surveillance (Chapter 1.4.) and review of the report of the *ad hoc* Group on surveillance (June 2017) (including proposed new definition of '*early warning system*')
   - 5.3. Procedures for self-declaration and for official recognition by the OIE (Chapter 1.6.)
   - 5.4. Zoning and compartmentalisation (Chapter 4.3.)
   - 5.5. Collection and processing of *in vitro* derived embryos from livestock and equids (Chapter 4.8.)
   - 5.6. Revised new chapter on vaccination (Chapter 4.X.)
   - 5.7. New chapter on management of outbreaks of listed diseases (Chapter 4.Y.)
   - 5.8. New chapter on introduction to recommendations for veterinary public health (Chapter 6.X.)
   - 5.9. The role of the Veterinary Services in food safety (Chapter 6.1.)
   - 5.10. Harmonisation of national antimicrobial resistance (AMR) surveillance and monitoring programmes (Chapter 6.7.) and review of the report of the *ad hoc* Group on AMR (August 2017)
   - 5.11. Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals (Article 6.8.1.) and review of the report of the *ad hoc* Group on AMR (August 2017)
   - 5.12. Introduction to the recommendations for animal welfare (Chapter 7.1.) (including proposed amendment of definition of '*animal welfare*' and a new article on guiding principles for the use of animal-based measures by the Animal Welfare Working Group)
   - 5.13. Revised new chapter on animal welfare and pig production systems (Chapter 7.X.) and review of the report of the *ad hoc* Group on pig production systems (August 2017)

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5.14. Infection with bluetongue virus (Chapter 8.3.)

5.15. Infection with *Brucella abortus*, *B. melitensis* and *B. suis* (Chapter 8.4.)

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

5.17. Infection with rinderpest virus (Article 8.15.2.)

5.18. Infection with *Burkholderia mallei* (glanders) (Chapter 12.10.)

5.19. Infection with classical swine fever virus (Chapter 15.2.)

6. New amendments or new chapters proposed for inclusion in the *Terrestrial Code*

6.1. New chapter on introduction to recommendations for disease prevention and control (Chapter 4.Z.) (including proposed amendment of the title of Section 4 of the *Terrestrial Code*)

6.2. New chapter on killing of reptiles for their skins, meat and other products (Chapter 7.Y.) and review of the report of the *ad hoc* Group on killing methods for farmed reptiles for their skins, meat and other products (August 2017)

6.3. New chapter on AW and laying hens production systems and review of the report of the *ad hoc* Group on laying hens production systems (November 2016)

6.4. New chapter on infection with *Trypanosoma evansi* (non-equine surra) (Chapter 8.X.)

6.5. Dourine (Chapter 12.3.)

6.6. Theileriosis (Chapter 11.12.) and review of the report of the *ad hoc* Group on theileriosis (February 2017)

7. Other issues

7.1. General comments of Member Countries on the texts circulated after the Code Commission's February 2017 meeting

7.2. Update of the Code Commission's work programme

7.3. Editorial corrections for the 2017 Edition of the *Terrestrial Code* including proposed replacement of similar terms currently used in the *Terrestrial Code* with 'pathogenic agent'

7.4. Any other business

7.4.1. Report of the meeting of the *ad hoc* Group on veterinarian paraprofessionals (August 2017)

7.4.2. Invasive Hornet *(Vespa velutina)*

7.4.3. International Transfer and laboratory containment of animal pathogens (Chapter 5.8.)

7.5. Date of next meetings

Annex 3

USER'S GUIDE

A. Introduction

1) The OIE *Terrestrial Animal Health Code* (hereafter referred to as the *Terrestrial Code*) establishes standards for the improvement of terrestrial animal health and welfare and veterinary public health worldwide. The purpose of this guide is to advise the Veterinary Authorities of OIE Member Countries on how to use the *Terrestrial Code*.

2) Veterinary Authorities should use the standards in the *Terrestrial Code* to set up measures providing for early detection, internal reporting, notification and control of pathogenic agents, including zoonotic ones, in terrestrial animals (mammals, birds and bees) and preventing their spread via international trade in animals and animal products, while avoiding unjustified sanitary barriers to trade.

3) The OIE standards are based on the most recent scientific and technical information. Correctly applied, they protect animal health and welfare and veterinary public health during production and trade in animals and animal products, and in the use of animals.

4) The absence of chapters, articles or recommendations on particular aetiological agents or commodities does not preclude the application of appropriate sanitary measures by the Veterinary Authorities, provided they are based on risk analyses conducted in accordance with the *Terrestrial Code*.

5) The complete text of the *Terrestrial Code* is available on the OIE Web site and individual chapters may be downloaded from: http://www.oie.int.

6) The year that a chapter was first adopted and the year of its last revision are noted at the end of each chapter.

B. *Terrestrial Code* content

1) Key terms and expressions used in more than one chapter in the *Terrestrial Code* are defined in the Glossary, in the case where common dictionary definitions are not deemed to be adequate. The reader should be aware of the definitions given in the Glossary when reading and using the *Terrestrial Code*. Defined terms appear in italics. In the on-line version of the *Terrestrial Code*, a hyperlink leads to the relevant definition.

2) The term '(under study)' is found in some rare instances, with reference to an article or part of an article. This means that this part of the text has not been adopted by the World Assembly of OIE Delegates and the particular provisions are thus not part of the *Terrestrial Code*.

3) The standards in the chapters of Section 1 are designed for the implementation of measures for the diagnosis, surveillance and notification of pathogenic agents. The standards include procedures for notification to the OIE, tests for international trade, and procedures for the assessment of the health status of a country, zone or compartment.

4) The standards in Section 2 are designed to guide the importing country in conducting import risk analysis in the absence of OIE recommendations on particular aetiological agents or commodities. The importing country should also use these standards to justify import measures which are more stringent than existing OIE standards.

5) The standards in the chapters of Section 3 are designed for the establishment, maintenance and evaluation of Veterinary Services, including veterinary legislation and communication. These standards are intended to assist the Veterinary Services of Member Countries to meet their objectives of improving terrestrial animal health and welfare and veterinary public health, as well as to establish and maintain confidence in their international veterinary certificates.

6) The standards in the chapters of Section 4 are designed for the implementation of measures for the prevention and control of pathogenic agents. Measures in this section include animal identification, traceability, zoning, compartmentalisation, disposal of dead animals, disinfection, disinsection and general hygiene precautions. Some chapters address the specific sanitary measures to be applied for the collection and processing of semen and embryos of animals.

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7) The standards in the chapters of Section 5 are designed for the implementation of general sanitary measures for trade. They address veterinary certification and the measures applicable by the exporting, transit and importing countries. A range of model veterinary certificates is provided to facilitate consistent documentation in international trade.

8) The standards in the chapters of Section 6 are designed for the implementation of preventive measures in animal production systems. These measures are intended to assist Member Countries in meeting their veterinary public health objectives. They include ante- and post-mortem inspection, control of hazards in feed, biosecurity at the animal production level, and the control of antimicrobial resistance in animals.

9) The standards in the chapters of Section 7 are designed for the implementation of animal welfare measures. The standards cover production, transport, and slaughter or killing, as well as the animal welfare aspects of stray dog population control and the use of animals in research and education.

10) The standards in each of the chapters of Sections 8 to 15 are designed to prevent the aetiological agents of OIE listed diseases, infections or infestations from being introduced into an importing country. The standards take into account the nature of the traded commodity, the animal health status of the exporting country, zone or compartment, and the risk reduction measures applicable to each commodity.

These standards assume that the agent is either not present in the importing country or is the subject of a control or eradication programme. Sections 8 to 15 each relate to the host species of the pathogenic agent: multiple species or single species of Apidae, Aves, Bovidae, Equidae, Leporidae, Caprinae and Suidae. Some chapters include specific measures to prevent and control the infections of global concern. Although the OIE aims to include a chapter for each OIE listed disease, not all OIE listed diseases have been covered yet by a specific chapter. This is work in progress, depending on available scientific knowledge and the priorities set by the World Assembly.

C. Specific issues

1. Notification

Chapter 1.1. describes Member Countries' obligations under OIE Organic Statutes. Listed and emerging diseases, as prescribed in Chapter 1.1., are compulsorily notifiable. Member Countries are encouraged to also provide information to the OIE on other animal health events of epidemiological significance.

Chapter 1.2. describes the criteria for the inclusion of ~~a disease,~~ an infection or infestation in the OIE List and Chapter 1.3. gives the current list. Diseases are divided into nine categories based on the host species of the aetiological agents.

2. Diagnostic tests and vaccines

It is recommended that specified diagnostic tests and vaccines in *Terrestrial Code* chapters be used with a reference to the relevant section in the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (hereafter referred to as the *Terrestrial Manual*). Experts responsible for facilities used for disease diagnosis and vaccine production should be fully conversant with the standards in the *Terrestrial Manual*.

3. Freedom from a disease, infection or infestation

Article 1.4.6. provides general principles for declaring a country or zone free from a disease, infection or infestation. This article applies when there are no specific requirements in the listed disease-specific chapter.

4 Prevention and control

Chapters 4.3. and 4.4. describe the measures that should be implemented to establish zones and compartments. Zoning and compartmentalisation should be considered as tools to control diseases and to facilitate safe trade.

Chapters 4.5. to 4.11. describe the measures which should be implemented during collection and processing of semen and embryos of animals, including micromanipulation and cloning, in order to prevent animal health risks, especially when trading these commodities. Although the measures relate principally to OIE listed diseases or infections, general standards apply to all infectious disease risks. Moreover, in Chapter 4.7. diseases that are not listed are marked as such but are included for the information of Member Countries.

Chapter 4.14. addresses the specific issue of the control of bee diseases and some of its trade implications. This chapter should be read in conjunction with the specific bee disease chapters in Section 9.

Chapter 6.4. is designed for the implementation of general biosecurity measures in intensive poultry production. Chapters 6.5., 6.12. and 6.13. ~~is an example of a~~ provide recommendations for some specific on-farm prevention and control plans for the ~~non-~~unlisted food-borne pathogen *Salmonella* ~~in poultry~~ as part of the Veterinary Services mission to avoid, eliminate or control food safety hazards in animal production.

Chapter 6.11. deals specifically with the zoonotic risk associated with the movements of non-human primates and gives standards for certification, transportation and import conditions for these animals.

5. Trade requirements

Animal health measures related to international trade should be based on OIE standards. A Member Country may authorise the importation of animals or animal products into its territory under conditions different from those recommended by the *Terrestrial Code*. To scientifically justify more stringent measures, the importing country should conduct a risk analysis in accordance with OIE standards, as described in Chapter 2.1. Members of the WTO should refer to the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).

Chapters 5.1. to 5.3. describe the obligations and ethical responsibilities of importing and exporting countries in international trade. Veterinary Authorities and all veterinarians directly involved in international trade should be familiar with these chapters. Chapter 5.3. also describes the OIE informal procedure for dispute mediation.

The OIE aims to include an article listing the commodities that are considered safe for trade without the need for risk mitigation measures specifically directed against a particular listed disease, infection or infestation, regardless of the status of the country or zone of origin for the agent in question, at the beginning of each listed disease-specific chapter in Sections 8 to 15. This is work in progress and some chapters do not yet contain articles listing safe commodities. When a list of safe commodities is present in a chapter, importing countries should not apply trade restrictions to such commodities with respect to the agent in question.

6. International veterinary certificates

An international veterinary certificate is an official document that the Veterinary Authority of an exporting country issues in accordance with Chapters 5.1. and 5.2. It lists animal health requirements and, where appropriate, public health requirements for the exported commodity. The quality of the exporting country's Veterinary Services is essential in providing assurances to trading partners regarding the safety of exported animals and products. This includes the Veterinary Services' ethical approach to the provision of veterinary certificates and their history in meeting their notification obligations.

International veterinary certificates underpin international trade and provide assurances to the importing country regarding the health status of the animals and products imported. The measures prescribed should take into account the health status of both exporting and importing countries, and zones or compartments within them, and be based upon the standards in the *Terrestrial Code*.

The following steps should be taken when drafting international veterinary certificates:

a) identify the diseases, infections or infestations from which the importing country is justified in seeking protection because of its own health status. Importing countries should not impose measures in regards to diseases that occur in their own territory but are not subject to official control programmes;

Annex 3 (contd)

b) for commodities capable of transmitting these diseases, infections or infestations through international trade, the importing country should apply the relevant articles in the listed disease-specific chapters. The application of the articles should be adapted to the disease status of the country, zone or compartment of origin. Such status should be established according to Article 1.4.6. except when articles of the relevant listed disease chapter specify otherwise;

c) when preparing international veterinary certificates, the importing country should endeavour to use terms and expressions in accordance with the definitions given in the Glossary. International veterinary certificates should be kept as simple as possible and should be clearly worded, to avoid misunderstanding of the importing country's requirements;

d) Chapters 5.10. to 5.13. provide, as further guidance to Member Countries, model certificates that should be used as a baseline.

7. Guidance notes for importers and exporters

It is recommended that Veterinary Authorities prepare 'guidance notes' to assist importers and exporters understand trade requirements. These notes should identify and explain the trade conditions, including the measures to be applied before and after export and during transport and unloading, and the relevant legal obligations and operational procedures. The guidance notes should advise on all details to be included in the health certification accompanying the consignment to its destination. Exporters should also be reminded of the International Air Transport Association rules governing air transport of animals and animal products.

Annex 4

CHAPTER 2.2.

CRITERIA APPLIED BY THE OIE FOR ASSESSING THE SAFETY OF COMMODITIES

Article 2.2.1.

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, the second article lists *commodities* that can be traded from a country or *zone* regardless of its status with respect to the specific *listed disease*. The criteria for their inclusion in the list of *safe commodities* are based on the absence of the pathogenic agent in the traded *commodity*, either due to its absence in the tissues from which the *commodity* is derived or to its inactivation by the processing or treatment that the *animal* products have undergone.

The assessment of the safety of the *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 pathogenic agent of concern are considered.

For the criteria in Article 2.2.2. to be applied, ~~It~~ it is 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 2.2.2.

Criteria

For an *animal* product to be considered a *safe commodity* for *international trade*~~,~~ as described in the User's guide and Article 2.2.1., 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 in an amount 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 applied to produce the *commodity* to be traded, while not being specifically directed at this pathogenic agent, inactivates 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);

   or

   c) biological (e.g. fermentation);

   or

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

Annex 5

CHAPTER 6.13.

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

Article 6.13.1.

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 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*.

Salmonella serotypes and their *prevalence* in pigs 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 pig and human populations when they develop and implement strategies for the prevention and control of *Salmonella* in commercial pig production systems.

Article 6.13.2.

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 commercially traded pigs or pig *meat*.

Article 6.13.3.

Purpose and scope

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

This chapter 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 OIE/FAO Guide to Good Farming Practices for Animal Production Food Safety.

[…]

Article 6.13.16.

Outdoor pig production

For outdoor pigs in commercial production systems, in addition to ~~Where practicable,~~ the prevention and control measures described in Articles 6.13.5. to 6.13.15., ~~should also be applied to outdoor pigs in commercial pig production systems to reduce *Salmonella infection*. In addition,~~ it is recommended that:

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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 designed to minimise attraction of, or access by, *wild* birds;

3) the location of other outdoor pig *herds* and the concentration and behaviour of *wild* birds in the area be considered.

Annex 6

CHAPTER 11.9.

INFECTION WITH LUMPY SKIN DISEASE VIRUS

[...]

Article 11.9.4.

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:

      i) 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, and during which period clinical, virological and serological *surveillance* ~~has been~~ conducted in accordance with Article 11.9.15. has demonstrated no occurrence of *infection* with LSDV;

      ii) 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, and during which period clinical *surveillance* alone ~~has been~~ conducted in accordance with Article 11.9.15. has demonstrated no occurrence of *infection* with LSDV;

   b) when a *stamping-out policy* is not applied, Article 11.9.3. 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 11.9.15. has demonstrated no occurrence of *infection* with LSDV.

Article 11.9.5.

Recommendations for importation from countries or zones free from LSD

For ~~domestic~~ 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 11.9.6.

Recommendations for importation from countries or zones not free from LSD

For ~~domestic~~ 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 between 60 days and one year prior to shipment;

Annex 6 (contd)

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 11.9.15.

Surveillance

1. 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. and under the responsibility of the *Veterinary Authority*.

The *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*;

b) a procedure for the rapid collection and transport of samples from suspected *cases* 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 *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* 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 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 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*.

Annex 7

CHAPTER 15.1.

INFECTION WITH AFRICAN SWINE FEVER VIRUS

[...]

Article 15.1.1bis.

Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any ASF related conditions, regardless of the ASF status of the *exporting country* or *zone*:

1) canned *meat*;

2) gelatine.

Article 15.1.2.

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

1) ASF is a *notifiable disease* in the entire 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 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 the species of *wild* and *feral* pigs and African *wild* suids present, their distribution and habitat in the country or *zone*;

5) for domestic and *captive wild* pigs, an appropriate *surveillance* programme in accordance with Articles15.1.27. to 15.1.30. and 15.1.32. 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 15.1.31., 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 15.1.31.; 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.~~

[...]

Annex 7 (contd)

Article 15.1.22.

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.

[...]

Annex 8

GLOSSARY

COMPARTMENT

means an animal *subpopulation* contained in one or more *establishments* under a common *biosecurity* management system with a ~~distinct~~ specific *animal health status* with respect to ~~a specific~~ one ~~disease~~ or more ~~specific diseases~~ *infections* or *infestations* for which required *surveillance*, ~~control and~~ *biosecurity* and control measures have been applied for the purpose of *international trade* or disease prevention and control in a country or *zone* ~~*international trade*~~.

CONTAINMENT ZONE

means an *infected* ~~defined~~ *zone* ~~around and~~ defined within a previously free country or *zone*, which includes ~~including~~ all suspected or confirmed *cases* ~~infected~~ ~~*establishments*, taking into account the epidemiological factors and results of investigations,~~ and where movement control, *biosecurity* and *sanitary measures* are applied to prevent the spread of, and to eradicate, the ~~*infection*~~ *infection* or *infestation* ~~are applied~~.

~~***DISEASE***~~

~~means the clinical or pathological manifestation of *infection* or *infestation*.~~

FREE ZONE

means a *zone* in which the absence of a specific ~~the disease,~~ *infection* or *infestation* ~~under consideration~~ in an animal *population* has been demonstrated ~~by~~ in accordance with the relevant requirements ~~specified in~~ of the *Terrestrial Code* ~~for free status being met. Within the *zone* and at its borders, appropriate *official veterinary control* is effectively applied for *animals* and animal products, and their transportation.~~

INFECTED ZONE

means a *zone* either in which an *infection* or *infestation* has been confirmed, or one that ~~does not meet the provisions for freedom of~~ is defined as such in the relevant chapters of the *Terrestrial Code.*

PROTECTION ZONE

means a *zone* where specific *biosecurity* and *sanitary measures* are implemented to prevent the entry of a pathogenic agent into a free country or *zone* from an ~~adjacent~~ neighbouring country or *zone* of a different *animal health status*.

~~***TRANSPARENCY***~~

~~means the comprehensive documentation of all data, information, assumptions, methods, results, discussion and conclusions used in the *risk analysis*. Conclusions should be supported by an objective and logical discussion and the document should be fully referenced.~~

VACCINATION

means the ~~successful immunisation~~ administration of a vaccine, ~~susceptible *animals* through the administration~~ in accordance with the manufacturer's instructions and the *Terrestrial Manual*, ~~where~~ when relevant, ~~of a vaccine comprising antigens appropriate to the~~ with the intention of inducing immunity in an *animal* or group of *animals* against one or ~~several~~ more pathogenic agents ~~disease to be controlled~~.

Annex 8 (contd)

ZONE/~~REGION~~

means a ~~clearly defined~~ part of a ~~territory~~ country defined by the *Veterinary Authority*, containing an animal *population* or *subpopulation* with a ~~distinct~~ specific *animal health status* with respect to an ~~specific disease, *infection* or *infestation* for which required *surveillance*, control and *biosecurity* measures have been applied for the purpose of *international trade*~~.

Annex 9

CHAPTER 2.1.

IMPORT RISK ANALYSIS

Article 2.1.1.

Introduction

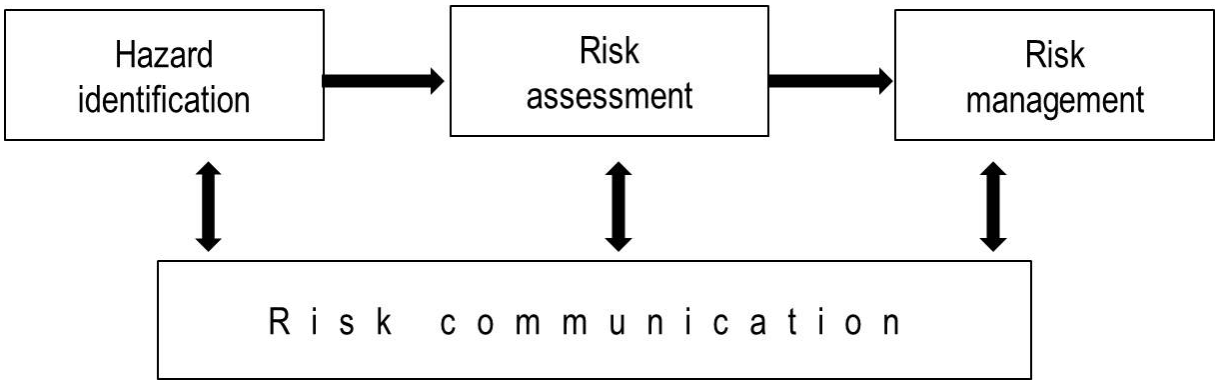
The importation of *animals* and animal products involves a degree of *disease risk* to the *importing country*. This *risk* may be represented by one or several *diseases* or *infections*.

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 9 (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.

[…]

Annex 10

CHAPTER 4.3.

ZONING AND COMPARTMENTALISATION

Article 4.3.1.

Introduction

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

The purpose of this chapter is to provide recommendations on the principles of zoning and compartmentalisation to Member Countries wishing to establish and maintain different *subpopulations* with specific health status within their territory. These principles should be applied in accordance with the relevant chapters of the *Terrestrial Code*. This chapter also outlines a process by which trading partners may recognise such *subpopulations*.

Establishing and maintaining a disease-free status throughout the country should be the final goal for Member Countries. However, given the difficulty of this ~~of establishing and maintaining a disease free status for an entire territory, especially for diseases the entry of which is difficult to control through measures at national boundaries~~, there may be benefits to a Member Country in establishing and maintaining a *subpopulation* with a ~~distinct~~ specific health status within its territory for the purposes of *international trade* or disease prevention or control. *Subpopulations* may be separated by natural or artificial geographical barriers or~~, in certain situations,~~ by the application of appropriate *biosecurity* management.

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

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

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

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

~~As well as contributing to the safety of *international trade*, zoning and compartmentalisation may assist disease control or eradication within a Member Country's territory.~~ Zoning may encourage the more efficient use of resources within certain parts of a country, ~~and~~ Cc~~c~~ompartmentalisation may allow the functional separation of a *subpopulation* from other domestic ~~*animals*~~ or *wild animals* through *biosecurity* ~~measures~~, which a *zone* ~~(through geographical separation)~~ would not achieve through geographical separation. In a country where a disease is endemic, establishment of *free zones* may assist in the progressive control and eradication of the disease. To facilitate disease control and the continuation of trade following a disease *outbreak* in a previously free country or *zone*, zoning may allow a Member Country to limit the extension of the disease to a defined restricted area, while preserving the status of the remaining territory. ~~the~~ For the same reasons, the use of compartmentalisation may allow a Member Country to take advantage of epidemiological links among *subpopulations* or common practices relating to *biosecurity*, despite diverse geographical locations~~, to facilitate disease control and/or the continuation of trade~~.

Annex 10 (cond)

A Member Country may thus have more than one *zone* or *compartment* within its territory.

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

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

Article 4.3.2.

General considerations

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

The procedures used to establish and maintain the ~~distinct~~ specific *animal health status* of a *zone* or *compartment* ~~will~~ depend on the epidemiology of the disease, including ~~in particular~~ the presence and role of *vectors* and susceptible *wildlife* ~~species,~~ and environmental factors, as well as on the application of *biosecurity* and *sanitary measures*.

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

The authority, organisation and infrastructure of the *Veterinary Services*, including *laboratories*, should be ~~clearly documented~~ established and should operate in accordance with ~~the~~ Chapters 3.1. and 3.2. ~~on the evaluation of *Veterinary Services* of the *Terrestrial Code*~~, to provide confidence in the integrity of the *zone* or *compartment*. The final authority ~~of~~ over the *zone* or *compartment*, for the purposes of domestic and *international trade*, lies with the *Veterinary Authority*. The *Veterinary Authority* should conduct an assessment of the resources needed and available to establish and maintain a *zone* or *compartment*. These include the human and financial resources and the technical capability of the *Veterinary Services* and of the relevant industry and production system (especially in the case of a *compartment*), including for *surveillance*, ~~and~~ diagnosis and, when appropriate, *vaccination*, treatment and protection against *vectors*.

In the context of maintaining the *animal health status* of a *population* or *subpopulation* of a country, *zone* or *compartment*, ~~references to 'import', 'importation' and 'imported animals/ products' found in the *Terrestrial Code* apply both to~~ importations into ~~a~~ the country as well as ~~and to the~~ movements of *animals* and their products into the *zones* ~~and~~ or *compartments*~~. Such movements~~ should be the subject of appropriate *sanitary measures* and *biosecurity* ~~to preserve the *animal health status* of the country, *zone*/ or *compartment*~~.

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

~~The *exporting country* should be able to demonstrate, through detailed documentation provided to the *importing country*, that it has implemented the recommendations in the *Terrestrial Code* for establishing and maintaining such a *zone* or *compartment*.~~

~~An *importing country* should recognise the existence of this *zone* or *compartment* when the appropriate measures recommended in the *Terrestrial Code* are applied and the *Veterinary Authority* of the *exporting country* certifies that this is the case.~~

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

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

~~Industry's responsibilities include the application of *biosecurity* measures, documenting and recording movements of *animals* and personnel, quality assurance schemes, monitoring the efficacy of the measures, documenting corrective actions, conducting *surveillance*, rapid reporting and maintenance of records in a readily accessible form.~~

Industry's responsibilities include, in consultation with the *Veterinary Services* if appropriate, the application of *biosecurity*, documenting and recording movements of *commodities* and personnel, managing quality assurance schemes, documenting the implementation of corrective actions, conducting *surveillance*, rapid reporting and maintenance of records in a readily accessible form.

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

Article 4.3.3.

Principles for defining and establishing a zone or compartment~~, including protection and containment zones~~

~~In conjunction with the above considerations, the~~ The following principles ~~should~~ apply when Member Countries define a *zone* or a *compartment*.

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

~~2) A *protection zone* may be established to preserve the health status of *animals* in a free country or *zone*, from adjacent countries or *zones* of different *animal health status*. Measures should be implemented based on the epidemiology of the disease under consideration to prevent introduction of the pathogenic agent and to ensure early detection.~~

~~These measures should include intensified movement control and *surveillance* and may include:~~

~~*a)* *animal identification* and *animal traceability* to ensure that *animals* in the *protection zone* are clearly distinguishable from other populations;~~

~~*b)* *vaccination* of all or at risk susceptible *animals*;~~

~~*c)* testing and/or *vaccination* of *animals* moved;~~

~~*d)* specific procedures for sample handling, sending and testing;~~

~~*e)* enhanced *biosecurity* including cleansing – *disinfection* procedures for transport means, and possible compulsory routes;~~

~~*f)* specific *surveillance* of susceptible *wildlife* species and relevant *vectors*;~~

~~*g)* awareness campaigns to the public or targeted at breeders, traders, hunters, *veterinarians*.~~

~~The application of these measures can be in the entire free *zone* or in a defined area within and/or outside the free *zone*.~~

~~3) In the event of limited *outbreaks* in a country or *zone* previously free of a disease, a *containment zone* may be established for the purposes of trade. Establishment of a *containment zone* should be based on a rapid response including:~~

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~~a) Appropriate standstill of movement of *animals* and other *commodities* upon notification of suspicion of the specified disease and the demonstration that the *outbreaks* are contained within this zone through epidemiological investigation (trace back, trace forward) after confirmation of *infection*. The primary *outbreak* has been identified and investigations on the likely source of the *outbreak* have been carried out and all *cases* shown to be epidemiologically linked.~~

~~b) A *stamping out policy* or another effective control strategy aimed at eradicating the disease should be applied and the susceptible animal population within the *containment zones* should be clearly identifiable as belonging to the *containment zone*. Increased passive and targeted *surveillance* in accordance with Chapter 1.4. in the rest of the country or *zone* should be carried out and has not detected any evidence of *infection*.~~

~~c) Measures consistent with the disease specific chapter should be in place to prevent spread of the *infection* from the *containment zone* to the rest of the country or *zone*, including ongoing *surveillance* in the *containment zone*.~~

~~d) For the effective establishment of a *containment zone*, it is necessary to demonstrate that there have been no new *cases* in the *containment zone* within a minimum of two *incubation periods* from the last detected *case*.~~

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

~~f) The *containment zone* should be managed in such a way that it can be demonstrated that *commodities* for *international trade* can be shown to have originated outside the *containment zone*.~~

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

2~~4~~) The factors defining a *compartment* should be established by the *Veterinary Authority* on the basis of relevant criteria such as management and husbandry practices related to *biosecurity*, and ~~made public~~ communicated to the relevant operators through official channels.

3~~5~~) *Animals* and *herds~~/~~* or *flocks* belonging to ~~such~~ *subpopulations* of *zones* or *compartments* ~~need to~~ should be recognisable as such through a clear epidemiological separation from other *animals* and all ~~things~~ factors presenting a ~~disease~~ *risk*. ~~For a *zone* or *compartment*, the~~ The *Veterinary Authority* should document in detail the measures taken to ensure the identification of the *subpopulation* and the *establishment* and maintenance of its health status through a *biosecurity plan*. The measures used to establish and maintain the ~~distinct~~ specific *animal health status* of a *zone* or *compartment* should be appropriate to the particular circumstances, and ~~will~~ depend on the epidemiology of the disease, environmental factors, the health status of *animals* in adjacent areas, applicable *biosecurity* ~~measures~~ (including movement controls, use of natural, ~~and~~ artificial or legal boundaries, ~~the~~ spatial separation of *animals*, control of fomites, and commercial management and husbandry practices), and *surveillance*.

4~~6~~) Relevant ~~*animals*~~ *commodities* within the *zone* or *compartment* should be identified in such a way that their movements are traceable. Depending on the system of production, identification may be done at the *herd~~,~~* or *flock* ~~lot~~ or individual animal level. Relevant ~~animal~~ movements of *commodities* into and out of the *zone* or *compartment* should be well documented and controlled. The existence of ~~a valid~~ an *animal identification system* is a prerequisite to assess the integrity of the *zone* or *compartment*.

5~~7~~) For a *compartment*, the *biosecurity plan* should describe the partnership between the relevant industry and the *Veterinary Authority*, and their respective responsibilities. It should also describe the ~~routine~~ standard operating procedures to provide clear evidence that the *surveillance* conducted, the ~~live~~ *animal identification* and *traceability* system, and the management practices are adequate to meet the definition of the *compartment*. In addition to information on controls of movements of relevant *commodities* ~~animal movement controls~~, the plan should include *herd* or *flock* production records, feed sources, *surveillance* results, birth and *death* records, visitor logbook, morbidity and mortality history, medications, *vaccinations*, documentation of training of relevant personnel and any other criteria necessary for evaluation of *risk management*. The information required may vary in accordance with the species and diseases under consideration. The *biosecurity plan* should also describe how the measures will be audited to ensure that the *risks* are regularly ~~re-assessed~~ reassessed and the measures adjusted accordingly.

Articles 4.3.4. to 4.3.7. describe different types of *zones* that can be established by Member Countries. However, other types of *zones* may be established for the purposes of disease control or trade.

Article 4.3.4.

Free zone

A *free zone* is one in which the absence of a specific *infection* or *infestation* in an animal population has been demonstrated in accordance with the relevant requirements of the *Terrestrial Code*.

In conjunction with Articles 4.3.2. and 4.3.3., and depending on the prevailing epidemiological situation, the attainment or maintenance of free status may require past or ongoing pathogen-specific and *vector surveillance*, as well as appropriate *biosecurity* and *sanitary measures*, within the *zone* and at its borders. The *surveillance* should be conducted in accordance with Chapter 1.4. and the relevant chapters of the *Terrestrial Code*.

The free status can apply to one or more susceptible animal species populations, domestic or *wild*.

So long as an ongoing *surveillance* demonstrates there is no occurrence of the specific *infection* or *infestation*, and principles determined for its definition and establishment are respected, the *zone* maintains its free status.

Article 4.3.5.

Infected zone

An *infected zone* is one either in which an *infection* or *infestation* has been confirmed, or that ~~does not meet~~ is defined as such in ~~the provisions for freedom of~~ the relevant chapters of the *Terrestrial Code.*

An *infected zone* in which an *infection* or *infestation* has been confirmed may be:

1) ~~–~~ a *zone* of a country where the ~~disease, *infection* or *infestation*~~ is present and has not yet been eradicated, while other *zones* of the country may be free; or

2) ~~–~~ a *zone* of a previously free country or *zone*, in which the ~~disease, *infection* or *infestation*~~ has been introduced or reintroduced, while the rest of the country or *zone* remains unaffected.

To gain free status in an *infected zone*, or regain free status following an ~~disease~~ *outbreak* in a previously *free zone*, Member Countries should follow the recommendations in the relevant chapters of the *Terrestrial Code*.

Article 4.3.6.

Protection zone

A *protection zone* may be established to preserve the *animal health status* of an *animal population* in a free country or a *free zone* by preventing the introduction of a pathogenic agent of a specific *infection* or *infestation* from ~~adjacent~~ neighbouring countries or *zones* of different *animal health status* to that animal *population*. A *protection zone* can be established within or outside the *free zone* or within the free country.

Biosecurity and *sanitary measures* should be implemented in the *protection zone* based on the animal management systems, the epidemiology of the disease under consideration and the epidemiological situation prevailing in the ~~adjacent~~ neighbouring infected countries or *zones*.

These measures should include intensified movement control and *surveillance* and specific *animal identification* and *animal traceability* to ensure that *animals* in the *protection zone* are clearly distinguishable from other populations, and may also include:

1) *vaccination* of all or at risk susceptible *animals*;

2) testing or *vaccination* of *animals* moved;

3) specific procedures for sample handling, dispatching and testing;

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4) enhanced *biosecurity* including *disinfection* procedures for *vehicles*/*vessels*~~;~~ and vehicles used for transportation of animal products ~~*commodities*~~, feed or fodder, and possible compulsory routes for their movements within, to or from the *zone*;

5) specific *surveillance* of susceptible *wildlife* and relevant *vectors*;

6) awareness campaigns aimed at the public or targeted at breeders, traders, hunters or *veterinarians*.

Anytime the status of the *protection zone* changes, the status should be determined in accordance with the relevant *listed disease*-specific chapters.

In the event of an emergency, such as a sudden increased *risk* to a free country or *zone*, a temporary *protection zone* may be established in a free country or *zone*. In such a situation, ~~M~~measures~~, such as *vaccination*,~~ implemented in that ~~a *protection zone* established in a free country or *zone*~~ will not affect the status of ~~the rest of~~ the free country or *zone*. However, ~~even if~~ some of ~~such~~ the measures, such as *vaccination*, may make it necessary to distinguish the status of the *protection zone* from the rest of the country or *zone*.

A temporary *protection zone* should be established for a defined period at the end of which either it is permanently distinguished from the rest of the country or *zone* or it is disestablished.

In the event of an occurrence, in a temporary *protection zone*, of a *case* of an *infection* or *infestation* for which it was established, this will not affect the status of the rest of the country or *zone*, provided that the *zone* was established at least two incubation periods before the occurrence.

Article 4.3.7.

Containment zone

In the event of *outbreaks* in a country or *zone* previously free from a disease, a *containment zone*, which includes all epidemiologically linked *outbreaks* may be established to minimise the impact on the rest of the country or *zone*.

A *containment zone* is an *infected zone* that should be managed in such a way that *commodities* for *international trade* can be shown to have originated from inside or outside the *containment zone*.

Establishment of a *containment zone* should be based on a rapid response, prepared in a contingency plan, and that includes:

1) appropriate control of movement of *animals* and other *commodities* upon declaration of suspicion of the specified disease;

2) epidemiological investigation (trace-back, trace-forward) after confirmation of *infection* or *infestation*, demonstrating that the *outbreaks* are epidemiologically related and all contained within the defined boundaries of the *containment zone*;

3) a *stamping-out policy* or another effective emergency control strategy aimed at eradicating the disease;

4) *animal identification* of the susceptible population within the *containment zone* enabling its recognition as belonging to the *containment zone*;

5) increased passive and targeted *surveillance* in accordance with Chapter 1.4. in the rest of the country or *zone* demonstrating no occurrence of *infection* or *infestation*;

6) *biosecurity* and *sanitary measures*, including ongoing *surveillance* and control of the movement of *animals* and other *commodities* within and from the *containment zone*, consistent with the *listed disease*-specific chapter, when there is one, to prevent spread of the *infection* or *infestation* from the *containment zone* to the rest of the country or *zone*.

For the effective establishment of a *containment zone*, it is necessary to demonstrate that either:

a) there have been no new *cases* in the *containment zone* within a minimum of two *incubation periods* from the disposal of the last detected *case*.

OR

b) the *containment zone* comprises an *infected zone* where *cases* may continue to occur and a *protection zone*, where no *outbreaks* have occurred for at least two *incubation periods*~~,~~ after the control measures above are in place, and that separates the *infected zone* from the rest of the country or *zone*.

The free status of the areas outside the *containment zone* is suspended pending the effective establishment of the *containment zone*. Once the *containment zone* has been established, the areas outside the *containment zone* regain free status.

The free status of the *containment zone* should be regained in accordance with the relevant *listed disease*-specific chapters or, if there are none, with Article 1.4.6.

Article 4.3.8.

Bilateral recognition by trading countries

While the OIE has procedures for official recognition of status for a number of ~~diseases or~~ *infections* (refer to Chapter 1.6.), for other ~~diseases,~~ *infections* or *infestations,* countries may recognise each other's status through a bilateral process. Trading partners should exchange information allowing the recognition of different *subpopulations* within their respective territories. This recognition process is best implemented through establishing parameters and gaining agreement on the necessary measures prior to *outbreaks* of disease.

The *Veterinary Services* of an *exporting country* should be able to explain to the *Veterinary Services* of an *importing country* the basis for claiming a specific *animal health status* for ~~the~~ a given *zone* or *compartment* under consideration.

The *exporting country* should be able to demonstrate, through detailed documentation provided to the *importing country*, that it has implemented the recommendations in the *Terrestrial Code* for establishing and maintaining such a *zone* or *compartment*.

In accordance with Chapter 5.3., an *importing country* should recognise the existence of this *zone* or *compartment* when the appropriate measures recommended in the *Terrestrial Code* are applied and the *Veterinary Authority* of the *exporting country* is able to ~~certifies~~ demonstrate~~s~~ that this is the case.

Annex 11

CHAPTER 4.8.

COLLECTION AND PROCESSING OF OOCYTES AND *IN VITRO* PRODUCED EMBRYOS/~~OOCYTES~~ FROM LIVESTOCK AND HORSES

Article 4.8.1.

Aims of control

Production of embryos *in vitro* involves the collection of oocytes from the ovaries of donors, *in vitro* maturation and fertilisation of the oocytes, then *in vitro* culture to the morula~~/~~ or blastocyst stage at which they are ready for transfer into recipients. The purpose of official sanitary control of *in vitro* produced embryos intended for movement internationally is to ensure that specific pathogenic organisms, which could be associated with such embryos, are controlled and transmission of *infection* to recipient animals and progeny is avoided. The conditions outlined in this chapter are also applicable where the movement of *in vitro* maturing (IVM) oocytes is intended.

Article 4.8.2.

Conditions applicable to the embryo production team

The embryo production team is a group of competent technicians, including at least one *veterinarian*, to perform the collection and processing of ovaries~~/~~ and oocytes and the production and storage of *in vitro* produced embryos. The following conditions should apply:

1) The team should be approved by the *Competent Authority*.

2) The team should be supervised by a team *veterinarian*.

3) The team *veterinarian* is responsible for all team operations which include the hygienic collection of ovaries and oocytes and all other procedures involved in the production of embryos intended for international movement.

4) Team personnel should be adequately trained in the techniques and principles of disease control. High standards of hygiene should be practised to preclude the introduction of *infection*.

5) The production team should have adequate facilities and equipment for:

   a) collecting ovaries ~~and/~~or oocytes;

   b) processing of oocytes and production of embryos at a permanent or mobile laboratory;

   c) storing oocytes ~~and/~~or embryos.

   These facilities need not necessarily be at the same location.

6) The embryo production team should keep a record of its activities, which should be maintained for inspection by the *Veterinary ~~Authority~~ Services* for a period of at least two years after the embryos have been exported.

7) The embryo production team should be subjected to regular inspection at least once a year by an *Official Veterinarian* to ensure compliance with procedures for the sanitary collection and processing of oocytes and the production and storage of embryos.

Annex 11 (contd)

Article 4.8.3.

Conditions applicable to the processing laboratories

A processing laboratory used by the embryo production team may be mobile or permanent. It may be contiguous with the oocyte recovery area or at a separate location. It is a facility ~~in which~~ where oocytes ~~which~~ that have been recovered from ovaries are then matured and fertilised, and where the resulting embryos are further cultured *in vitro*.

Embryos may also be subjected to any required treatments such as washing and storage and quarantine in this laboratory.

Additionally:

1) The laboratory should be under the direct supervision of the team *veterinarian* and regularly inspected by an *Official Veterinarian*.

2) While embryos for export are being produced prior to their storage in ampoules, vials or straws, no oocyte~~/~~ or embryo of a lesser health status should be recovered or processed in the same laboratory.

3) The laboratory should be protected against rodents and insects.

4) The processing laboratory should be constructed with materials which permit its effective cleansing and *disinfection*. This should be done frequently and always before and after each occasion when embryos for export are processed.

5) The processing laboratory should have and use appropriate facilities to handle and process embryos for export, in accordance with the recommendations in the Manual of the International Embryo Transfer Society (IETS).

Article 4.8.4.

Conditions applicable to donor animals

Oocytes for the *in vitro* production of embryos are obtained from donors basically in two different ways: individual collection or batch collection. The recommended conditions for these differ.

Individual collection usually involves the aspiration of oocytes from the ovaries of individual live animals on the farm where the animal resides, or at the laboratory. Occasionally oocytes may also be recovered from individual live donors by aspiration from surgically excised ovaries. When oocytes are recovered from individual live animals, the conditions for these donors should resemble those set out in Article 4.7.4.

In these cases the cleaning and sterilisation of equipment (e.g. ultrasound guided probes) is especially important and should be carried out between each donor in accordance with the recommendations in the Manual of the ~~International Embryo Transfer Society (~~IETS~~)~~[4].

Batch collection involves the removal of ovaries from batches of donors slaughtered at a *slaughterhouse*/*abattoir* ~~(hereafter '*abattoir*')~~; these ovaries are then transported to the processing laboratory where the oocytes are recovered from the ovarian follicles by aspiration or slicing techniques. Batch collection has the disadvantage that it is usually impractical to relate the ovaries which are transported to the laboratory to the donors which were slaughtered at the *slaughterhouse*/*abattoir*. Nevertheless, it is critical to ensure that only healthy tissues are obtained and that they are removed from the donors and transported to the laboratory in a hygienic manner.

Additionally:

1) The *Veterinary* ~~*Authority*~~ *Services* should have knowledge of the *herd~~(s)~~* or *flock~~(s)~~* from which the donor animals have been sourced.

2) The donor animals should not originate from *herds* or *flocks* that are subject to veterinary restrictions for foot and mouth disease~~, rinderpest and~~ or peste des petits ruminants, and neither should the removal of any tissue or aspiration of oocytes take place in an *infected zone*, or one that is subject to veterinary restrictions for those diseases.

3) In the case of oocyte recovery from live donors, post-collection surveillance of the donors and donor *herd~~(s)~~* or *flock~~(s)~~* should be conducted based on the recognised *incubation periods* of the diseases of concern to determine retrospectively the health status of donors.

4) In the case of oocyte recovery from batches of ovaries collected from a~~n~~ *slaughterhouse/abattoir*, ~~the *abattoir*~~ it should be officially approved and under the supervision of a *veterinarian* whose responsibility is to ensure that ante-~~mortem~~ and post-mortem inspections of potential donor animals are carried out, and to certify them to be free of clinical or pathological signs of the diseases listed in point 2.

5) Donor animals slaughtered at a~~n~~ *slaughterhouse/abattoir* should not ~~have been~~ be animals designated for compulsory *slaughter* for a *notifiable disease* ~~and~~ or ~~should not~~ be slaughtered at the same time as such animals ~~donors from which ovaries and other tissues will be removed~~.

6) Batches of ovaries and other tissues collected from a~~n~~ *slaughterhouse/abattoir* should not be transported to the processing laboratory before confirmation has been obtained that ante- and post-mortem inspection of donors has been ~~satisfactorily completed~~ carried out with favourable results.

7) Equipment for the removal and transport of ovaries and other tissues should be cleaned and sterilised before use and used exclusively ~~used~~ for these purposes.

8) Records of the identities and origins of all donors should be maintained for inspection by the *Veterinary ~~Authority~~ Services* for a period of at least two years after the embryos have been exported. While this may be difficult to achieve in the case of batch collection, it is to be expected that the identities of the *herds* or *flocks* from which the donors originated will be maintained.

Article 4.8.5.

Optional tests and treatments

A supplementary approach for ensuring that *in vitro* produced embryos do not transmit disease is by testing various materials to confirm the absence of pathogenic ~~organisms~~ agents listed in point 2 of Article 4.8.4.

Tests may also be used to assess whether quality control procedures being applied in the processing laboratory are of an acceptable standard.

Tests may be carried out on the following materials:

1) non-viable oocytes~~/~~ or embryos from any stage of the *in vitro* production line from batches intended for export;

2) samples of *in vitro* maturation medium taken prior to mixing the oocytes with semen for the fertilisation process;

3) samples of embryo culture medium taken immediately prior to embryo storage~~.~~;

4) a pool of the last three washes from the 10 washes performed on the embryos.

These samples should be stored at 4°C and tested within 24 hours. If this is not possible, then the samples should be stored frozen at minus 70°C or lower.

Annex 11 (contd)

Additionally:

1) Semen used to fertilise oocytes *in vitro* should have been collected and processed in accordance with Chapter 4.5. and meet the health requirements ~~and standards set out~~ in Chapter 4.6. as appropriate to the species.

   When the donor of the semen used to fertilise the oocytes is dead, and when the health status of the semen donor concerning a particular infectious disease or diseases of concern was not known at the time of semen collection, additional tests on the spare embryos may be required to verify that these infectious diseases were not transmitted.

   An alternative may be to test an aliquot of semen from the same collection date.

2) Any biological product of animal origin, including co-culture cells and media constituents, used in oocyte recovery, maturation, fertilisation, culture, washing and storage should be free ~~of~~ from ~~living pathogens~~ pathogenic agents. Media should be sterilised prior to use by approved methods in accordance with the ~~IETS~~ Manual[4] of the IETS and handled in such a manner as to ensure that sterility is maintained. Antibiotics should be added to all fluids and media as recommended in the ~~IETS~~ Manual of the IETS[4].

3) All equipment used to recover, handle, culture, wash, freeze and store oocytes~~/~~ or embryos should be new or cleaned and sterilised prior to use as recommended in the ~~IETS~~ Manual of the IETS[4].

Article 4.8.6.

Risk management

With regard to disease transmission, transfer of *in vitro* produced embryos is a low risk method for moving animal genetic material although the *risk* is not quite as low as for *in vivo* derived embryos. It should be noted that categorisation of diseases~~/~~ and ~~disease~~ pathogenic agents by the IETS, as described for *in vivo* derived embryos in Article 4.7.14., does not apply in the case of *in vitro* produced embryos. Irrespective of the animal species, there are three phases in the embryo production and transfer process that determine the final level of *risk*. These are as follows:

1) the first phase comprises the risk potential for ovary, ~~/~~ oocyte~~/~~ or embryo contamination and depends on:

   a) the disease situation in the *exporting country* ~~and/~~or *zone*;

   b) the health status of the *herds* or *flocks* and the donors from which the ovaries, ~~/~~ oocytes, ~~/~~ ~~or~~ embryos or semen for fertilisation of oocytes are collected;

   c) the ~~pathogenic~~ characteristics of the ~~specified disease~~ pathogenic agents listed in point 2 of Article 4.8.4.;

2) the second phase covers risk mitigation by the use of internationally accepted procedures for the processing of embryos which are set out in the ~~IETS~~ Manual of the IETS[4]. These include the following:

   a) after the *in vitro* culture period is finished the embryos should be washed at least ~~ten~~ 10 times with at least 100–fold dilutions between each wash, and a fresh pipette should be used for transferring the embryos through each wash;

   b) only embryos from the same donor (in the case of individual collection) or from the same batch (in the case of batch collection) should be washed together, and no more than ten embryos should be washed at any one time;

   c) sometimes, for example when inactivation or removal of certain viruses (e.g. bovine herpesvirus-1, or Aujeszky's disease virus) is required, the standard washing procedure should be modified to include additional washes with the enzyme trypsin, as described in the ~~IETS~~ Manual of the IETS[4];

d) the *zona pellucida* of each embryo, after washing, should be examined over its entire surface area at not less than 50X magnification to ensure that it is intact and free ~~of~~ from adherent material;

3) the third phase, which is applicable to diseases listed in point 2 of Article 4.8.4. encompasses the *risk* reductions resulting from:

a) post-collection surveillance of the donors and donor *herds* or *flocks* based on the recognised incubation periods of the diseases of concern to determine retrospectively the health status of the donors whilst the embryos are stored (in species where effective storage by cryopreservation is possible) in the *exporting country*. Post-collection *surveillance* of donors is not, of course, possible in the case of batch collection from a~~n~~ *slaughterhouse*/*abattoir*, although surveillance of the *herds* or *flocks* of origin may be possible;

b) testing of oocytes~~,~~/ embryos, co-culture cells, media and other samples (e.g. blood) (as referred to in Article 4.8.5.) in a *laboratory* for presence of ~~disease~~ pathogenic agents.

Article 4.8.7.

Conditions applicable to the storage and transport of oocytes and embryos

Oocytes and *in vitro* produced embryos can be stored and transported fresh, chilled or frozen.

Fresh embryos may undergo culture in portable incubators during transportation and should arrive at the recipient animal within five days, in time for transfer of the mature blastocysts. Chilled embryos should be transferred within 10 days of chilling.

The *Veterinary Services* should have knowledge of the variety of oocyte and embryo storage systems available and should have procedures in place for the safe and timely inspection and certification of these oocytes and embryos to ensure their viability.

1) Only embryos from the same individual donor or from the same batch collection should be stored together in the same ampoule, vial or straw.

2) For frozen oocytes and embryos

a) Sterile ampoules, vials or straws should be sealed prior to freezing or after vitrification and should be labelled according to the ~~IETS~~ Manual of the IETS[1].

b) The frozen oocytes and embryos should ~~if possible, depending on the species,~~ be frozen in ~~fresh~~ liquid nitrogen that has not been used previously ~~or other cryoprotectant and~~ then stored in ~~fresh cryoprotectant~~ liquid phase nitrogen that has not been used previously or in the vapour phase of liquid nitrogen ~~cleaned~~ disinfected containers under strict hygienic conditions at a storage place.

c) Liquid nitrogen containers should be sealed prior to *shipment*.

3) For fresh or chilled oocytes and embryos

a) Sterile ~~Ampoules~~ ampoules, vials or straws should be sealed prior to storing in portable incubators ~~at the time of freezing~~ and should be labelled in accordance with the ~~IETS~~ Manual of the IETS[1].

b) The fresh or chilled oocytes and embryos should be stored under strict hygienic conditions in portable incubators disinfected in accordance with the ~~IETS~~ Manual of the IETS[1] and manufacturer's instructions.

c) Portable incubators should be sealed prior to *shipment*.

~~4) Liquid nitrogen containers should be sealed prior to shipment from the *exporting* country.~~

4~~5~~) Oocytes and embryos ~~Embryos~~ should not be exported until the appropriate veterinary certificates are completed.

Annex 11 (contd)

Article 4.8.8.

Procedure for micromanipulation

When micromanipulation of the embryos is to be carried out, this should be done after completion of the treatments described in point 2 of Article 4.8.6. and conducted in accordance with Chapter 4.9.

Annex 12

DRAFT CHAPTER 4.X.

VACCINATION

Article 4.X.1.

Introduction and objectives

~~In general,~~ *Vaccination* is intended to prevent and control ~~and prevent~~ the occurrence of a disease and reduce the transmission of the pathogenic agent. ~~For the purpose of disease control~~ Ideally, vaccines should induce immunity that~~, ideally,~~ prevents *infection*. However, some vaccines may only prevent clinical signs, or reduce multiplication and shedding of the pathogenic agent.

Vaccination may contribute to improvement of *animal* and human health, *animal welfare*, agricultural sustainability and to reduction of the use of *antimicrobial agents* in *animals*.

The objective of this chapter is to provide guidance to *Veterinary Authorities* for the successful ~~implementation~~ use of *vaccination* in support of disease prevention and control programmes. The recommendations in this chapter may be refined by the specific approaches described in the *listed disease*-specific chapters of the *Terrestrial Code*. Furthermore, the recommendations in this chapter may also be used for any diseases for which a vaccine exists.

The *vaccination* strategy applied depends on biological, technical and policy considerations, available resources and the feasibility of implementation. ~~The recommendations in this chapter are intended for all diseases for which a vaccine exists.~~

~~In addition to other disease control measures, *vaccination* may be a component of a disease control programme.~~ The prerequisites to enable a Member Country to successfully implement *vaccination* include compliance with:

1) the recommendations on *surveillance* in Chapter 1.4.;

2) the relevant provisions in Chapters 3.1. and 3.4.;

3) the recommendations on *vaccination* in the *listed disease*-specific chapters of the *Terrestrial Code*;

4) the relevant general and specific recommendations for ~~principles of~~ veterinary vaccine production and quality control in ~~Chapter 1.1.8. of~~ the *Terrestrial Manual.*

~~The objective of this chapter is to provide guidance to Member Countries for successful implementation of *vaccination* in support of disease control programmes. The recommendations in this chapter may be refined by the specific approaches described in the disease specific chapters of the *Terrestrial Code*.~~

~~Standards for vaccines are described in the *Terrestrial Manual*.~~

Article 4.X.2.

Definitions

For the purposes of this chapter:

Vaccination programme: means a plan to apply *vaccination* to an epidemiologically appropriate proportion of the susceptible animal population for the purpose of disease prevention or control.

Emergency vaccination: means a *vaccination* programme applied in immediate response to an *outbreak* or increased *risk* of introduction or emergence of a disease.

Systematic vaccination: means an ongoing routine *vaccination* programme.

Annex 12 (contd)

Vaccination coverage: means the proportion of the target population to which vaccine was administered during a specified timeframe.

Population immunity: means the proportion of the target population effectively immunised at a specific time.

Article 4.X.3.

Vaccination programmes

The objectives and strategy of a *vaccination* programme should be defined by the *Veterinary Authority* before the implementation of ~~the~~ *vaccination*, taking into account the epidemiology of the ~~disease~~ *infection* , its impact and zoonotic potential, the species affected and their distribution.

If these factors indicate that the programme should be expanded beyond national boundaries, the *Veterinary Authority* should liaise with the *Veterinary Authorities* of neighbouring countries. When appropriate, a regional approach to harmonise *vaccination* programmes is recommended.

Veterinary Authorities should liaise with public health authorities when developing *vaccination* programmes against zoonoses.

Vaccination programmes may include systematic *vaccination* and emergency *vaccination*.

1) Systematic *vaccination* in infected countries aims to reduce the incidence, prevalence or impact of a disease with the objective of prevention, control and possible eradication. In ~~disease~~ free countries or *zones*, the objective of systematic *vaccination* is to prevent the introduction of a pathogenic agent from an infected ~~adjacent~~ neighbouring country or *zone*, or to limit the impact in the case of ~~an~~ the introduction of that pathogenic agent ~~disease~~.

2) Emergency *vaccination* provides an adjunct to the application of other essential *biosecurity* and disease control measures and may be applied to control *outbreaks*. Emergency *vaccination* may be used in response to:

   a) an *outbreak* in a ~~disease~~ free country or *zone*;

   b) an *outbreak* in a country or *zone* that applies systematic *vaccination*, but when ~~vaccines are~~ revaccination is applied to boost existing immunity;

   c) an *outbreak* in a country or *zone* that applies systematic *vaccination*, but when the vaccine employed does not provide protection against the strain of the pathogenic agent involved in the *outbreak;*

   d) a change in the *risk* of introduction of a pathogenic agent or emergence of a disease in a free country or *zone*.

Vaccination programmes should ~~consider other~~ be integrated with other ongoing animal health related activities involving the target population. This can improve the efficiency of the programme and reduce the cost by ~~sharing~~ optimisation of resources.

Article 4.X.4.

Launching a vaccination programme

When deciding whether to initiate a *vaccination* programme the *Veterinary Authority* should consider, among others, the following:

1) the epidemiology of the ~~disease~~ *infection*;

1bis) the probability that the disease cannot be rapidly contained by means other than *vaccination*;

2) the ~~an increased~~ *incidence* of an existing disease;

3) the ~~an increased~~ likelihood of introduction of a pathogenic agent or emergence of a disease;

3bis) the zoonotic potential of the disease;

4) the density of the exposed susceptible animal~~s~~ *population*;

5) the ~~an insufficient~~ level of population immunity;

6) the *risk* of exposure of specific *subpopulations* of susceptible animals;

7) the suitability of a *vaccination* programme as an alternative to or an adjunct to other disease control measures such as a *stamping-out policy;*

7bis) the existence of an *animal identification system* to differentiate vaccinated from unvaccinated *subpopulations*;

8) the availability of ~~an appropriate~~ a safe and effective vaccine ~~and human, financial, and material resources~~;

8bis) the availability of human, financial, and material resources;

9) the cost-benefit analysis ~~considerations~~ of the *vaccination* programme, including the impact on trade.

Article 4.X.5.

Vaccination strategies

Different *vaccination* strategies may be applied alone or in combination, taking into account the epidemiological and geographical characteristics of occurrence of the disease. The following strategies may be applied:

1) **Blanket vaccination:** *vaccination* of all susceptible animals in an area or an entire country or *zone*.

2) **Ring vaccination:** *vaccination* ~~primarily~~ of all susceptible animals in a delineated area surrounding the location ~~*establishments*~~ where an *outbreak* has occurred. ~~To prevent outward spread of disease, *vaccination* should be applied from the outer limit boundary of the area inwards.~~

3) **Barrier vaccination:** *vaccination* in an area along the border of an infected country or *zone* to prevent the spread of ~~disease~~ *infection* into or from a neighbouring country or *zone*.

4) **Targeted vaccination:** v*accination* of a *subpopulation* of susceptible animals ~~defined by a greater likelihood of exposure or severity of the consequences~~.

Article 4.X.6~~7~~.

Choice of vaccine

Depending on the disease, several vaccines may be available. To achieve the objectives of the *vaccination* programme, the choice of a vaccine is a critical element that depends on ~~different~~ several factors including:

1. Availability and cost

   a) availability of the vaccine including marketing authorisation and ~~in~~ adequate quantities at the time required;

   b) capacity of the providers to supply the vaccine for the duration of the *vaccination* campaign and to respond to increased needs;

Annex 12 (contd)

c) flexibility in the number of doses per vial to match the structure of the target population;

d) a comparison of the costs of vaccines that meet the technical specifications established in the *vaccination* programme.

2. Vaccine characteristics

a) Physical characteristics

– route and ease of administration;

– volume of dose;

– type of adjuvant and other components.

b) Biological characteristics

– immunity against circulating strains;

– live, inactivated or biotechnology-derived vaccines;

– number of strains and pathogens included in the vaccine;

– potency of the vaccine;

– onset of immunity;

– shelf-life and expiry date;

– thermostability;

– duration of the effective immunity;

– number of doses required to achieve effective immunity;

– ability to be monitored for vaccine-induced ~~antibodies~~ immunity;

– effect on the ability to differentiate infected from vaccinated animals, at the individual or group level;

– suitability of vaccine formulation for species and age of animals in the target population;

– safety for the users, the consumers and the environment.

c) Side effects

– adverse reactions;

– transmission of live vaccine strains ~~or reversion of attenuated strains to virulent.~~;

– reversion of attenuated strains to virulence.

Article 4.X.7~~6~~.

Other critical elements of a vaccination programme

In addition to the choice of vaccine, the *vaccination* programme should include the following other critical elements. ~~and~~ The *vaccination* programme should be communicated to all stakeholders.

Annex 12 (contd)

1. Legal basis

There should be a legal basis for the *vaccination* programme, including for possible compulsory compliance and for compensation of animal owners for possible adverse reactions in their animals. ~~The legal basis for a *vaccination* campaign, including a legal obligation for the *vaccination* and compensation for farmers for possible side effects, should be in place.~~

2. Target population

The *vaccination* programme should define the animal population to be vaccinated and the geographical area where the target population is located.

The target population may include the entire susceptible population or an epidemiological relevant *subpopulation* depending on the likelihood of exposure, the consequences of the disease, the role of the different *subpopulations* in the epidemiology of the ~~disease~~ *infection* and the resources available. The target population may include *wildlife*.

Factors to consider in determining the target population may include species, age, maternal immunity, sex, production types, geographical distribution as well as the number of *animals* and *herds*. These factors should be reviewed and updated regularly.

3~~2~~. Vaccination coverage

~~In practical terms, it~~ It may be difficult to immunise the entire target population. The *vaccination* programme should define the minimum *vaccination* coverage necessary to achieve ~~for the minimum~~ a sufficient population immunity ~~required to achieve~~ to fulfil the objectives of the programme. The minimum *population* immunity required will vary according to the epidemiology of the disease, density of susceptible animals, efficacy of the vaccine and geographical factors.

Measuring population immunity during the monitoring of the *vaccination* programme may assist ~~to~~ in identifying subsets of the target *population* that have not been adequately immunised.

4~~3~~. Stakeholder involvement

Veterinary Services ~~The *vaccination* programme~~ should demonstrate good governance of the *vaccination* programme by ~~the *Veterinary Services* and by~~ clearly identifying the involvement of different stakeholders including other ~~government agencies~~ governmental organisations, ~~farmers~~ animal owners, farmer organisations, private sector veterinarians, non-governmental organisations, *veterinary paraprofessionals*, local government authorities and vaccine suppliers. Stakeholder acceptance of *vaccination* is crucial for the success of the *vaccination* programme. Different stakeholders should preferably be involved in the planning and implementation of *vaccination*, the awareness campaigns, the monitoring of *vaccination*, the production and delivery of vaccines and the financing of the *vaccination* programme.

5~~4~~. Resources

Vaccination programmes may often span several years. To achieve the desired objective, human, financial and material resources should be available throughout the estimated duration of the *vaccination* programme.

6~~5~~. Actions and timeline

The *vaccination* programme should describe the responsibilities, expected deliverables and timeline for each activity.

7~~6~~. Timing of vaccination campaigns

The *vaccination* programme should describe the periodicity of ~~the~~ any *vaccination* campaigns. Depending on the disease and type of vaccine, animals may be vaccinated once or several times during their lifetime.

Annex 12 (contd)

The objective of ~~the~~ a *vaccination* campaign ~~is~~ should be to achieve the ~~necessary~~ *vaccination* coverage necessary to attain or maintain ~~and~~ the minimum population immunity in the target *population* within a defined timeframe. The *vaccination* campaign should be implemented in such a manner as to ensure that the majority of the target *population* is immunised within as short a time as possible. The *vaccination* programme should include a detailed description of the implementation of ~~the~~ *vaccination* campaigns, including frequency and starting and ending dates of each campaign.

The frequency, timing and duration of ~~the~~ *vaccination* campaigns should be determined taking into consideration the following factors:

a) vaccine characteristics and manufacturer's directions for use;

a*bis*) vaccine storage facilities and delivery systems;

b) accessibility of the target population;

c) animal handling facilities;

d) animal body condition and physiological state;

e) geographical factors;

f) climate conditions;

fbis) *vector* activity;

g) awareness, acceptance and engagement of stakeholders;

h) types of production systems and animal movement patterns;

i) timing of agricultural, social or cultural activities;

j) availability of resources.

8~~7~~. Auditing of ~~the~~ vaccination campaigns

The *vaccination* programme should include periodic auditing of all the participants in ~~the~~ any *vaccination* campaigns. Auditing ensures that all components of the system function and provide verifiable documentation of procedures. Auditing may detect deviations of procedures from those documented in the programme.

Indicators related to auditing of ~~the~~ a *vaccination* campaign may include:

a) proportion of the targeted *population* of *animals* and *herds* vaccinated within the defined timeframe;

b) number of vaccine doses used compared with number of animals vaccinated;

bbis) number of animals vaccinated compared to census figures for the relevant animal *population*;

c) number of reports of breaches of the cold chain;

d) performance of vaccinator teams ~~in respect of~~ in complying with the standard operating procedures;

e) timing and ~~length~~ duration of the campaign;

f) overall cost and cost per individual animal vaccinated.

To enable auditing of the *vaccination* programme, a recording system should be in place to measure the indicators above.

Annex 12 (contd)

Article 4.X.8.

Logistics of vaccination

Vaccination campaigns should be planned in detail and well in advance considering the following elements:

1. Procurement of vaccine

The vaccine selected for use in a *vaccination* programme should have been ~~be~~ subjected to the ~~registration marketing authorisation~~ relevant regulatory approval procedure of the country, which is congruent with the recommendation of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary ~~Medical~~ Medicinal Products (VICH).

For systematic *vaccination* campaigns, the process of procurement of the selected vaccine should be initiated in advance to ensure timely delivery to meet the timeframe of the *vaccination* campaign.

National disease contingency plans should provide for emergency *vaccination*. These provisions may allow for simplified procedures to procure vaccine and grant authorisation for temporary use. If *vaccination* is to be used systematically, definitive ~~marketing authorisation~~ relevant regulatory approval ~~registration~~ should be obtained.

Vaccine banks, established in accordance with Chapter 1.1.10. of the *Terrestrial Manual*, facilitate the timely procurement of vaccines.

1bis. Procurement of equipment and consumables

In addition to the vaccine itself, the planning of the *vaccination* campaigns should include the procurement of all necessary equipment and consumables.

2. Implementation of the vaccination programme

~~In addition to the vaccine itself, the planning of the *vaccination* campaigns should include the procurement of all necessary equipment and consumables as well as the establishment of s~~Standard operating procedures should be established to:

a) implement the communication plan;

b) establish, maintain and monitor the fixed and mobile components of the cold chain;

c) store, transport and administer the vaccine;

d) clean and disinfect equipment and *vehicles,* including heat sterilisation of reusable equipment;

e) dispose of waste;

~~*e*~~*bis)* determine the disposition of partially used or unused containers (ampoules, vials, bottles, etc.) of vaccine;

~~*e*~~*ter)* implement *biosecurity* to ensure *vaccination* teams do not transmit the pathogenic agent between *establishments*;

f) identify vaccinated animals;

g) ensure the safety and welfare of animals ~~and *vaccination* teams~~;

~~*g*~~*bis)* ensure the safety of *vaccination* teams;

h) record activities of vaccination teams;

i) document *vaccinations*.

Annex 12 (contd)

The availability of appropriate animal handling facilities ~~at the *vaccination* site~~ is essential to ensure effective *vaccination* as well as safety and welfare of *animals* and *vaccination* teams.

3. Human resources

Vaccination should be conducted by appropriately trained and authorised personnel under the supervision of the *Veterinary Authority*. The *vaccination* programme should provide for periodic training sessions including updated written standard operating procedures for field use.

The number of *vaccination* teams should be sufficient to implement the *vaccination* campaign within the defined timeframe. The *vaccination* teams should be adequately equipped and have means of transport to reach the places where *vaccination* is carried out ~~sites~~.

4. Public awareness and communication

The *Veterinary Authority* should develop a communication strategy in accordance with Chapter 3.3., which should be directed at all stakeholders and public to ensure awareness and acceptability of the *vaccination* programme, its objectives and potential benefits.

The communication plan may include details on the timing and location of the *vaccination*, target *population* and other technical aspects that may be relevant for the public to know.

5. Animal identification

Animal identification allows for the differentiation of vaccinated from ~~non-~~unvaccinated animals and is required for the monitoring and certification of *vaccination*.

Identification can range from temporary to permanent identifiers and can be individual or group-based. *Animal identification* should be ~~carried out~~ implemented in accordance with Chapters 4.1. and 4.2.

6. Record keeping and vaccination certificates

Vaccination programmes under the *Veterinary Authority's* responsibility should provide for maintenance of detailed records of the vaccinated population.

Whenever needed, the *Veterinary Services* should consider issuing official certificates of the *vaccination* status of animals or groups of animals.

7. Additional animal health related activities

In addition to *vaccination* against a specific pathogenic agent, *vaccination* programmes may include other animal health-related activities such as *vaccination* against other pathogenic agents, treatments, *surveillance*, *animal identification* and communication.

Including additional animal health-related activities may enhance the acceptability of the *vaccination* programme. These activities should not negatively affect the primary objective of the *vaccination* programme.

Simultaneous *vaccination* against multiple pathogenic agents may be conducted, provided that compatibility has been demonstrated and the efficacy of the immune response against each of the pathogenic agents is not compromised.

Article 4.X.9.

Evaluation and monitoring of a vaccination programme

~~The~~ A *vaccination* programme should provide for outcome-based evaluation and monitoring to assess the achievements of the *vaccination* programme. Evaluation and monitoring should be carried out periodically during the campaign to enable the timely application of corrective measures and to enhance the sustainability of the *vaccination* programme.

Based on the objectives and targets of the *vaccination* programme, the following outcomes should be assessed:

1) *vaccination* coverage stratified by species, geographical location and type of production system;

2) population immunity measured by testing, stratified by species, geographical location and type of production system;

3) frequency and severity of ~~adverse reactions~~ side effects;

4) reduction of *incidence*, ~~or~~ *prevalence* or impact of the disease.

If the objectives and targets of the *vaccination* programme are not achieved, the reasons for this should be identified and addressed.

Article 4.X.10.

Exit strategy of a vaccination programme

The *vaccination* programme may provide for an exit strategy to cease *vaccination*. The cessation of *vaccination* may apply to the entire target population or to a subset of it, as defined by the *risk* of exposure and as determined by the *Veterinary Authority*.

Criteria to cease *vaccination* may include:

1) eradication of the disease in a country or *zone* has been achieved;

2) *risk analysis* demonstrates sufficient reduction of likelihood of introduction of the pathogenic agent or emergence of the disease;

3) reduction of the incidence, ~~or~~ prevalence or impact of the disease to a level where alternative measures such as a *stamping-out policy* may be ~~sufficient~~ more appropriate to achieve disease control;

4) inability of the programme to meet the desired objectives;

5) adverse public reaction to the *vaccination* programme~~.~~;

6) a revised cost-benefit analysis leads to decision to cease the *vaccination* programme.

When the achievement of ~~disease~~ free status requires the cessation of *vaccination*, the *Veterinary Authority* should prohibit *vaccination* and take appropriate measures to control remaining vaccine stocks as well as vaccine importation.

The cessation of *vaccination* may require the revision of the contingency plan and enhanced *biosecurity, sanitary measures* and *surveillance* for early detection of disease.

Article 4.X.11.

Impact on disease status and management of vaccinated animals

Vaccination has proved its capacity to help prevent, control and eradicate several diseases in addition to or as alternative to *stamping-out* policy. However, depending on the disease and type of vaccine used, *vaccination* may mask underlying *infections*, affect disease *surveillance* and have implications for the movement of vaccinated animals and their products.

When appropriate, *vaccination* programmes should include provisions for the management of vaccinated animals such as '*vaccination* to live' or 'suppressive *vaccination*' policies. *Listed* ~~*D*~~*disease*-specific chapters of the *Terrestrial Code* provide additional recommendations on the management of vaccinated animals.

Annex 12 (contd)

~~Disease f~~Free countries or *zones* applying systematic or emergency *vaccination* in response to an ~~change in the~~ increased *risk* of occurrence of a disease should inform trading partners and the OIE, as appropriate. In the absence of *cases* and unless otherwise specified in the relevant ***listed*** *disease*-specific chapters, *vaccination* of animals does not affect the ~~disease~~ status of the country or *zone*~~,~~ and should not disrupt trade.

Annex 13

CHAPTER 6.X.

INTRODUCTION TO RECOMMENDATIONS FOR VETERINARY PUBLIC HEALTH

Article 6.X.1.

Veterinary public health is a component of public health that focuses on the application of veterinary science and that includes all actions directly or indirectly linked with *animals*, their products and by-products, so long as they contribute to the protection and improvement of the physical, mental and social well-being of humans.

Veterinary science has a rich history of contributions to public health, especially with regard to the provision of safe and adequate food, the prevention, control and eradication of zoonoses, the improvement of *animal welfare* and contributing to biomedical research.

Veterinary Services play a key role in preventing, mitigating and controlling *risks* to public health at the origin or sources of *infection*. In particular, *Veterinary Services* contribute to public health in several areas such as food security, food safety (with respect to foodborne diseases as well as residues and pollutants), control of zoonoses and responses to natural disasters and bioterrorism.

Furthermore, a number of anthropogenic factors influence the occurrence of *emerging diseases*. These factors include among others population growth and eating habits and their consequences such as increasing food demand and intensification of production systems; increased movements and trade of *animals* and their products and derived products; the use and misuse of *antimicrobial agents* generating resistance; the disruption of ecosystems; and climate change, among others.

In this context, *Veterinary Services* are integrated into the “One Health” approach to the prevention of contagious diseases and preservation of the integrity of ecosystems for the benefit of human health, the health of and domestic *animals* and *wildlife,* animal health, including domestic *animals* and *wildlife,* and biodiversity.

Veterinary training and education should take into account the role of *Veterinary Services* in public health at national, regional and global level in the development of these veterinary public health capabilities in the local, regional and global context.

Annex 14a

CHAPTER 6.1.

THE ROLE OF ~~THE~~ VETERINARY SERVICES IN FOOD SAFETY SYSTEMS

Article 6.1.1.

Introduction

Veterinarians are trained in both animal health (including foodborne zoonoses) and food ~~safety~~ hygiene, which makes them uniquely equipped to play a central role in ensuring food safety, especially the safety of food of animal origin.

Close cooperation and effective communication between all ~~actors~~ participants in a food safety system, including *veterinarians*, other relevant professionals and stakeholders, is critical for the effective operation of the ~~food safety~~ system. ~~Food safety systems are now considerably different from those of earlier years and this provides a wider role for the *Veterinary Services*. The characteristics of these systems are global,~~ Indeed, ~~T~~the global, regional, national and local implications of food safety systems, ~~in reach,~~ especially in relation to the globalisation of the food supply, ~~which requires a greater~~ demands a high level of engagement and collaboration between *Competent Authorities* responsible for animal health, food safety and public health, in line with the One Health approach. This provides a wider role and greater responsibilities for *Veterinary Services*. ~~There is a particular emphasis on risk-based food safety systems where implementation is a responsibility shared with a wide range of actors along with assurance of non-food safety requirements that are of high importance to consumers.~~Food safety activities performed by *Veterinary Services* should be integrated to the greatest extent possible with the activities of all other responsible ~~public~~ agencies throughout the food chain.

~~The education and training of *veterinarians*, which includes both *animal* health (including *zoonoses*) and food safety components, makes them uniquely equipped to play a central role in ensuring food safety, especially the safety of foods of *animal* origin. In addition to *veterinarians*, other professionals are involved in ensuring an integrated food safety system throughout the food chain.~~

Article 6.1.2.

Purpose and scope

The purpose of this chapter is to provide guidance to Member Countries on the role and responsibilities of ~~the~~ *Veterinary Services* in food safety systems.

This chapter should be read in conjunction with Chapter~~s~~ 4.1., Chapter 4.2., and relevant chapters of Sections 6 and 7.

~~The OIE and Codex Alimentarius Commission, through the development and implementation of standards and guidelines, contribute to improving food safety and human health by reducing risks that may arise at the farm and any subsequent stages in the food production continuum. Therefore, this~~This chapter should also be read in conjunction with the Codex Alimentarius Principles and Guidelines for National Food Control Systems (CAC/GL 82-2013), General Principles of Food Hygiene (CAC/RCP 1-1969), Code of Hygienic Practice for Meat (CAC/RCP 58-2005), Code of Practice on Good Animal Feeding (CAC/RCP 54-2004), ~~and~~ Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food Producing Animals (CAC/GL 71-2009), and other relevant Codex texts ~~on hygienic practices, food import and export certification systems and antimicrobial resistance~~.

Annex 14a (contd)

Article 6.1.3.

Characteristics of a food safety system

1. ~~Farm to plate approach~~ Food chain approach

Food safety is best assured by an integrated, multidisciplinary approach~~, considering~~ that considers the ~~whole~~ entire food chain. ~~Everyone in the food chain, such as food business operators, the *Veterinary Services* and consumers, has a responsibility to ensure that food is safe.~~ A ~~modern~~ food safety system should take into account the complexity of food production and the ~~increased~~ globalisation of the food supply, and should be risk-based. ~~The application of traceability systems and sharing of food chain information will enhance the effectiveness of a food safety system. The food safety system~~ It should ~~include consideration of~~ consider *hazards* and potential ~~risks~~ associated *risks* at ~~with~~ each ~~component~~ stage of the food chain, ~~namely~~ i.e. primary production, transport, processing, storage and distribution, and integrate *risk management* responses to such *risks* at the most appropriate points along ~~these~~ ~~throughout~~ the food chain ~~continuum~~. The prevention, detection, and control of foodborne *hazards* throughout the food chain is generally more effective in reducing or eliminating the *risk* of unwanted health effects than relying on controls of the final product.The application of traceability systems and sharing food chain information enhance the effectiveness of a food safety system. Everyone involved in the food chain, including food business operators, *Veterinary Services* and consumers, has a responsibility to ensure that food is safe.

2. Risk-based food safety systems

Risk-based food safety systems include measures based on good practices (such as good agricultural practice ~~Good Agricultural Practice~~, good hygienic practice ~~Good Hygienic Practice~~), hazard analysis and critical control points (HACCP) principles and *risk* *analysis* ~~assessment~~. The design and application of a risk-based food safety system depends ~~this risk-based approach depend~~ on the availability of adequate scientific information and effective utilisation of the technical resources of food business operators and *Competent Authorities*. ~~and technical resources of the *Competent Authority*. Monitoring and review are essential to evaluate the performance of a risk-based food safety system.~~ Monitoring food safety outcomes and reviewing control measures are essential to ensure the effective performance of a risk-based food safety system. For example, providing information on the occurrence of *infections* on the farm prior to dispatch of animals for *slaughter* may allow more targeted, risk-based inspection at the *slaughterhouse/abattoir*.

~~For international trade, a risk-based approach to food safety systems contributes to the determination of equivalence between trading partners.~~

3. ~~Primary r~~Responsibilities of food business operators for food safety

Food business operators, including feed producers, farmers, processors, wholesalers, distributors, importers, exporters and retailers, have primary responsibility for ensuring the safety of their products and should be able to demonstrate that they comply with relevant food safety regulatory requirements. ~~The food~~ Food business operators have a responsibility to inform the *Competent Authority* in their country of any non-compliance associated with their product and take action to manage the *risk* e.g. the withdrawal of the product.

4. Responsibilities of the relevant Competent Authorities ~~Competent Authority~~

~~Each Member Country should establish its objectives for *animal* health and public health protection, through consultation with stakeholders (especially livestock producers, processors and consumers) in accordance with the social, economic, cultural, religious and political contexts of the country. Based on these objectives and the analysis of scientific information, the~~ *Competent Authorities* ~~*Authority* has~~ are responsible for developing ~~the responsibility to develop national legislation and~~ policies, legislation and regulations relevant to food safety. ~~The *Competent Authority*~~ They should also take steps to ~~raise awareness of these both~~ communicate these within ~~the~~ their country and ~~to~~ with trading partners.

Competent Authorities should collaborate with other responsible agencies to ensure that roles and responsibilities for food safety systems, including responses to foodborne disease *outbreaks*, are addressed in a coordinated manner.

~~The *Competent Authority* should ensure~~ The relevant *Competent Authorities* should verify that the control systems used by food business operators are appropriate, validated, and effective, and operated in such a way that the regulatory requirements ~~standards~~ are met. This ~~should be verified~~ can be achieved through activities such as inspection and audit. In the event of noncompliance, appropriate corrective actions and sanctions should be applied.

When the *Competent Authority* delegates some control responsibilites to a third party, it should assess and regulary reassess that third party's competency.

~~5.~~ ~~Animal and public health roles of the Veterinary Services~~

~~At the national level the activities of the *Competent Authority* serve both public and *animal* health objectives. In the case of food safety, this duality of roles provides an opportunity for the *Veterinary Services* to perform complementary activities throughout the food chain in coordination with other relevant agencies. It is important that this duality of functions is recognised, and relevant public health and *animal* health activities are integrated.~~

Article 6.1.4.

The ~~role~~ roles and responsibilities of ~~the~~ Veterinary Services in a food safety system

1. Roles and responsibilities ~~Responsibilities~~ of ~~the~~ Veterinary Services

~~The~~ *Veterinary Authorities* ~~*Authority*~~ or other *Competent Authorities* ~~*Authority*~~ should provide an appropriate institutional environment to allow ~~the~~ *Veterinary Services* to implement the necessary policies and standards, and ensure adequate resources for them to carry out their tasks in a sustainable manner. ~~Within the~~ *Veterinary Services* ~~there~~ should ~~be~~ have a clear chain of command and ~~well-documented assignment of~~ respective roles and responsibilities should be clearly defined and well documented. ~~and chain of command. In developing policies and national standards for food safety, the *Veterinary Authority* or other *Competent Authority* should collaborate with other responsible agencies to ensure that food safety risks are addressed in a coordinated manner.~~

~~In order for *Veterinary Services* to make the best possible contribution to food safety, it is important that the education and training of *veterinarians* and *veterinary para-professionals* meet appropriate levels of competence and that there are national programmes for ongoing professional development.~~

~~The~~ *Veterinary Services* should ~~be responsible for, or involved in,~~ be fully involved in the design and implementation of ~~national control programmes of~~ a risk-based food safety system appropriate to their mandate and organisational structure at the national level. ~~Implementation includes verification, audit, assurance and certification.~~ In the implementation of food safety systems for food~~s~~ of animal origin, ~~the~~ *Veterinary Services* should retain responsibility for verification and audit and facilitate a flexible approach to operational activities.

~~Where food safety activities are delegated outside of the *Veterinary Services*, the~~ *Veterinary Services* should retain overall responsibility for the delivery and performance of any activities ~~that they~~ delegated to third party providers. ~~competency standards and performance of the delegated activities.~~

~~In addition to *veterinarians*, several other professional groups are involved in ensuring food safety throughout the food chain, including analysts, epidemiologists, food technologists, human and environmental health professionals, microbiologists and toxicologists. Irrespective of the roles assigned to the different professional groups and stakeholders by the administrative system in the country, close cooperation and effective communication between all involved is imperative to achieve the best results from the combined resources.~~

~~In view of the competencies within the *Veterinary Services*, they~~ Where relevant, ~~the~~ *Veterinary Services* should contribute to other food safety related activities, such as investigations of foodborne disease *outbreaks*, food ~~defence~~ defense, disaster management, and identifying emerging *risks*. In addition, *Veterinary Services* should contribute to the development and management of coordinated *surveillance* and control programmes for foodborne pathogens of public health importance.

Annex 14a (contd)

In order for *Veterinary Services* to make the best possible contribution to ensuring food safety, the education and training of *veterinarians* and *veterinary paraprofessionals* should include appropriate training in food safety systems and ongoing professional development.

2. Activities of Veterinary Services throughout the food chain

~~The *Veterinary Services* have a significant role to play throughout the food safety system.~~ Depending on the ~~role and~~ responsibilities of the *Competent Authority*, the responsibilities of the *Veterinary Services* may be limited to the first part of the food chain (from farm to *slaughterhouse/abattoir* and associated premises for further processing) while in other cases the *Veterinary Services* may be responsible for the whole food chain.

a) Primary production

Through their presence on farms and ~~appropriate~~ collaboration with farmers, *Veterinary Services* play a key role in ensuring that *animals* are kept under good sanitary and hygienic conditions, and in *biosecurity* and ~~in the~~ early detection, *surveillance* and treatment of animal diseases, including conditions of public health significance. ~~The *Veterinary Services* advise on animal husbandry practices, *biosecurity* and interventions that limit the transmission of animal diseases, including foodborne *zoonoses*.~~

~~Because of the importance of traceability throughout the food chain, the verification by the *Veterinary Services* of *animal identification* is an important function.~~

In regard to food safety, ~~The~~ *Veterinary Services* ~~assist~~ provide guidance to farmers on practices that ~~how to~~ prevent or minimise physical and chemical hazards (~~e.g.~~ for example, mycotoxins, environmental contaminants ~~drug~~ and pesticide residues~~, mycotoxins and environmental contaminants~~) in primary production, including ~~through~~ animal feed.

~~Producers' organisations, particularly those with veterinary advisers, are in a good position to provide awareness and training as they are regularly in contact with farmers and are well placed to understand their priorities. Technical support from the *Veterinary Services* is important and both private *veterinarians* and employees of the *Veterinary Authority* can assist. The~~ *Veterinary Services* play a central role in ensuring the responsible and prudent use of ~~biological products and~~ *veterinary medicinal products* ~~drugs~~, including *antimicrobial agents* in accordance with Chapter 6.9. in animal husbandry. This helps to minimise the ~~*risk*~~ likelihood of noncompliant levels of veterinary drug residues ~~developing antimicrobial resistance and unsafe levels of veterinary drug residues~~ in food~~s~~ of animal origin and the development of antimicrobial resistance.

Veterinary Services also play an important role in ensuring traceability throughout the food chain by verifying *animal identification* in accordance with Chapters 4.1. and 4.2.

b) ~~Processing~~ Slaughter, processing and distribution

Activities at the *slaughterhouse/abattoir* should be designed and implemented according to an integrated, risk-based approach in accordance with Chapter 6.2. ~~The~~ *Veterinary Services* have an essential role in ensuring that these activities, including meat inspection, minimise ~~processing (including meat inspection) and distribution minimises~~ foodborne *risks* to public health. This may be provided by supervision and verification of process control and direct involvement in operational activities such as ante-~~mortem~~ and post-mortem inspection. *Slaughterhouse/abattoir* inspection of live *animals* ~~(ante-mortem)~~ and their carcasses ~~(post-mortem)~~ plays a key role both in ~~both~~ the *surveillance* network for animal diseases and zoonoses, and in ensuring the safety and suitability of *meat* and by-products for their intended uses. Control or reduction of biological *hazards* of public health and animal health importance by ante- and post-mortem meat inspection is a core responsibility of ~~the~~ *Veterinary Services*. ~~and they should have primary responsibility for the development and effective implementation of relevant inspection programmes. Chapter 6.2. provides recommendations for the control of biological hazards of *animal* health and public health importance through ante- and post-mortem meat inspection.~~

The *Veterinary Services* may be responsible for overseeing the control measures during processing and distribution of food of animal origin. ~~The *Veterinary Services* also~~ They also play an important role in raising the awareness of food producers, processors and distributors regarding ~~other stakeholders of the~~ measures required to assure food safety.

~~*Veterinarians* provide essential inputs in terms of scientific information, risk assessment, validation of control measures, and monitoring and review of public health outcomes, in the design and implementation of a risk-based food safety system.~~

~~*Veterinarians* have an important role in ensuring food safety in various parts of the food chain, for example through the application of HACCP based controls and other quality assurance systems during food processing and distribution.~~

c) Assurance schemes and certification of food of animal origin ~~animal products~~ for international trade

~~The *Veterinary Services* have an important role in providing public health assurance for products of *animal* origin. When assurance is required for *animal* products *international trade* assurance may take the form of certification of consignments. In which case, the *Veterinary Services* ensure that *international veterinary certificates* comply with *animal* health and food safety standards. Certification of *animal* products in relation to *animal diseases*, including foodborne *zoonoses*, and *meat* hygiene should be the responsibility of the *Veterinary Services*. Certification may be provided by other professionals in connection with food processing and hygiene (e.g. pasteurisation of *milk products*).~~

Veterinary Services have an ~~essential~~ important role in overseeing assurance schemes and an essential role in certifying that food of animal origin complies with animal health and food safety standards.

Other *Competent Authorities* may also be involved in providing assurances and certification of food of animal origin (for example, pasteurisation of *milk products*) for *international trade*.

3. Foodborne disease outbreaks

~~Most reported *outbreaks* of foodborne disease in humans are due to contamination of foods with zoonotic agents during primary production or processing. The~~ *Veterinary Services* play a key role in the investigation of, and response to, ~~such~~ foodborne disease *outbreaks* which may be attributable to or involve animal products. ~~throughout the food chain and in formulating and~~ including the implementation of ~~implementing~~ control measures ~~as appropriate once the source of the *outbreak* has been identified~~. This work should be carried out in close collaboration with ~~human and environmental~~ public health professionals, analysts, epidemiologists, food producers, processors and traders and any others involved.

~~The *Veterinary Services* can play a leading role in development and application of new epidemiological and diagnostic tools to better attribute outbreaks of foodborne diseases to specific *animal* reservoirs.~~

~~In the view~~ Because of the global nature of the food trade, ~~the~~ *Veterinary Services* should work with other national agencies in reporting to international emergency foodborne disease networks, such as the International Network of Food Safety Authorities (INFOSAN), and in utilising such information for preparedness.

~~4. Animal and public health roles of the Veterinary Services~~

~~This complementary role of the *Veterinary Services* is clearly illustrated in relation to inspection and monitoring at the *slaughterhouse*, for both *animal* health and public health hazards.~~

~~The *Veterinary Services* contribute to the development and management of coordinated *surveillance* and control programmes related to foodborne pathogens of public health importance, such as *Salmonella* and *Trichinella*.~~

Annex 14b

CHAPTER 6.1.

THE ROLE OF VETERINARY SERVICES IN FOOD SAFETY SYSTEMS

Article 6.1.1.

Introduction

Veterinarians are trained in both animal health (including foodborne zoonoses) and food hygiene, which makes them uniquely equipped to play a central role in ensuring food safety, especially the safety of food of animal origin.

Close cooperation and effective communication between all participants in a food safety system, including *veterinarians*, other relevant professionals and stakeholders, is critical for the effective operation of the system. Indeed, the global, regional, national and local implications of food safety systems, especially in relation to the globalisation of the food supply, demands a high level of engagement and collaboration between *Competent Authorities* responsible for animal health, food safety and public health, in line with the One Health approach. This provides a wider role and greater responsibilities for *Veterinary Services*. Food safety activities performed by *Veterinary Services* should be integrated to the greatest extent possible with the activities of all other responsible agencies throughout the food chain.

Article 6.1.2.

Purpose and scope

The purpose of this chapter is to provide guidance to Member Countries on the role and responsibilities of *Veterinary Services* in food safety systems.

This chapter should be read in conjunction with Chapter 4.1., Chapter 4.2., and relevant chapters of Sections 6 and 7.

This chapter should also be read in conjunction with the Codex Alimentarius Principles and Guidelines for National Food Control Systems (CAC/GL 82-2013), General Principles of Food Hygiene (CAC/RCP 1-1969), Code of Hygienic Practice for Meat (CAC/RCP 58-2005), Code of Practice on Good Animal Feeding (CAC/RCP 54-2004), Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food Producing Animals (CAC/GL 71-2009), and other relevant Codex texts.

Article 6.1.3.

Characteristics of a food safety system

1. Food chain approach

   Food safety is best assured by an integrated, multidisciplinary approach that considers the entire food chain. A food safety system should take into account the complexity of food production and the globalisation of the food supply, and should be risk-based. It should consider *hazards* and potential associated *risks* at each stage of the food chain, i.e. primary production, transport, processing, storage and distribution, and integrate *risk management* responses to such *risks* at the most appropriate points along the food chain. The prevention, detection, and control of foodborne *hazards* throughout the food chain is generally more effective in reducing or eliminating the *risk* of unwanted health effects than relying on controls of the final product. The application of traceability systems and sharing food chain information enhance the effectiveness of a food safety system. Everyone involved in the food chain, including food business operators, *Veterinary Services* and consumers, has a responsibility to ensure that food is safe.

Annex 14 (contd)

2. Risk-based food safety systems

Risk-based food safety systems include measures based on good practices (such as good agricultural practice, good hygienic practice), hazard analysis and critical control points (HACCP) principles and *risk analysis*. The design and application of a risk-based food safety system depends on the availability of adequate scientific information and effective utilisation of the technical resources of food business operators and *Competent Authorities*. Monitoring food safety outcomes and reviewing control measures are essential to ensure the effective performance of a risk-based food safety system. For example, providing information on the occurrence of *infections* on the farm prior to dispatch of animals for *slaughter* may allow more targeted, risk-based inspection at the *slaughterhouse/abattoir*.

3. Responsibilities of food business operators for food safety

Food business operators, including feed producers, farmers, processors, wholesalers, distributors, importers, exporters and retailers, have primary responsibility for ensuring the safety of their products and should be able to demonstrate that they comply with relevant food safety regulatory requirements. Food business operators have a responsibility to inform the *Competent Authority* in their country of any non-compliance associated with their product and take action to manage the *risk* e.g. the withdrawal of the product.

4. Responsibilities of the relevant Competent Authorities

Competent Authorities are responsible for developing policies, legislation and regulations relevant to food safety.They should also take steps to communicate these within their country and with trading partners.

Competent Authorities should collaborate with other responsible agencies to ensure that roles and responsibilities for food safety systems, including responses to foodborne disease *outbreaks*, are addressed in a coordinated manner.

The relevant *Competent Authorities* should verify that the control systems used by food business operators are appropriate, validated, and effective, and operated in such a way that the regulatory requirements are met. This can be achieved through activities such as inspection and audit. In the event of noncompliance, appropriate corrective actions and sanctions should be applied.

When the *Competent Authority* delegates some control responsibilites to a third party, it should assess and regulary reassess that third party's competency.

Article 6.1.4.

The roles and responsibilities of Veterinary Services in a food safety system

1. Roles and responsibilities of Veterinary Services

Veterinary Authorities or other *Competent Authorities* should provide an appropriate institutional environment to allow *Veterinary Services* to implement the necessary policies and standards, and ensure adequate resources for them to carry out their tasks in a sustainable manner. *Veterinary Services* should have a clear chain of command and respective roles and responsibilities should be clearly defined and well documented.

Veterinary Services should be fully involved in the design and implementation of a risk-based food safety system appropriate to their mandate and organisational structure at the national level. In the implementation of food safety systems for food of animal origin, *Veterinary Services* should retain responsibility for verification and audit and facilitate a flexible approach to operational activities.

Veterinary Services should retain overall responsibility for the delivery and performance of any activities delegated to third party providers.

Where relevant, *Veterinary Services* should contribute to other food safety related activities, such as investigations of foodborne disease *outbreaks*, food defense, disaster management, and identifying emerging *risks*. In addition, *Veterinary Services* should contribute to the development and management of coordinated *surveillance* and control programmes for foodborne pathogens of public health importance.

In order for *Veterinary Services* to make the best possible contribution to ensuring food safety, the education and training of *veterinarians* and *veterinary paraprofessionals* should include appropriate training in food safety systems and ongoing professional development.

2. Activities of Veterinary Services throughout the food chain

Depending on the responsibilities of the *Competent Authority*, the responsibilities of the *Veterinary Services* may be limited to the first part of the food chain (from farm to *slaughterhouse/abattoir* and associated premises for further processing) while in other cases the *Veterinary Services* may be responsible for the whole food chain.

a) Primary production

Through their presence on farms and collaboration with farmers, *Veterinary Services* play a key role in ensuring that *animals* are kept under good sanitary and hygienic conditions, and in *biosecurity* and early detection, *surveillance* and treatment of animal diseases, including conditions of public health significance.

In regard to food safety, *Veterinary Services* provide guidance to farmers on practices that prevent or minimise physical and chemical hazards (for example, mycotoxins, environmental contaminants and pesticide residues) in primary production, including animal feed.

Veterinary Services play a central role in ensuring the responsible and prudent use of *veterinary medicinal products*, including *antimicrobial agents* in accordance with Chapter 6.9. in animal husbandry. This helps to minimise the likelihood.of noncompliant levels of veterinary drug residues in food of animal origin and the development of antimicrobial resistance.

Veterinary Services also play an important role in ensuring traceability throughout the food chain by verifying *animal identification* in accordance with Chapters 4.1. and 4.2.

b) Slaughter, processing and distribution

Activities at the *slaughterhouse/abattoir* should be designed and implemented according to an integrated, risk-based approach in accordance with Chapter 6.2. *Veterinary Services* have an essential role in ensuring that these activities, including meat inspection, minimise foodborne *risks* to public health. This may be provided by supervision and verification of process control and direct involvement in operational activities such as ante- and post-mortem inspection. *Slaughterhouse/abattoir* inspection of live *animals* and their carcasses plays a key role both in the *surveillance* network for animal diseases and zoonoses, and in ensuring the safety and suitability of *meat* and by-products for their intended uses. Control or reduction of biological *hazards* of public health and animal health importance by ante- and post-mortem meat inspection is a core responsibility of *Veterinary Services*.

The *Veterinary Services* may be responsible for overseeing the control measures during processing and distribution of food of animal origin. They also play an important role in raising the awareness of food producers, processors and distributors regarding measures required to assure food safety.

c) Assurance schemes and certification of food of animal origin for international trade

Veterinary Services have an important role in overseeing assurance schemes and an essential role in certifying that food of animal origin complies with animal health and food safety standards.

Other *Competent Authorities* may also be involved in providing assurances and certification of food of animal origin (for example, pasteurisation of *milk products*) for *international trade*.

3. Foodborne disease outbreaks

Veterinary Services play a key role in the investigation of, and response to, foodborne disease *outbreaks* which may be attributable to or involve animal products, including the implementation of control measures. This work should be carried out in close collaboration with public health professionals, analysts, epidemiologists, food producers, processors and traders and any others involved.

Annex 14 (contd)

Because of the global nature of the food trade, *Veterinary Services* should work with other national agencies in reporting to international emergency foodborne disease networks, such as the International Network of Food Safety Authorities (INFOSAN), and in utilising such information for preparedness.

Annex 15

CHAPTER 6.7.

HARMONISATION OF NATIONAL ANTIMICROBIAL RESISTANCE SURVEILLANCE AND MONITORING PROGRAMMES

Article 6.7.1.

Objective

This chapter provides criteria for the~~:~~

~~1)~~ development of national antimicrobial resistance surveillance and monitoring programmes, and the

~~2)~~ harmonisation of existing national antimicrobial resistance surveillance and monitoring programmes~~,~~

in food-producing animals and in products of animal origin intended for human consumption.

Article 6.7.2.

Purpose of surveillance and monitoring

Active ~~(targeted)~~ surveillance and monitoring are core parts of national antimicrobial resistance surveillance programmes. Passive surveillance and monitoring may offer additional information (refer to Chapter 1.4.). The OIE encourages ~~C~~cooperation between all Member Countries conducting antimicrobial resistance surveillance and monitoring ~~should be encouraged~~.

Surveillance and monitoring of antimicrobial resistance is necessary to:

1) assess and determine the trends and sources of antimicrobial resistance in bacteria;

2) detect the emergence of new antimicrobial resistance mechanisms;

3) provide the data necessary for conducting *risk analyses* as relevant to animal and human health;

4) provide a basis for policy recommendations for animal and human health;

5) provide information for evaluating antimicrobial prescribing practices and, for prudent use recommendations;

6) assess and determine effects of actions to combat antimicrobial resistance.

Article 6.7.3.

General aspects ~~The development~~ of antimicrobial resistance surveillance and monitoring programmes

~~1. General aspects~~

Surveillance of antimicrobial resistance and ~~at targeted intervals or ongoing~~ monitoring of the prevalence of, and trends in, resistance in bacteria from *animals*, ~~animal feed,~~ food~~, environment~~ and humans, constitutes a critical part of animal health and food safety strategies aimed at limiting the spread of antimicrobial resistance and optimising the choice of *antimicrobial agents* used in therapy. Animal feed and the environment should also be considered according to national priorities.

Surveillance or ~~M~~monitoring of bacteria from products of animal origin intended for human consumption collected at different steps of the food chain, including processing, packing and retailing, should also be considered.

Annex 15 (contd)

National antimicrobial resistance monitoring and surveillance programmes should be scientifically based and may include the following components:

1~~a~~) statistically based surveys;

2~~b~~) sampling and testing of food-producing animals on the farm, at live animal markets or at *slaughter*;

3~~c~~) an organised sentinel programme, for example targeted sampling of food-producing animals, *herds*, *flocks*, and *vectors* (e.g. birds, rodents);

4~~d~~) analysis of veterinary practice and diagnostic *laboratory* records;

5~~e~~) sampling and testing of products of animal origin intended for human consumption~~.~~;

6) sampling and testing of feed ingredients or feed.

Article 6.7.4.

Sampling

1~~2~~. Sampling strategies

a) Sampling should be conducted on a statistical basis. The sampling strategy should ensure:

– the sample is representative of the population of interest;

– the robustness of the sampling method.

b) The following criteria are to be considered:

– sample source such as food-producing animal, food, animal feed;

– animal species;

– category of *animal* within species such as age group, production type;

– health status of the *animals* such as healthy, diseased;

– sample selection method such as targeted, systematic random, non-random;

– type of sample (~~e.g.~~ such as ~~faecal,~~ faeces, caeca, carcass, food product~~)~~;

– sample size.

2~~3~~. Sample size

The sample size should be large enough to allow detection or determine prevalence of, or trends in, existing and emerging antimicrobial resistance phenotypes.

The sample should avoid bias and ~~provide a~~ be representative ~~sample~~ of the animal *population*, process, product or other unit of interest whilst taking into account the expected prevalence of the bacteria in the sample type, the expected prevalence of the resistance phenotype and the desired level of precision and confidence.

The sample size calculation in Table 1 is based on independent samples. If there is any clustering at the *establishment* or animal level, the sample size should be adjusted accordingly.

~~Sample size estimates for prevalence of antimicrobial resistance in a large population are provided in Table 1 below.~~

Table 1. Sample size estimates for prevalence in a large population

Expected prevalence	90% Level of confidence			95% Level of confidence		
	Desired precision			Desired precision		
	10%	5%	1%	10%	5%	1%
10%	24	97	2,429	35	138	3,445
20%	43	173	4,310	61	246	6,109
30%	57	227	5,650	81	323	8,003
40%	65	260	6,451	92	369	9,135
50%	68	270	6,718	96	384	9,512
60%	65	260	6,451	92	369	9,135
70%	57	227	5,650	81	323	8,003
80%	43	173	4,310	61	246	6,109
90%	24	97	2,429	35	138	3,445

3~~4~~. Sample sources (Table 2)

Member Countries should examine their livestock production systems on the basis of available information and assess which sources are likely to contribute most to a potential risk to animal and human health.

~~a) Animal feed~~

~~Member Countries should consider including animal feed in surveillance and monitoring programmes as they may become contaminated with antimicrobial resistant bacteria, e.g. *Salmonella*.~~

a~~b~~) Food-producing animals

Categories of food-producing animals considered for sampling should be relevant to the country's production system. Resource allocation should be guided by production volume of the food-producing animal species and the *prevalence* of resistant bacteria.

b~~c~~) Food

Member Countries should consider including products of animal origin intended for human consumption, produced locally or imported, in surveillance and monitoring programmes, as foodborne transmission is considered to be an important route for the transfer of antimicrobial resistance.

c) Animal feed

Member Countries should consider including animal feed in *surveillance* and *monitoring* programmes as they may become contaminated with antimicrobial resistant bacteria, *e.g. Salmonella*.

4~~5~~. Type of sample to be collected (Table 2)

Feed samples representative of the batch should be collected in amounts sufficient for isolation of resistant bacteria of concern (at least 25 g) and should be linked to pathogen surveillance programmes.

Faecal samples should be collected in amounts sufficient for isolation of the resistant bacteria of concern (at least 5 g from bovine and porcine and whole caeca from *poultry*).

~~Sampling of carcasses at the *slaughterhouse*/*abattoir* provides information on *slaughter* practices, *slaughter* hygiene and the level of microbiological contamination and cross-contamination of *meat*. Further sampling of the product at retail sales level may provide additional information on the overall microbiological contamination from *slaughter* to the consumer.~~

Annex 15 (contd)

Existing food processing microbiological monitoring, risk-based management and other food safety programmes may provide useful samples for surveillance and monitoring of resistance in the food chain after *slaughter*.

~~Table 2 provides examples of sampling sources, sample types and monitoring outcomes.~~

Table 2. Examples of sampling sources, sample types and ~~monitoring~~ output

Source	Type	Output	Additional information required or additional stratification
Herd or flock of origin	Faeces or bulk milk	Prevalence of resistant bacteria originating from animal populations (of different production types) Relationship between resistance – and antimicrobial use	Age categories, production types, etc. Antimicrobial use over time
Abattoir	Faeces	Prevalence of resistant bacteria originating from animals at slaughter	
	Caeca or intestines	As above	
	Carcass	Prevalence of resistant bacteria after carcass dressing, representative of the ~~H~~hygiene~~,~~ of the process and the contamination during slaughter	
Processing, packing	Food products	Prevalence of resistant bacteria after processing, representative of the ~~H~~hygiene~~,~~ of the process and the contamination during processing and handling	
Point of sale (Retail)	Food products	Prevalence of resistant bacteria originating from food, exposure data for consumers	
Various origins	Animal feed	Prevalence of resistant bacteria originating from animal feed, exposure data for animals	

Article 6.7.5.

Bacteria subjected to surveillance and monitoring

~~6.~~ ~~Bacterial isolates~~

The following categories of bacteria ~~could~~ may be included in surveillance and monitoring programmes ~~monitored~~:

1~~a~~) Animal bacterial pathogens relevant to the countries' priorities

a) Surveillance and monitoring of antimicrobial resistance in animal bacterial pathogens is important~~, both~~ to:

~~*i)*~~ - detect emerging resistance that may pose a concern for animal and human health;

~~*ii)*~~ - detect changes in susceptibility patterns;

~~*iii)*~~ - provide information for *risk analysis*;

~~*iv)*~~ - provide data ~~guide~~ for veterinarians ~~in~~ to inform their ~~prescribing~~ treatment decisions~~.~~;

- provide information for epidemiological studies and trend analysis.

b) Information on the occurrence of antimicrobial resistance in animal bacterial pathogens is in general either derived from ~~routine~~ clinical material sent to veterinary diagnostic *laboratories* or from an active monitoring programme. ~~These samples, often derived from severe or recurrent clinical cases including therapy failure, may provide biased information.~~ Although antimicrobial resistance information provided by diagnostic *laboratories* is primarily for treatment purposes, it is also useful for identification of novel resistance patterns and can possibly assist in identifying emerging resistance. However, in order to estimate accurately the prevalence of antimicrobial resistance in the bacterial pathogen, in a larger population of animals, an active sampling programme should be implemented.

c) To promote a harmonised global approach to the selection of animal bacterial pathogens for inclusion in national surveillance and monitoring programmes, bacteria should be selected using the following criteria:

- impact on animal health and welfare;
- implication of antimicrobial resistance in the bacterial pathogen on therapeutic options in veterinary practice;
- impact on food security and on production (economic importance of associated diseases);
- bacterial diseases responsible for the majority of veterinary antimicrobial usage (stratified by usage of different classes or their importance);
- existence of validated susceptibility testing methodologies for the bacterial pathogen;
- existence of quality assurance programmes or other pathogen reduction options that are non-antimicrobial, such as vaccines and Good Agricultural Practices.

The table below, derived using the above criteria, lists suggested animal bacterial pathogens for inclusion in a surveillance or monitoring programme of food-producing animals. This list is not exhaustive and should be adapted according to the situation in the country.

Table 3. Examples of target animal species and animal bacterial pathogens that may be included in resistance surveillance and monitoring programmes

Target animals	**Respiratory pathogens**	**Enteric pathogens**	**Udder pathogens**	**Other pathogens**
Cattle	*Pasteurella multocida*	*Escherichia coli*	*Staphylococcus aureus*	
	Mannheimia haemolytica	*Salmonella* spp.	*Streptococcus* spp.	
Pigs	*Actinobacillus pleuropneumoniae*	*Escherichia coli*		*Streptococcus suis*
		Salmonella spp.		
Poultry		*Salmonella* spp.		*Escherichia coli*

2~~b~~) Zoonotic bacteria

a~~i~~) *Salmonella*

Salmonella should be sampled from ~~animal feed,~~ food-producing animals, ~~and~~ animal-derived food products and animal feed. For the purpose of consistency and harmonisation, ~~feed samples should preferably be taken at the feed mill and~~ animal samples should ~~be~~ preferably be taken at the *slaughterhouse/abattoir* from healthy *animals* and feed samples should preferably be taken at the feed mill.

Annex 15 (contd)

Surveillance and monitoring programmes may also include bacterial isolates originating from other sources obtained from designated ~~national~~ *laboratories* ~~originating from other sources~~.

Isolation and identification of bacteria and bacterial strains should follow nationally or internationally standardised procedures.

Serovars of public health importance such as *S.* Typhimurium and *S.* Enteritidis should be included in surveillance and monitoring programmes. The inclusion of other relevant serovars will depend on the epidemiological situation in each country.

All *Salmonella* isolates should be characterised by serotyped and, where appropriate, ~~phage-typed according to standard~~ genotypic methods used at ~~the nationally~~ designated *laboratories*. ~~For those countries that have the capabilities, *Salmonella* could be genotyped using genetic finger-printing methods.~~

b~~ii~~) *Campylobacter*

Campylobacter ~~jejuni~~ and ~~C. coli~~ should be isolated from food-producing animals and associated food products ~~(primarily from *poultry*)~~. Isolation and identification of these bacteria should follow nationally or internationally standardised procedures. *Campylobacter* isolates should be identified to the species level.

c~~iii~~) Other bacteria that are pathogenic for humans ~~emerging bacterial pathogens~~

Other ~~emerging~~ bacterial that are ~~pathogens~~ pathogenic for humans such as methicillin-resistant *Staphylococcus aureus* (MRSA)~~,~~ and *Listeria monocytogenes* ~~or others which are pathogenic to humans~~, may be included in resistance surveillance and monitoring programmes.

3~~c~~) Commensal bacteria

E. coli and *enterococci* (*Enterococcus faecium* and *E. faecalis*) may be sampled from animal feed, food-producing animals and products of animal origin intended for human consumption.

These bacteria are commonly used in surveillance and monitoring programmes as indicators, providing information on the potential reservoir of antimicrobial resistance genes, which may be transferred to pathogenic bacteria. It is considered that these bacteria should be isolated from healthy *animals*, preferably at the *slaughterhouse*/*abattoir*, for the purpose of consistency and harmonisation ~~and be monitored for antimicrobial resistance~~.

Article 6.7.6.

~~7.~~ **Storage of bacterial strains**

If possible, isolates should be preserved at least until reporting is completed. Preferably, appropriate isolates should be permanently stored. Bacterial strain collections, established by storage of all isolates from certain years, will provide the possibility of conducting retrospective studies.

Article 6.7.7.

~~8.~~ **Antimicrobial susceptibility testing**

Clinically important *antimicrobial agents* or classes used in human and veterinary medicine should be included in antimicrobial resistance surveillance programmes. Member Countries should refer to the OIE list of *antimicrobials* of veterinary importance for surveillance and monitoring purposes~~. However~~, recognising that the number of tested *antimicrobial agents* may have to be limited according to financial resources.

Appropriately validated antimicrobial susceptibility testing methods should be used in accordance with ~~Guideline~~ Chapter 3.1. of the *Terrestrial Manual*, concerning laboratory methodologies for bacterial antimicrobial susceptibility testing. Antimicrobial susceptibility data should be reported not only qualitatively (susceptible or resistant), but also quantitatively (minimum inhibitory concentrations [MICs] or inhibition zone diameters)~~, rather than qualitatively~~.

Article 6.7.8.

~~9.~~ **Recording, storage and interpretation of data**

1~~a~~) Because of the volume and complexity of the information to be stored and the need to keep these data available for an undetermined period of time, careful consideration should be given to database design.

2~~b~~) The storage of raw (primary, non-interpreted) data is essential to allow the evaluation in response to various kinds of questions, including those arising in the future.

3~~c~~) Consideration should be given to the technical requirements of computer systems when an exchange of data between different systems (comparability or compatibility of automatic recording of laboratory data and transfer of these data between and within resistance surveillance and monitoring programmes) is envisaged. Results should be collected in a suitable national database~~. They should be~~ and recorded quantitatively:

a~~i~~) as distributions of MICs in micrograms per millilitre;

b~~ii~~) or inhibition zone diameters in millimetres.

4~~d~~) The information to be recorded should include, where possible, the following aspects:

a~~i~~) sampling programme;

b~~ii~~) sampling date;

c~~iii~~) animal species and production type;

d~~iv~~) type of sample;

e~~v~~) purpose of sampling;

f~~vi~~) type of antimicrobial susceptibility testing method used;

g~~vii~~) geographical origin (geographical information system data where available) of *herd*, *flock* or *animal*;

h~~viii~~) *animal* factors ~~(e.g.~~ such as age, condition, health status, identification, sex~~).~~;

i) exposure of *animals* to *antimicrobial agents*;

j) bacterial isolation rate.

5~~e~~) The reporting of *laboratory* data should include the following information:

a~~i~~) identity of *laboratory*,

b~~ii~~) isolation date,

c~~iii~~) reporting date,

d~~iv~~) bacterial species,

and, where relevant, other typing characteristics, such as:

Annex 15 (contd)

e~~v~~) serotype or serovar,

f~~vi~~) phage type,

g~~vi~~) antimicrobial susceptibility result or resistance phenotype,

h~~vii~~) genotype.

6~~f~~) ~~The proportion of isolates regarded as resistant should be reported,~~ The number of isolates regarded as resistant should be reported as a proportion of the number of isolates tested, including the defined interpretive criteria used.

7~~g~~) In the clinical setting, breakpoints are used to categorise bacterial strains as susceptible, intermediate or resistant. These clinical breakpoints may be elaborated on a national basis and may vary between Member Countries.

8~~h~~) The bacterial isolation methods, antimicrobial susceptibility testing methods, standards and guidelines used should be recorded.

9~~i~~) For surveillance and monitoring purposes, use of the microbiological breakpoint (also referred to as epidemiological cut-off point), which is based on the distribution of MICs or inhibition zone diameters of the specific bacterial species tested, is preferred. When using microbiological breakpoints, only the bacterial population with acquired resistance that clearly deviates from the distribution of the normal susceptible population will be designated as resistant.

10~~j~~) Ideally, data should be collected at the individual isolate level~~,~~. This will allow ~~allowing~~ antimicrobial resistance patterns to be recorded over time ~~to be recorded~~, along with relevant data on usage of *antimicrobial agents* and management practices.

Article 6.7.9.

~~10.~~ **Reference laboratory and annual reports**

1~~a~~) Member Countries should designate a national reference centre that assumes the responsibility to:

a~~i~~) coordinate the activities related to the antimicrobial resistance surveillance and monitoring programmes;

b~~ii~~) coordinate and collect information from participating ~~surveillance~~ laboratories within the country;

c~~iii~~) produce an annual report on the antimicrobial resistance situation in the country.

2~~b~~) The national reference centre should have access to the:

a~~i~~) raw data;

b~~ii~~) complete results of quality assurance and inter-laboratory calibration activities;

c~~iii~~) inter-laboratory proficiency testing results;

d~~iv~~) information on the structure of the surveillance or monitoring system;

e~~v~~) information on the chosen laboratory methods.

Annex 16

CHAPTER 6.8.

MONITORING OF THE QUANTITIES AND USAGE PATTERNS OF ANTIMICROBIAL AGENTS USED IN FOOD-PRODUCING ANIMALS

Article 6.8.1.

~~Definition and~~ Ppurpose

~~For the purpose of this chapter, therapeutic use of *antimicrobial agents* means the administration of *antimicrobial agents* to *animals* for treating and controlling infectious diseases.~~

The purpose of the~~se~~ recommendations in this chapter is to describe an approach to the monitoring of the quantities of *antimicrobial agents* used in food-producing animals.

In order to evaluate antimicrobial exposure in food-producing animals, quantitative information should be collected to monitor usage patterns by animal species, *antimicrobial agents* or class of *antimicrobial agents*, route of administration and type of use: ~~(~~therapeutic (to treat, control or prevent) or nontherapeutic (including growth promotion) ~~and route of administration~~.

Article 6.8.1bis.

Definitions

For the purposes of the *Terrestrial Code*,

Therapeutic use of antimicrobial agents means the administration of an *antimicrobial agent* to an individual or a group of *animals* to treat, control or prevent *infection* or disease:

– to treat means to administer an *antimicrobial agent* to an individual or a group of *animals* showing clinical signs of an infectious disease;

– to control means to administer an *antimicrobial agent* to a group of *animals* containing sick *animals* and healthy *animals* (presumed to be infected), to minimise or resolve clinical signs and to prevent further spread of the disease;

– to prevent means to administer, using an appropriate dose and for a limited, defined duration, an *antimicrobial agent* to an individual or a group of *animals* at risk of developing a specific *infection* or in a specific situation where disease is likely to occur if the drug is not administered.

Nontherapeutic use of antimicrobial agents means the administration of *antimicrobial agents* to *animals* for any purpose other than to treat, control or prevent *infection* or disease; it includes growth promotion.

Growth promotion means the administration of *antimicrobial agents* to *animals* in their feed or water to increase the rate of weight gain or the efficiency of feed utilisation.

[…]

Annex 17

CHAPTER 7.1.

INTRODUCTION TO THE RECOMMENDATIONS FOR ANIMAL WELFARE

Article 7.1.1.

~~Definition~~ General considerations

Animal welfare means the physical and psychological state ~~of well-being~~ of ~~how~~ an *animal* ~~is coping with~~ in relation to the conditions in which it lives and dies.

An *animal* ~~is in a good state of~~ enjoys good welfare if ~~(as indicated by scientific evidence)~~ it is healthy, comfortable, well nourished, safe, it is not suffering from unpleasant states such as pain, fear and distress and it is able to express ~~innate~~ behaviours that are important for its physical and psychological state ~~well-being. and if it is not suffering from unpleasant states such as pain, fear, and distress~~.

Good *animal welfare* requires disease prevention and appropriate veterinary ~~treatment~~ care, shelter, management and nutrition, a stimulating environment, humane handling and humane *slaughter* or *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.

[…]

Annex 17 (contd)

GLOSSARY

[...]

ANIMAL WELFARE

means the physical and psychological state ~~of well-being~~ of ~~how~~ an *animal* ~~is coping with~~ in relation to the conditions in which it lives and dies. ~~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*/*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.~~

[...]

Annex 18

CHAPTER 7.1.

INTRODUCTION TO THE RECOMMENDATIONS FOR ANIMAL WELFARE

[...]

Article 7.1.X.

Guiding principles for the use of measures to assess animal welfare

1) For the OIE *animal welfare* standards to be applicable globally, they should ~~put more~~ emphasise ~~on~~ favourable ~~good~~ outcomes for the *animals*, although, in some circumstances, it may be necessary to recommend ~~than on~~ specific conditions of the *animals*' environment and management. Outcomes are generally measured by assessing *animals*' enjoyment of the "five freedoms" decribed in Article 7.1.2.

2) For each principle listed in Article 7.1.4., the most relevant criteria (or measurables), ideally comprising animal-based measures, should be included in the standard. Any given animal-based measure may be linked to more than one principle.

~~3)~~ ~~Users of the standard should select the most appropriate animal-based measures for their farming system or conditions, from among those listed in the standard. Outcomes can be measured by an assessment of individuals or animal groups, or a representative sample of those, using data from establishments, transport or slaughterhouses/abattoirs.~~

3~~4~~) Standards should, whenever possible, define explicit targets or thresholds that should be met for animal-based measures. Such target values should be based on relevant science and experience of experts. To guide users, *Competent Authorities* and other relevant bodies should collect data that can be used to set relevant target values.

4~~5~~) In addition to animal-based measures, resource-based measures and management-based measures should be defined on the basis of science and expert experience showing that a welfare outcome is clearly linked to a resource or to a management procedure.

5) Users of the standard should select the most appropriate animal-based measures for their farming system or conditions, from among those listed in the standard. Outcomes can be measured by an assessment of individuals or animal groups, or a representative sample of those, using data from *establishments*, transport or *slaughterhouses/abattoirs*.

6) Whatever the basis of the measure, if outcomes are unsatisfactory, users should consider what changes to resources or management are necessary to improve outcomes.

Annex 19

DRAFT CHAPTER 7.X.

ANIMAL WELFARE AND PIG PRODUCTION SYSTEMS

Article 7.X.1.

Definitions

~~'Pig production systems' are defined as all commercial~~ 'Commercial pig production systems' means those systems in which the purpose of the operation includes some or all of the breeding, rearing and management of pigs (*Sus scrofa*) ~~intended~~ for the production of commercially traded pigs or pig *meat*.

For the purposes of this chapter, 'management' is defined at the farm management level and at the *animal handler* level. At the level of farm management, human resources management practices, including selection and training of handlers, and animal management practices, such as best practice in housing and husbandry and implementation of welfare protocols and audits, all have an impact on *animal welfare*. At the *animal handler* level this requires a range of well-developed husbandry skills and knowledge of how to care for animals.

For the purposes of this chapter, 'environmental enrichment' means increasing the complexity (e.g. foraging opportunities, social housing) of the animal's environment to foster the expression of normal behaviour, provide cognitive stimulation and reduce the expression of abnormal behaviour ~~and provide cognitive stimulation~~. The ~~endpoint~~ aim of providing enrichment should be to improve the ~~biological functioning~~ physical and psychological state of the animal (Newberry, 1995; Mellor, 2015 and 2016).

For the purposes of this chapter 'stereotypy' is a repetitive behaviour induced by frustration, repeated attempts to cope or central nervous system dysfunction. It is expressed as a sequence of abnormal behaviours~~, repetitive and unvarying behaviours~~ which have no obvious purpose or function. ~~caused by known factors such as frustration, coping attempts~~. Permanent ~~or~~ dysfunction of the central nervous system in response to stressful conditions may mean that developed stereotypies may not resolve despite later changes to the environment or other treatment. Some stereotypies commonly observed in pigs include sham chewing, stone chewing, tongue rolling, teeth grinding, bar biting and floor licking (NFACC, 2014; Tuyttens, 2007; Mason ~~and Latham,~~ 20084).

For the purposes of this chapter 'apathy' means that the animal ceases to respond to stimuli that would normally elicit a response (Wood-Gush and Vestergaard, 1989). Furthermore, apathetic behaviour has been described as an abnormal or maladaptive behaviour, indicated by reduced activity, lack of interest or concern (i.e. indifference) and lack of feeling or emotion (impassiveness).

For the purposes of this chapter 'agonistic behaviour' is a continuum of behaviours expressed in conflict situations, and includes offence, defence and submissive or escape components. The behaviours involved may include contact, such as biting and pushing, or non-contact, such as threats in the form of body postures and gestures. Aggressive behaviour is a component of agonistic behaviour (Petherick and Blackshaw, 1987).

Article 7.X.2.

Scope

This chapter addresses the welfare aspects of commercial domestic pig production systems. ~~However,~~ *Captive wild* pigs are not considered.

Article 7.X.3.

Commercial pig production systems

Commercial pig production systems include:

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1. Indoors systems

These are systems in which pigs are kept indoors, and are fully dependent on humans to provide for basic animal needs such as food feed and water. The type of housing depends on the environment, climatic conditions and management system. The animals may be kept in groups or individually.

2. Outdoors systems

These are systems in which pigs live outdoors with shelter or shade, have some autonomy over access to shelter or shade, and but may be fully dependent on humans to provide for basic animal needs such as food feed and water. They Pigs are typically confined in paddocks or pastures according to their production stage. The animals may be kept in groups or individually.

3. Combination systems

These are systems in which pigs are managed in any combination of indoor and outdoor production systems, depending on weather or production stage.

Article 7.X.4.

Criteria (or measurables) for the welfare of pigs

The following outcome-based criteria (or measurables), specifically animal-based criteria, can be useful indicators of *animal welfare*. The use of these indicators and their appropriate thresholds should be adapted to the different situations in which pigs are managed. Consideration should also be given to the design of the systems. These criteria can be considered as a tools to monitor the efficiency of design and management, given that both of these can affect *animal welfare.*

1. Behaviour

Certain behaviours could indicate an *animal welfare* and health problem. These include changes of in feed and water intake, altered locomotory behaviour and or posture, altered lying time, postures and patterns, altered respiratory rate and panting, coughing, shivering and huddling, certain vocalisations, and increased agonistic behaviours (including aggression), and stereotypic, apathetic or other abnormal behaviours (e.g. tail biting).

Certain behaviours are indicators of good *animal welfare*. These may include positive social and play behaviour.

Stereotypy is defined as a sequence of invariant motor acts, which provide no obvious gain or purpose for the animal. Some stereotypies commonly observed in pigs include sham chewing, tongue rolling, teeth grinding, bar biting and floor licking.

2. Morbidity rates

Rates of iInfectious and metabolic diseases, lameness, peri-partum peripartum and post-procedural complications, injury and other forms of morbidity, above recognised thresholds, may be direct or indirect indicators of the *animal welfare* status of the whole at the *herd* level. Understanding the aetiology of the disease or syndrome is important for detecting potential *animal welfare* problems. Mastitis and metritis, leg and hoof problems, shoulder ulcers in sows, skin lesions, respiratory and digestive diseases, and reproductive diseases are also particularly important animal health problems for pigs. Scoring systems, such as for body condition, lameness and injuries, and information gathered at the *slaughterhouse/abattoir*, can provide additional information.

Both clinical and *post mortem* pathologic examination and pathology should be utilised as indicators of disease, injuries and other problems that may compromise *animal welfare*.

3. Mortality and culling rates

Mortality and culling rates affect the length of productive life and, like morbidity rates, may be direct or indirect indicators of ~~the~~ *animal welfare* at the *herd* level ~~status~~. Depending on the production system, estimates of mortality and culling rates can be obtained by analysing the causes of *death* and culling and their temporal and spatial patterns of occurrence. Mortality and culling rates, and their causes, when known, should be recorded regularly, e.g. daily, and used for monitoring e.g. monthly, annually.

Necropsy is useful in establishing the cause of *death*.

4. Changes in body weight and body condition

In growing animals, body weight changes outside the expected growth rate, especially excessive sudden weight loss, are indicators of poor *animal welfare* and health.

~~In mature animals, b~~Body condition outside an acceptable range or large variation amongst individual animals in the group may be an indicator of compromised *animal welfare*~~,~~ and health, and reproductive efficiency in mature animals.

5. Reproductive efficiency

Reproductive efficiency can be an indicator of *animal welfare* and health status. ~~Future performance of sows or gilts can be affected by under- or over-nutrition at different stages of rearing~~. Poor reproductive efficiency, compared with the targets expected for a particular breed or hybrid, can indicate *animal welfare* problems (Hemsworth *et al.*, 1981, 1986, 1989, 1994; Munsterjelm *et al.*, 2006).

Examples may include:

– low conception rates,
– high abortion rates,
– metritis and mastitis,
– ~~low~~ small litter size (total born),
– low numbers born alive,
– high numbers of stillborns or mummies.

6. Physical appearance

Physical appearance may be an indicator of *animal welfare* and health. Attributes of physical appearance that may indicate compromised *animal welfare* include:

– body condition outside an acceptable range,
– presence of ectoparasites,
– abnormal texture or hair loss,
– excessive soiling with faeces ~~in indoor systems~~,
– ~~reddish~~ skin discolouration,
– swellings, injuries or lesions,
– discharges (e.g. from nose or eyes, including tear staining) (Telkänranta *et al.*, 2016),
– feet and leg abnormalities,
– abnormal posture (e.g. rounded back, head low),
– emaciation or dehydration ~~(in piglets)~~.

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7. Handling response

Improper handling or lack of human contact can result in fear and distress in pigs. Fear of humans may be an indicator of poor *animal welfare* ~~and health~~. Indicators may include:

– evidence of poor human-animal relationship, such as marked avoidance of handlers and abnormal or excessive vocalisation ~~disturbed behaviour~~ when being moved or when *animal handlers* interact with pigs ~~enter a pen~~,

– animals slipping or falling during handling,

– injuries sustained during handling, such as bruising, lacerations and fractured legs,

~~– animals vocalising abnormally or excessively during restraint and handling.~~

8. Lameness

Pigs are susceptible to a variety of infectious and non-infectious musculoskeletal disorders. These disorders may ~~lead to~~ cause lameness and ~~to~~ gait abnormalities. Pigs that are lame or have gait abnormalities may have difficulty reaching ~~food~~ feed and water and may experience pain and distress. Musculoskeletal problems have many causes, including genetic, nutrition, sanitation, floor quality, and other environmental and management factors. There are several gait scoring systems available.

9. Complications from common procedures

Some painful or potentially painful procedures such as surgical castration, tail docking, teeth clipping or grinding, tusk trimming, identification, nose ringing and hoof care are ~~commonly~~ performed in pigs to facilitate management, ~~to~~ meet market or environmental requirements ~~and improve human safety~~ and improve human safety or ~~and~~ safeguard *animal welfare*.

However, if these procedures are not performed properly, *animal welfare* and health can be unnecessarily compromised.

Indicators of ~~such~~ problems associated with these procedures could include:

– post-procedure *infection* and swelling,

– post-procedure lameness,

– behaviour indicating pain, fear, distress or suffering (Mellor and Patterson-Kane, 2009) ~~and distress~~,

– increased morbidity, mortality and culling rates,

– reduced feed and water intake,

– post procedure body condition and weight loss.

Article 7.X.5.

Recommendations

Ensuring good welfare of pigs is contingent on several management factors, including system design, environmental management, and animal management practices which include responsible husbandry and provision of appropriate care. Serious problems can arise in any system if one or more of these elements are lacking.

Articles 7.X.6. to 7.X. 2~~7~~6. provide recommendations for measures applied to pigs.

Each recommendation in Article 7.X.6. to 7.X.24. includes a list of relevant animal ~~outcome~~-based criteria (or measurables) derived from Article 7.X.4.

This does not exclude other criteria being used where or when appropriate.

~~Article 7.X.6.~~

~~**Housing**~~

~~When new facilities are planned or existing facilities are modified, professional advice on design in regards to welfare and health of animals should be sought.~~

~~Housing systems and their components should be designed, constructed and regularly inspected and maintained in a manner that reduces the risk of injury, disease or stress for pigs. Facilities should to allow for the safe, efficient and humane management and movement of pigs.~~

~~There should be a separate area where sick and injured animals can be treated and monitored. When a separated space is provided, this should accommodate all the needs of the animal e.g. recumbent or lame animals or animals with severe wounds may require additional bedding or an alternative floor surface.~~

~~Pigs should not be tethered as part of their normal housing systems.~~

~~Good outcomes in the welfare and health of animals can be achieved in a range of housing systems. The design and management of the system are critical for achieving that.~~

~~Pigs are social animals and prefer living in groups, therefore housing systems where pregnant sows and gilts can be kept in groups are recommended.~~

~~Outcome based criteria (or measurables): physical appearance (injuries), behaviour, changes in body weight and body condition, handling response, reproductive efficiency, lameness and morbidity, mortality and culling rates.~~

Article 7.X.6~~7~~.

Training of ~~P~~personnel ~~training~~

Pigs should be cared for by a sufficient number of personnel, who collectively possess the ability, knowledge and competence necessary to maintain the welfare and health of the animals.

All people responsible for pigs should be competent through formal training or practical experience in accordance with their responsibilities. This includes understanding of and skill in animal handling, nutrition, reproductive management techniques, behaviour, *biosecurity*, signs of disease, and indicators of poor *animal welfare* such as stress, pain and discomfort, and their alleviation.

~~Outcome~~ Animal ~~-~~based criteria (or measurables): handling response, physical appearance, behaviour, changes in body weight, body condition, reproductive efficiency, lameness and morbidity, mortality and culling rates and complications from common procedures.

Article 7.X.7~~8~~.

Handling and inspection

Pigs should be inspected at least once a day when fully dependent on humans to provide for basic needs such as ~~food~~ feed and water and to identify welfare and health problems.

Some animals should be inspected more frequently, for example, farrowing sows, new born piglets, newly weaned pigs, ~~and~~ newly-mixed gilts and sows, sick or injured pigs and those showing abnormal behaviours such as ~~tail nibbling and~~ tail biting.

Pigs identified as sick or injured should be given appropriate treatment at the first available opportunity by competent *animal handlers*. If *animal handlers* are unable to provide appropriate treatment, the services of a *veterinarian* should be sought.

Annex 19 (contd)

Recommendations on the handling of pigs are also found in Chapter 7.3. In particular handling aids that may cause pain and distress (e.g. electric goads) should be used only when other methods fail ~~in extreme circumstances~~ and provided that the animal can move freely and is able to move away from the handling aid. The use of electric ~~prods~~ goads should be avoided (see also point 3 of Article 7.3.8.), and ~~in any case~~ should not be repeatedly used on the same animal, and not be used in sensitive areas including the udder, face, eyes, nose, ears or ~~ano-genital~~ anogenital region.

Exposure of pigs to sudden movement, loud noises or changes in visual contrasts should be minimised where possible to prevent stress and fear reactions. Pigs should not be improperly or aggressively handled ~~aggressively~~ (e.g. kicked, thrown, dropped, walked on top of, held or pulled by one front leg, ears or tail). Pigs that become distressed during handling should be attended to immediately.

Pigs should be restrained only for as long as necessary and only appropriate, well-maintained restraint devices should be used.

Well designed and maintained handling facilities assists proper handling.

~~Outcome -~~ Animal ~~-~~based criteria (or measurables): physical appearance, behaviour, changes in body weight and body condition, handling response, reproductive efficiency, lameness and morbidity, mortality and culling rates.

Article 7.X.~~8~~9.

Painful procedures

Some procedures such as surgical castration, tail docking, teeth clipping or grinding, tusk trimming, identification, and nose ringing ~~are~~ may be ~~commonly~~ performed in pigs. These procedures should only be performed when necessary to facilitate management, ~~to~~ meet market or environmental requirements ~~and improve human safety,~~ improve human safety or ~~and~~ safeguard *animal welfare*.

These procedures are painful or have the potential to cause pain. They ~~and thus~~ should be performed ~~only when necessary and~~ in such a way as to minimise any pain ~~and~~, distress or suffering to the animal~~, e.g. using anaesthesia, or analgesia or both under the recommendation or supervision of a *veterinarian*~~.

Options for enhancing *animal welfare* in relation to these procedures include the internationally recognised 'three Rs' ~~which involves~~: replacement (e.g. using entire males or immunocastrated males ~~vs.~~ rather than castrated males), reduction (e.g. tail docking and teeth clipping only when necessary) and refinement (e.g. providing analgesia or anaesthesia under the recommendation or supervision of a *veterinarian*) (Bonastre *et al.*, 2016 and Hansson *et al.*, 2011).

Ovariectomy should not be performed without anaesthesia and prolonged analgesia. An immunological product that reversibly and effectively suppresses ovarian function in pigs is available. Immunological prevention of oestrus should be encouraged to avoid ovariectomy (Dalmau *et al.*, 2015).

~~Outcome -~~ Animal ~~-~~based criteria (or measurables): complications from common procedures, morbidity rates, mortality and culling rates, abnormal behaviour, physical appearance and changes in weight and body condition.

Article 7.X.~~9~~10.

Feeding and provision of water~~ing of animals~~

The amount of feed and nutrients pigs require in any management system is affected by factors such as climate, the nutritional composition and quality of the diet, the age, gender, genetics, size and physiological state of the pigs (e.g. pregnancy, lactation, growth), and their state of health, growth rate, previous feeding levels and level of activity and exercise.

All pigs should receive adequate ~~quantities~~ quantity and quality of feed and nutrients each day to enable each pig to:

– maintain good health;

– meet its physiological ~~and behavioural~~ requirements ~~demands;~~ and,

– meet its requirements for foraging (Bergeron *et al.*, 2008; Brouns *et al.*, 1994; Ramonet *et al.*, 1999; Robert *et al.*, 1993 and 1997).

– ~~avoid metabolic and nutritional disorders.~~

Feed and water should be provided in such a way as to prevent ~~undue~~ excessive or injurious competition ~~and injury~~.

Pigs should be fed a diet with sufficient fibrous feedstuffs in order to reduce ~~as much as possible~~ the occurrence of gastric ulcers (Herskin *et al.*, 2016).

All pigs should have access to an adequate supply of ~~palatable~~ drinkable water ~~at a temperature that does not inhibit drinking and~~ that meets their physiological requirements and is free from contaminants hazardous to pig health (Patience, 2013).

~~Outcome~~ Animal-based criteria (or measurables): changes in body weight and body condition, physical appearance (emaciation, dehydration ~~in piglets~~), behaviour (agonistic behaviour at feeding and watering places and abnormal behaviour such as tail biting), mortality and culling rates, and morbidity rates ~~(gastric ulcers)~~.

Article 7.X.10~~11~~.

Environmental enrichment

Animals should be provided with an environment that provides complexity, manipulability and cognitive stimulation (e.g. foraging opportunities, social housing) to foster normal behaviour (e.g. rooting, ~~and~~ biting~~/~~ foraging or chewing materials other than feedstuffs), reduce abnormal behaviour (e.g. tail, ear, leg and flank biting and apathetic behaviour) and improve their ~~well-being~~ physical and psychological state ~~biological function~~ (Dudnik *et al.*, 2006; Elmore *et al.*, 201; Newberry, 1995; Van de Weerd *et al.*, 2006; Wittaker *et al.*, 1999).

Pigs should be provided with multiple forms of enrichment that aim to improve their welfare ~~of the animals~~ through the enhancement of their physical and social environments, such as:

– sufficient quantity of suitable materials to enable pigs to fulfil their ~~innate~~ needs to explore and look for feed (edible materials), bite (chewable materials), root (investigable materials) and manipulate ~~(manipulable~~ materials~~)~~ (Bracke *et al.*, 2006)~~:~~. ~~a~~Novelty is another aspect that is important in maintaining interest in the provided material~~(s)~~ (Trickett *et al.*, 2009; Abou-Ismaila and Mendl, 2016; Tarou and Bradshaw 2007);

– social enrichment ~~which~~ that involves either keeping pigs in groups or individually with visual, olfactory and auditory contact with other pigs;

– positive human contact (such as regular direct physical contact associated with positive events, which may include feed, pats, rubs, scratching and talking when the opportunity arises) (Hemsworth and Coleman, 2011; Hemsworth and Coleman, 1994).

~~Outcome~~ Animal-based criteria (or measurables): physical appearance (injuries), behaviour (stereotypies, tail biting), changes in body weight and body condition, handling response, reproductive efficiency, lameness and morbidity, mortality and culling rates.

Article 7.X.11~~12~~.

Prevention of abnormal behaviour

In pig production there ~~are~~ is a number of abnormal behaviours that can be prevented or minimised with appropriate management procedures.

Annex 19 (contd)

Many of these problems are multifactorial and minimising their occurrence requires an examination of the whole environment and of several management factors. ~~However some r~~Recommendations ~~to~~ Management procedures that may reduce the~~ir~~ occurrence of some of these behavioural problems include:

1) Oral stereotypies (e.g. bar biting, sham chewing, excessive drinking) ~~in adult pigs~~ can be minimised by providing environmental enrichment and increasing feeding time and satiety by increasing fibre content in the diet or foraging roughage (Robert *et al.*,1997; Bergeron *et al.*, 2000).

2) Tail biting may be reduced by providing an adequate enrichment material and an adequate diet (avoiding deficiencies of ~~sodium~~ minerals (Fraser, 1987) or essential ~~amino-acids~~ amino acids), and avoiding high stocking densities and competition for feed and water (Walker and Bilkei, 2005). Other factors to consider include animal characteristics (breed, genetics, gender) and social environment (*herd* size, mixing animals) (Schroder-Petersen and Simonsen, 2001; EFSA, 2007; Taylor *et al.*, 2010), general health, thermal comfort and air quality.

3) Belly nosing and ear sucking may be reduced by increasing the weaning age, and providing feed to piglets prior to weaning to avoid the abrupt change of feed (Marchant-Forde, 2009; Sybesma, 1981; Worobec, 1999).

4) Vulva biting may be reduced by minimising competition for resources, including feed and water ~~in accessing the feeding area~~ (Bench *et al.*, 2013; Leeb *et al.*, 2001; Rizvi *et al.*, 1998).

~~Outcome~~ Animal~~-~~based criteria (or measurables): physical appearance (injuries), behaviour (abnormal behaviour), morbidity rates, mortality and culling rates, reproductive efficiency and changes in body weight and body condition.

Article 7.X.12~~6~~.

Housing (including outdoor production systems)

When new facilities to accommodate pigs are planned or existing facilities are modified, professional advice on design in regards to welfare and health of animals should be sought.

Housing systems and their components should be designed, constructed and regularly inspected and maintained in a manner that reduces the risk of injury, disease ~~or~~ and stress for pigs. Facilities should ~~to~~ allow for the safe, efficient and humane management and movement of pigs. In systems where pigs could be exposed to adverse weather conditions they should have access to shelter to avoid thermal stress and sunburn.

There should be a separate pen or area where sick and injured animals or animals that exhibit abnormal behaviour can be isolated, treated and monitored. Certain animals may need to be kept individually. When a separated space is provided, this should accommodate all the needs of the animal e.g. recumbent or lame animals or animals with severe wounds may require additional bedding or an alternative floor surface, and water and ~~food~~ feed ~~must~~ should be within reach.

Pigs should not be tethered as part of their normal housing systems.

Good outcomes in the welfare and health of animals can be achieved in a range of housing systems. The design and management of the system are critical for achieving ~~that~~ these outcomes.

~~Pigs~~ Sows and gilts, like other pigs, are social animals and prefer living in groups (Stolba and Wood-Gush, 1989; Newberry and Wood-Gush, 1988; Gonyou, 2001), therefore ~~housing systems where~~ pregnant sows and gilts should preferably be housed ~~can be kept~~ in groups ~~are recommended~~ (Anil *et al.*, 2005; Barnett *et al.*, 2001; Boyle *et al.*, 2002; Broom *et al.*, 1995; Karlen *et al.*, 2007; Marchant and Broom, 1996; McGlone *et al.*, 2004; AVMA, 2015). ~~Sows and gilts can be successfully mixed early after breeding, without any reproduction consequences (Spoolder *et al.*, 2009).~~

~~Outcome~~ Animal~~-~~based criteria (or measurables): physical appearance (injuries), behaviour, changes in body weight and body condition, handling response, reproductive efficiency, lameness and morbidity, mortality and culling rates.

Annex 19 (contd)

Article 7.X.13.

Space allowance

Space allowance should be managed taking into account different areas for lying, standing, and feeding and elimination. Crowding Stocking density should not adversely affect normal behaviour of pigs and durations of time spent lying.

Insufficient and inadequate space allowance may increase stress, the occurrence of injuries and have an adverse effect on growth rate, feed efficiency, reproduction and behaviour such as locomotion, resting, feeding and drinking, agonistic and abnormal behaviour (Gonyou *et al.*, 2006; Ekkel, 2003; Turner, 2000).

1. Group housing

   Floor space may interact with a number of factors such as temperature, humidity, floor type and feeding systems to affect pig welfare (Marchant–Forde, 2009; Verdon, 2015). All pigs should be able to lie down rest simultaneously, and each animal lie down, to stand up and move freely. Sufficient space should be provided to enable animals to have access to feed, water, to separate lying and elimination areas and to avoid aggressive animals.

   Group housing systems should provide sufficent space and opportunities to avoid or escape from potential aggressors.

   If abnormally aggressive behaviour is seen, corrective measures should be taken, such as increasing space allowance and providing barriers where possible or individually housing the aggressive pig.

   In outdoor systems where pigs have some autonomy over diet selection, stocking density should be matched to the available feed supply.

   Outcome Animal-based criteria (or measurables): reduction or variation in body weight and body condition, increasing agonistic and abnormal behaviour such as tail biting, injuries, morbidity, mortality and culling rates, and physical appearance (e.g. excessive presence of faeces on the skin).

2. Individual pens

   Pigs should only be housed in individual pens if necessary. In individual pens, pigs mustshould be provided with sufficient space so that they can stand up, turn around and lie comfortably in a natural position, and that provides separate areas for separation of dunging elimination, lying and eating areas.

   Outcome Animal-based criteria (or measurables): increasing abnormal behaviour (stereotypies), morbidity, mortality and culling rates, and physical appearance (e.g. excessive presence of faeces on the skin, injuries).

3. Stalls and (crates)

   Feeding, insemination and gestation and insemination stalls and farrowing crates Stalls should must be sized appropriately to allow pigs to:

   – be able to stand up in their natural stance without contact with either side of the stall or crate,
   – stand up without in their natural stance without contact with touching the top bars,
   – stand in a stall without simultaneously touching both ends of the stall or crate,
   – lie comfortably on their sides without disturbing neighbouring pigs or being injured by another pig.

   Outcome Animal-based criteria (or measurables): physical appearance (e.g. injuries), increasing abnormal behaviour (stereotypies), reproductive efficiency, lameness and morbidity, mortality and culling rates (e.g. piglets).

Annex 19 (contd)

Article 7.X.14.

Flooring, bedding, resting surfaces

In all production systems pigs need a well-drained, dry and comfortable place to rest.

Floor management in indoor production systems can have a significant impact on pig welfare (Temple *et al.*, 2012; Newton *et al.*, 1980). 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. Areas with excessive faecal accumulation are not suitable for resting.

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, the slat and gap widths should be appropriate to the claw size of the pigs to prevent injuries.

Slopes of the floor pens should allow water to drain and not pool in the pens.

In outdoor systems, pigs should be rotated between paddocks or pastures to ensure good hygiene and minimise risk of diseases.

If bedding or rubber matting is provided it should be suitable (e.g. hygienic, non-toxic) and maintained to provide pigs with a clean, dry and comfortable place on which to lie.

Outcome Animal based criteria (or measurables): physical appearance (e.g. injuries, presence of faeces on the skin, bursitis), lameness and morbidity rates (e.g. respiratory disorders, reproductive tract infections).

Article 7.X.15.

Air quality

Good air quality and ventilation are important for the welfare and health of pigs and reduce the risk of respiratory discomfort, anddiseases and abnormal behaviour. Dust, toxins, micro-organisms microorganisms and noxious gases, including ammonia, hydrogen sulphide, and methane caused by decomposing animal waste, can be problematic in indoor systems due to decomposing animal waste (Drummond *et al.*, 1980).

Air quality is influenced strongly by management and building design in housed systems. Air composition is influenced by stocking density, the size of the pigs, flooring, bedding, waste management, building design and ventilation system (Ni *et al.*, 1999).

Proper ventilation is important for effective heat dissipation in pigs and to prevent the build-up of effluent gases (e.g. ammonia and hydrogen sulphide), including those from manure and dust in the housing unit. The ammonia level concentration in enclosed housing should not exceed 25 ppm. A useful indicator is that if air quality at the level of the pigs is unpleasant for humans it is also most likely to be a problem for pigs.

Outcome Animal based criteria (or measurables): morbidity, mortality and culling rates, physical appearance (excessive soiling and tear staining), behaviour (especially respiratory rate, or coughing and tail biting), change in body weight and body condition.

Article 7.X.16.

Thermal environment

Although pigs can adapt to different a range of thermal environments, particularly if appropriate breeds and housing are used for the anticipated conditions, sudden fluctuations in temperature can cause heat or cold stress.

1. Heat stress

   Heat stress is a serious problem in pig production. It can cause significant discomfort, as well as reductions in weight gain and fertility, or sudden death (Werremann and Bazer, 1985).

The risk of heat stress for pigs is influenced by environmental factors including air temperature, relative humidity, wind speed, ventilation rates, stocking density, shade and wallow availability in outdoor systems~~,~~ and animal factors including breed, age and body condition (Heitman and Hughes, 1949; Quiniou and Noblet, 1999).

Animal handlers should be aware of the risk that heat stress poses to pigs and of the thresholds in relation to heat and humidity that may require action. If the risk of heat stress reaches too high levels the *animal handlers* should institute an emergency action plan that gives priority to access to additional water and could include provision of shade and wallows in outdoor systems, fans, reduction of stocking density, water-based cooling systems (dripping or misting), and provision of cooling systems as appropriate for the local conditions.

~~Outcome~~ Animal ~~-~~based criteria (or measurables): behaviour (feed and water intake, respiratory rate, panting, lying postures and patterns, agonistic behaviour), physical appearance (presence of faeces on the skin, sunburn), morbidity, mortality and culling rates, and reproductive efficiency.

2. Cold stress

Protection from cold should be provided when ~~these~~ conditions are likely ~~create a serious risk to the~~ to compromise ~~to~~ the welfare of pigs, particularly in neonates and young pigs and others that are physiologically compromised (e.g. ill animals). ~~This~~ Protection can be provided by insulation, extra bedding, heat mats or lamps and natural or man-made shelters in outdoor systems (Blecha and Kelley, 1981).

~~Outcome~~ Animal ~~-~~based criteria (or measurables): morbidity, mortality and culling rates, physical appearance (long hair, piloerection), behaviour (especially abnormal postures, shivering and huddling) and changes in body weight and body condition.

Article 7.X.17.

Noise

~~Pigs are able to cope with a range of adaptable to different levels and types of noise. However, e~~Exposure of pigs to sudden or loud noises should be ~~minimised~~ avoided ~~where possible~~ to prevent stress and fear ~~reactions~~. Ventilation fans, feeding machinery or other indoor or outdoor equipment should be constructed, placed, operated and maintained in such a way that they cause the least possible amount of noise (Algers and Jensen, 1991).

~~Outcome~~ Animal ~~-~~based criteria (or measurables): behaviour (e.g. fleeing and abnormal or excessive vocalisation), physical appearance (e.g. injuries), reproductive efficiency, changes in body weight and body condition.

Article 7.X.18.

Lighting

Indoor systems should have light levels sufficient to allow all pigs to see one another, to investigate their surroundings visually and to show other normal behaviour patterns and to be seen clearly by staff to allow adequate inspection of the pigs. The lighting regime ~~shall~~ should be such as to prevent health and behavioural problems. It should follow a 24-hour rhythm and include sufficient uninterrupted dark and light periods, preferably no less than 6 hours for both.

~~A minimum of 40 lux of lighting is recommended for a minimum of 6 hours per day (Martelli *et al.*, 2005; Taylor *et al.*, 2006).~~

Artificial light sources should be located so as not to cause discomfort to the pigs.

~~Outcome~~ Animal ~~-~~based criteria (or measurables): behaviour (locomotive behaviour), morbidity rate, reproductive efficiency, physical appearance (injuries) and changes in body weight and body condition.

Annex 19 (contd)

Article 7.X.19.

Farrowing and lactation

Sows and gilts need time to adjust to their farrowing accommodation before farrowing. Nesting material should be ~~provided~~ available to sows and gilts where possible for at least one day prior to ~~some days before~~ farrowing (Yun *et al.*, 2014; Lawrence *et al.*, 1994; Jarvis *et al.*, 1998). Sows and gilts should be observed frequently around their expected farrowing times. As some sows and gilts need assistance during farrowing, there should be sufficient space and competent staff.

~~When new buildings are planned, loose housing systems for farrowing sows and gilts should be considered. (Baxter *et al.*, 2012; Cronin *et al.*, 2014; KilBride *et al.*, 2012; Morrison *et al.*, 2013; Weber, 2007).~~

~~Outcome~~ Animal ~~-~~based criteria (or measurables): mortality and culling rates (piglets and sows), morbidity rates (metritis and mastitis), behaviour (~~stereotypies~~ restlessness and savaging), reproductive efficiency, physical appearance (injuries).

Article 7.X.20.

Weaning

Weaning ~~can be~~ is a stressful time for sows and piglets and good management is required. Problems associated with weaning are generally related to the piglets' size and physiological maturity. ~~Early weaning systems require good management and nutrition of the piglets.~~

Weaned piglets should be moved into clean and disinfected housing separate from where sows are kept, in order to minimise the transmission of diseases to the piglets.

~~An average~~ Piglets should be weaned~~ing age of~~ at three weeks or older, unless otherwise recommended by a *veterinarian* for disease control puposes ~~is recommended~~ (Hameister *et al.*, 2010; Smith *et al.*, 2010; Gonyou *et al.*, 1998; Worobec *et al.*, 1999). Early weaning systems require good management and nutrition of the piglets.

Delaying weaning to the age of four weeks or more may produce benefits such as improved gut immunity,less diarrhoea and less use of *antimicrobial agents* (EFSA, 2007; Hameister *et al.*, 2010; McLamb *et al.*, 2013; Smith *et al.*, 2010; Gonyou *et al.*, 1998, Bailey *et al.*, 2001).

Regardless of age, low weight piglets require additional care and can benefit from being kept in small groups in specialised pens until they are able to be moved to the common nursery area.

Newly weaned pigs are susceptible to disease challenges, so adherence to high-level hygiene protocols and appropriate diet is important. The area that piglets are weaned into should be clean, ~~and~~ dry and warm.

All newly weaned pigs should be monitored during the first two weeks after weaning for any signs of ill-health or abnormal stress.

~~Outcome~~ Animal ~~-~~based criteria (or measurables): mortality and culling rates (piglets), morbidity rates (respiratory disease, diarrhoea), behaviour (belly nosing and ear sucking), physical appearance (injuries) and changes in body weight and body condition.

Article 7.X.21.

Mixing

Mixing of unfamiliar pigs can result in fighting to establish a dominance hierarchy, and therefore mixing should be minimised as much as possible (Moore *et al.*, 1994; Fabrega *et al.*, 2013). When mixing, strategies to reduce aggression ~~and injuries~~ should be implemented. ~~and a~~ Animals should be observed after mixing and interventions applied if the aggression is intense or prolonged, and pigs become injured ~~supervised~~.

Measures to prevent excessive fighting and injuries can include (Arey and Edwards, 1998; Verdon *et al.*, 2015):

– providing additional space and a non-slippery floor,

– feeding before mixing,

– feeding on the floor in the mixing area,

– ~~provision of~~ providing straw or other suitable enrichment materials in the mixing area,

– providing opportunities to escape and to hide from other pigs, such as visual barriers,

– mixing previously familiarised animals whenever possible,

– mixing young animals ~~should be mixed~~ as soon after weaning as possible,

– avoiding the addition of ~~adding~~ one or small number of animals to a large established group.

~~Outcome~~ Animal-based criteria (or measurables): mortality, morbidity and culling rates, behaviour (agonistic), physical appearance (injuries), changes in body weight and body condition and reproductive efficiency.

Article 7.X.22.

Genetic selection

Welfare and health considerations should balance any decisions on productivity and growth rate when choosing a breed or hybrid for a particular location or production system.

Selective breeding can improve the welfare of pigs for example by selection to improve maternal behaviour, piglet viability, temperament and resistance to stress and disease and to reduce tail biting and aggressive behaviour (Turner *et al.*, 2006). Including social effects into breeding programmes may also reduce negative social interactions and increase positive ones and may have major positive effects on group-housed animals. (Rodenburg *et al.*, 2010)

~~Outcome~~ Animal-based criteria (or measurables): physical appearance, behaviour (e.g. maternal and agonistic behaviour), changes in body weight and body condition, handling response, reproductive efficiency, lameness, and morbidity, mortality and culling rates.

Article 7.X.23.

Protection from predators and pests

In outdoor and combination systems pigs should be protected from predators.

Where practicable, ~~P~~pigs should also be protected from pests such as excessive numbers of flies and mosquitoes.

~~Outcome~~ Animal-based criteria (or measurables): morbidity, mortality and culling rates, behaviour, and physical appearance (injuries).

Article 7.X.24.

Biosecurity and animal health

1. Biosecurity and disease prevention

   Biosecurity plans should be designed, implemented and maintained, commensurate with the best possible *herd* health status, available resources and infrastructure, and current disease risk and, for *listed diseases* in accordance with relevant recommendations in the *Terrestrial Code*.

Annex 19 (contd)

These *biosecurity plans* should address the control of the major sources and pathways for spread of pathogenic agents including:

– ~~pigs, including~~ introductions to the *herd*, especially from different sources,

– ~~young~~ semen ~~coming from different sources~~,

– other domestic animals, *wildlife* and pests,

– people, including sanitation practices,

– equipment, including *vehicles*, tools and facilities,

– ~~*vehicles*,~~

– ~~air,~~

– air, water ~~supply~~, ~~semen,~~ feed and bedding,

– waste, including manure, ~~waste~~ garbage and disposal of dead animals,

– ~~semen~~.

~~Outcome~~ Animal ~~-~~based criteria (or measurables): morbidity, mortality and culling rates, reproductive efficiency, changes in weight and body condition, physical appearance (signs of disease).

a) Animal health management

Animal health management should optimise the ~~physical and behavioural~~ welfare and health of ~~the~~ pigs in the *herd*. It includes the prevention, treatment and control of diseases and conditions affecting the *herd* (in particular respiratory, reproductive and enteric diseases).

There should be an effective programme for the prevention and treatment of *diseases* and conditions, formulated in consultation with a *veterinarian*~~, when appropriate~~. This programme should include *biosecurity* and quarantine protocols, the acclimatisation of replacements, *vaccinations*, and good colostrum management, the recording of production data (e.g. number of sows, piglets per sow per year, feed conversion, and body weight at weaning), morbidity, mortality and culling rates and medical treatments. It should be kept up to date by the *animal handler*. Regular monitoring of records aids management and quickly reveals problem areas for intervention.

For parasitic burdens (e.g. endoparasites, ectoparasites and protozoa) and ~~fly~~ insect control, a programme should be implemented to monitor, control and treat, as appropriate.

Lameness can be a problem in pigs. *Animal handlers* should monitor the state of feet and legs and take measures to prevent lameness and maintain foot and leg health.

Those responsible for the care of pigs should be aware of early specific signs of *disease*, pain, distress or suffering ~~or distress~~, such as coughing, abortion, diarrhoea, changes in locomotory behaviour or apathetic behaviour, and non-specific signs such as reduced feed and water intake, changes in weight and body condition, changes in behaviour or abnormal physical appearance.

Pigs at higher risk will require more frequent inspection by *animal handlers*. If *animal handlers* suspect the presence of a *disease* or are not able to correct the causes of *disease*, pain, distress or suffering ~~or distress~~, they should seek advice from those having training and experience, such as *veterinarians* or other qualified advisers, as appropriate.

~~Non-ambulatory~~ Nonambulatory pigs should not be transported or moved unless absolutely necessary for treatment, recovery, or diagnosis. Such movements should be done carefully using methods that avoid dragging the animal or lifting it in a way that might cause further pain, suffering or exacerbate injuries.

Animal handlers should also be competent in assessing fitness to transport, as described in Chapter 7.3.

In case of disease or injury, when treatment has failed, is not feasible or recovery is unlikely (e.g. pigs that are unable to stand up, unaided or refuse to eat or drink), the animal should be humanely killed as soon as possible in accordance with Chapter 7.6.

Outcome Animal-based criteria (or measurables): morbidity, mortality and culling rates, reproductive efficiency, behaviour (apathetic behaviour), lameness, physical appearance (injuries) and changes in body weight and body condition.

b) Emergency plans for disease outbreaks

Emergency plans should cover the management of the farm in the event of an emergency disease *outbreak*, consistent with national programmes and recommendations of *Veterinary Services* as appropriate.

Article 7.X.25.

Emergency Contingency plans

Where the failure of power, water and or feed supply systems could compromise *animal welfare,* pig producers should have contingency plans in place to cover the failure of these systems. These plans may include the provision of fail-safe alarms to detect malfunctions, back-up generators, contact information for key service providers, ability to store water on farm, access to water cartage services, adequate on-farm storage of feed and an alternative feed supply.

Preventive measures for emergencies should be input-based rather than outcome-based. Contingency plans should be documented and communicated to all responsible parties. Alarms and back-up systems should be checked regularly.

Article 7.X.26.

Disaster management

Plans should be in place to minimise and mitigate the effect of disasters (e.g. earthquake, fire, flooding, blizzard and hurricane). Such plans may include evacuation procedures, identifying high ground, maintaining emergency feed and water stores, destocking and humane *killing* when necessary.

Procedures for humane *killing* procedures for of sick or injured pigs should be part of the disaster management plan and should follow the recommendations of Chapter 7.6. of the *Terrestrial Code* should be part of the disaster management plan.

Reference to emergency contingency plans can also be found in Article 7.X.25.

Article 7.X.27.

Euthanasia (Humane killing)

Allowing a sick or injured animal to linger unnecessarily is unacceptable. Therefore, for sick and injured pigs a prompt diagnosis should be made to determine whether the animal should be treated or humanely killed.

The decision to kill an animal humanely and the procedure itself should be undertaken by a competent person.

For a description of acceptable methods for humane *killing* of pigs see Chapter 7.6.

The *establishment* should have documented procedures and the necessary equipment for on-farm humane *killing*. Staff should be trained in humane *killing* procedures appropriate for each class of pig.

Annex 19 (contd)

Reasons for humane *killing* may include:

– severe emaciation, weak pigs that are ~~non-ambulatory~~ nonambulatory or at risk of becoming ~~non-ambulatory~~ nonambulatory,

– severely injured or ~~non-ambulatory~~ nonambulatory pigs that will not stand up, refuse to eat or drink, or have not responded to ~~therapy~~ treatment,

– rapid deterioration of a medical condition for which ~~therapies have~~ treatment has been unsuccessful,

– ~~severe, debilitating pain,~~ severe pain that cannot be alleviated,

– ~~compound fracture,~~

– ~~spinal injury,~~

– ~~central nervous system disease,~~

– multiple joint *infections* with chronic weight loss,

– piglets that are premature and unlikely to survive, or have a debilitating congenital defect, and

– as part of disaster management response.

~~For a description of acceptable methods for humane *killing* of pigs see Chapter 7.6.~~

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Annex 20

CHAPTER 8.3.

INFECTION WITH BLUETONGUE VIRUS

Article 8.3.1.

General provisions

For the purposes of the *Terrestrial Code*, bluetongue is defined as an *infection* of ruminants and camelids with bluetongue virus (BTV) that is transmitted by *Culicoides vectors*.

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

1) BTV has been isolated from a sample from a ruminant or camelid or a product derived from that ruminant or camelid, or

2) antigen or ribonucleic acid specific to BTV has been identified in a sample~~s~~ from a ruminant or camelid showing clinical signs consistent with bluetongue, or epidemiologically linked to a suspected or confirmed *case*, or

3) antigen or ribonucleic acid specific to a BTV live vaccine strain has been ~~detected~~ identified in a sample from a ruminant or camelid that is unvaccinated, or has been vaccinated with an inactivated vaccine, or with a different live vaccine strain, showing clinical signs consistent with bluetongue, or epidemiologically linked to a suspected or confirmed *case*, or

4~~3~~) antibodies to structural or nonstructural proteins of BTV that are not a consequence of *vaccination* have been identified in a sample from a ruminant or camelid that either shows clinical signs consistent with bluetongue, or is epidemiologically linked to a suspected or confirmed *case*.

For the purposes of the *Terrestrial Code*, the *infective period* for bluetongue shall be 60 days.

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

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 8.3.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the BTV status of the ruminant and camelid populations of the *exporting country* or *zone*.

Article 8.3.2.

Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any bluetongue-related conditions regardless of the bluetongue status of the *exporting country*:

1) *milk* and *milk products*;

2) *meat* and *meat products*;

3) hides and skins;

4) wool and fibre;

5) *in vivo* derived bovine embryos collected, processed and stored in accordance with Chapter 4.7.

Annex 20 (contd)

Article 8.3.3.

Country or zone free from bluetongue

1) Historical freedom as described in Chapter 1.4. does not apply to bluetongue.

2) A country or a *zone* may be considered free from bluetongue when *infection* with BTV is notifiable in the entire country and either:

   a) a *surveillance* programme in accordance with Articles 8.3.14. to 8.3.17. has demonstrated no evidence of *infection* with BTV in the country or *zone* during the past two years; or

   b) an ongoing *surveillance* programme has found no *Culicoides* for at least two years in the country or *zone*.

3) A country or *zone* free from bluetongue in which ongoing *vector surveillance*, performed in accordance with point 5 of Article 8.3.16., has found no *Culicoides* will not lose its free status through the introduction of vaccinated, seropositive or infective ruminants or camelids, or their semen or embryos from *infected* countries or ~~infected~~ *zones*.

4) A country or *zone* free from bluetongue in which *surveillance* has found evidence that *Culicoides* are present will not lose its free status through the introduction of seropositive or vaccinated ruminants or camelids, or semen or embryos from infected countries *or* ~~*infected*~~ *zones*, provided:

   a) an ongoing *surveillance* programme focused on transmission of BTV and a consideration of the epidemiology of *infection* with BTV, in accordance with Articles 8.3.14. to 8.3.17. and Chapter 4.3., has demonstrated no evidence of transmission of BTV in the country or *zone*; or

   b) the ruminants or camelids, their semen and embryos were introduced in accordance with this chapter.

5) A country or *zone* free from bluetongue adjacent to an infected country or ~~infected~~ *zone* should include a *zone* in which *surveillance* is conducted in accordance with Articles 8.3.14. to 8.3.17.

Article 8.3.4.

Country or zone seasonally free from bluetongue

1) A country or *zone* seasonally free from bluetongue is, respectively, an infected country or a part of an infected country or ~~an *infected*~~ *zone*, for which *surveillance* conducted in accordance with Articles 8.3.14. to 8.3.17. demonstrates no evidence either of transmission of BTV or of adult *Culicoides* for part of a year.

2) For the application of Articles 8.3.7., 8.3.9. and 8.3.11., the ~~seasonally~~ free ~~period~~ season is taken to commence the day following the last evidence of transmission of BTV (as demonstrated by the *surveillance* programme), and of the cessation of activity of adult *Culicoides*.

3) For the application of Articles 8.3.7., 8.3.9. and 8.3.11., the ~~seasonally~~ free ~~period~~ season is taken to conclude either:

   a~~1~~) at least 28 days before the earliest date that historical data show transmission of BTV may recommence; or

   b~~2~~) immediately if current climatic data or data from a *surveillance* programme indicate transmission of BTV or an earlier resurgence of activity of adult *Culicoides*.

4) A seasonally free *zone* in which ongoing *surveillance* has found no evidence that *Culicoides* are present will not lose its free status through the introduction of vaccinated, seropositive or infective ruminants or camelids, or semen or embryos from infected countries or ~~*infected*~~ *zones*.

Article 8.3.5.

Country or zone infected with BTV

For the purposes of this chapter, a country or *zone* infected with BTV is one that does not fulfill the requirements to qualify as either free or seasonally free from bluetongue.

Article 8.3.6.

Recommendations for importation from countries or zones free from bluetongue

For ruminants and camelids

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

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

AND

2) the animals were kept in a country or *zone* free from bluetongue since birth or for at least 60 days prior to shipment; or

3) the animals were kept in a country or *zone* free from bluetongue for at least 28 days, then were subjected, with negative results, to a serological test to detect antibodies to the BTV group and remained in the free country or *zone* until shipment; or

4) the animals were kept in a ~~free~~ country or *zone* free from bluetongue for at least 14 days, then were subjected, with negative results, to an agent identification test, and remained in the free country or *zone* until shipment; or

5) the animals:

   ~~*a)* were kept in a country or *zone* free from bluetongue for at least seven days;~~

   a~~b~~) were vaccinated, at least 60 days before the introduction into the free country or *zone*, against all serotypes demonstrated to be present in the source population through a *surveillance* programme as described in Articles 8.3.14. to 8.3.17.;

   b~~c~~) were identified as having been vaccinated;

   c~~d~~) remained in the free country or *zone* for at least seven days until shipment;

AND

6) if the animals were exported from a free *zone* within an infected country, either:

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

   b) were protected from attacks from *Culicoides* in accordance with point 2 of Article 8.3.13. at all times when transiting through an infected zone; or

   c) had been vaccinated in accordance with point 5 above.

Article 8.3.7.

Recommendations for importation from countries or zones seasonally free from bluetongue

For ruminants and camelids

Annex 20 (contd)

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

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

AND

2) were kept during the ~~seasonally~~ free ~~period~~ season in a seasonally free country or *zone* since birth or for at least 60 days prior to shipment; or

3) were kept during the ~~seasonally~~ free ~~period~~ season in a seasonally free country or *zone* for at least 28 days prior to shipment, and were subjected during the residence period in the *zone* to a serological test to detect antibodies to the BTV group, with negative results, carried out at least 28 days after the commencement of the residence period; or

4) were kept during the ~~seasonally~~ free ~~period~~ season in a seasonally free country or *zone* for at least 14 days prior to shipment, and were subjected during the residence period in the *zone* to an agent identification test, with negative results, carried out at least 14 days after the commencement of the residence period; or

5) were:

   a) ~~were kept during the seasonally free period~~ season ~~in a seasonally free *zone* and were~~ vaccinated, at least 60 days before ~~the introduction into the free country or *zone*~~ shipment, against all serotypes demonstrated to be present in the source population through a *surveillance* programme in accordance with Articles 8.3.14. to 8.3.17.; ~~and~~

   b) ~~were~~ identified as having been vaccinated; ~~and~~

   c) kept during the free season ~~remained~~ in the seasonally free ~~country or~~ *zone* for at least seven days and until shipment;

AND

6) either:

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

   b) were protected from attacks from *Culicoides* in accordance with point 2 of Article 8.3.13. at all times when transiting through an *infected zone*; or

   c) were vaccinated in accordance with point 5 above.

Article 8.3.8.

Recommendations for importation from countries or zones infected with BTV

For ruminants and camelids

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

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

AND

2) were protected from attacks from *Culicoides* in accordance with Article 8.3.13. in a *vector*-protected *establishment* for at least 60 days prior to shipment and during transportation to the *place of shipment*; or

3) were protected from attacks from *Culicoides* in accordance with Article 8.3.13. in a *vector*-protected *establishment* for at least 28 days prior to shipment and during transportation to the *place of shipment*, and were subjected during that period to a serological test to detect antibodies to the BTV group, with negative results, carried out at least 28 days after introduction into the *vector*-protected *establishment*; or

4) were protected from attacks from *Culicoides* in accordance with Article 8.3.13. in a *vector*-protected *establishment* for at least 14 days prior to shipment and during transportation to the *place of shipment*, and were subjected during that period to an agent identification test, with negative results, carried out at least 14 days after introduction into the *vector*-protected *establishment*; or

5) were:

   a) vaccinated, at least 60 days before shipment, against all serotypes demonstrated to be present in the source population through a *surveillance* programme in accordance with Articles 8.3.14. to 8.3.17.;

   b) identified as having been vaccinated; or

6) were demonstrated to have antibodies for at least 60 days prior to dispatch against all serotypes demonstrated to be present in the source population through a *surveillance* programme in accordance with Articles 8.3.14. to 8.3.17.

Article 8.3.9.

Recommendations for importation from countries or zones free or ~~zones~~ seasonally free from bluetongue

For semen of ruminants and camelids

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

1) the donor males:

   a) showed no clinical sign of bluetongue on the day of collection~~;~~ and

   ~~*b)*~~ were kept in a country or *zone* free from bluetongue or in a seasonally free country or *zone* during the ~~seasonally~~ free season ~~period~~ for at least 60 days before commencement of, and during, collection of the semen; or

   b~~*c*~~*)* comply with point 1 of Article 8.3.10.;~~were subjected to a serological test to detect antibodies to the BTV group, with negative results, between 28 and 60 days after the last collection for this consignment, and, in case of a seasonally free *zone*, at least every 60 days throughout the collection period; or~~

   ~~*d)* were subjected to an agent identification test on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;~~

2) the semen was collected, processed and stored in accordance with Chapters 4.5. and 4.6.

Article 8.3.10.

Recommendations for importation from countries or zones infected with BTV

For semen of ruminants and camelids

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

1) the donor males:

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

Annex 20 (contd)

AND

b) were kept in a *vector*-protected *establishment* in accordance with point 1 of Article 8.3.13. for at least 60 days before commencement of, and during, collection of the semen; or

c*)* were subjected to a serological test to detect antibodies to the BTV group, with negative results~~, at least every 60 days throughout the collection period and~~ between 28 and 60 days after ~~the final~~ each collection for this consignment; or

d) were subjected to an agent identification test on blood samples collected at commencement and conclusion of, and at least every ~~7~~ seven days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;

2) the semen was collected, processed and stored in accordance with Chapters 4.5. and 4.6.

Article 8.3.11.

Recommendations for importation from countries or zones free or ~~zones~~ seasonally free from bluetongue

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

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

1) the donor females:

a) showed no clinical sign of bluetongue on the day of collection; and

~~*b)*~~ were kept in a country or *zone* free from bluetongue or in a seasonally free country or zone during the ~~seasonally~~ free ~~period~~ season for at least the 60 days prior to, and at the time of, collection of the embryos; or

b) comply with point 1 of Article 8.3.12.*;*

~~*c)* were subjected to a serological test to detect antibodies to the BTV group, between 28 and 60 days after collection, with negative results; or~~

~~*d)* were subjected to an agent identification test on a blood sample taken on the day of collection, with negative results;~~

2) the embryos were collected, processed and stored in accordance with Chapters 4.7., 4.8. and 4.9., as relevant.

Article 8.3.12.

Recommendations for importation from countries or zones infected with BTV

For *in vivo* derived embryos of ruminants (other than bovine embryos) and other BTV susceptible animals and for *in vitro* produced bovine embryos

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

1) the donor females:

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

AND

b) were kept in a *vector*-protected *establishment* in accordance with point 1 of Article 8.3.13. for at least 60 days before commencement of, and during, collection of the embryos; or

c) were subjected to a serological test to detect antibodies to the BTV group, between 28 and 60 days after collection, with negative results; or

d) were subjected to an agent identification test on a blood sample taken on the day of collection, with negative results;

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 to fertilise the oocytes complied with Article 8.3.9. or Article 8.3.10.

Article 8.3.13.

Protecting animals from *Culicoides* attacks

1. Vector-protected establishment or facility

The *establishment* or facility should be approved by the *Veterinary Authority* and the means of protection should at least comprise the following:

a) appropriate physical barriers at entry and exit points, such as double-door entry-exit system;

b) openings of the building are *vector* screened with mesh of appropriate gauge impregnated regularly with an approved insecticide in accordance with manufacturers' instructions;

c) *vector surveillance* and control within and around the building;

d) measures to limit or eliminate breeding sites for *vectors* in the vicinity of the *establishment* or facility;

e) standard operating procedures, including description of back-up and alarm systems, for operation of the *establishment* or facility and transport of animals to the place of *loading*.

2. During transportation

When transporting animals through infected countries or *zones*, *Veterinary Authorities* should require strategies to protect animals from attacks from *Culicoides* during transport, taking into account the local ecology of the *vector*.

a) Transport by road

Risk management strategies may include:

i) treating animals with insect repellents prior to and during transportation;

ii) *loading*, transporting and *unloading* animals at times of low *vector* activity (i.e. bright sunshine, low temperature);

iii) ensuring *vehicles* do not stop en route during dawn or dusk, or overnight, unless the animals are held behind insect proof netting;

iv) darkening the interior of the *vehicle*, for example by covering the roof or sides of *vehicles* with shade cloth;

v) *surveillance* for *vectors* at common stopping and *unloading* points to gain information on seasonal variations;

vi) using historical information or information from appropriately verified and validated bluetongue epidemiological models to identify low risk ports and transport routes.

b) Transport by air

Prior to *loading* the animals, the crates, containers or jet stalls should be sprayed with an insecticide approved in the country of dispatch.

Crates, containers or jet stalls in which animals are being transported and the cargo hold of the aircraft should be sprayed with an approved insecticide when the doors have been closed and prior to take-off. All possible insect harbourage should be treated. The spray containers should be retained for inspection on arrival.

In addition, during any stopover in countries or *zones* not free from bluetongue, prior to the opening of any aircraft door and until all doors are closed, netting of appropriate gauge impregnated with an approved insecticide should be placed over crates, containers or jet stalls.

Article 8.3.14.

Introduction to surveillance

Articles 8.3.14. to 8.3.17. define the principles and provide guidance on *surveillance* for *infection* with BTV, complementary to Chapter 1.4. and for *vectors* complementary to Chapter 1.5.

Bluetongue is a *vector*-borne *infection* transmitted by various species of *Culicoides* in a range of ecosystems.

The purpose of *surveillance* is the detection of transmission of BTV in a country or *zone* and not determination of the status of an individual animal or *herds*. *Surveillance* deals with the evidence of *infection* with BTV in the presence or absence of clinical signs.

An important component of the epidemiology of bluetongue is the capacity of its *vector*, which provides a measure of disease *risk* that incorporates *vector* competence, abundance, biting rates, survival rates and extrinsic *incubation period*. However, methods and tools for measuring some of these *vector* factors remain to be developed, particularly in a field context. Therefore, *surveillance* for bluetongue should focus on transmission of BTV in domestic ruminants and camelids.

The impact and epidemiology of bluetongue widely differ in different regions of the world and therefore it is not appropriate to provide specific recommendations for all situations. Member Countries should provide scientific data that explain the epidemiology of bluetongue in the country or *zone* concerned and adapt the *surveillance* strategies for defining their status to the local conditions. There is considerable latitude available to Member Countries to justify their status at an acceptable level of confidence.

Surveillance for bluetongue should be in the form of a continuing programme.

Article 8.3.15.

General conditions and methods for surveillance

1) A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. In particular:

a) a formal and ongoing system for detecting and investigating *outbreaks* of disease should be in place;

b) a procedure should be in place for the rapid collection and transport of samples from suspected *cases* of *infection* with BTV to a *laboratory* for diagnosis;

c) a system for recording, managing and analysing diagnostic and *surveillance* data should be in place.

2) The bluetongue *surveillance* programme should:

a) in a free country or *zone* or seasonally free *zone*, have an early warning system which obliges farmers and workers, who have regular contact with domestic ruminants, as well as diagnosticians, to report promptly any suspicion of bluetongue to the *Veterinary Authority*.

An effective *surveillance* system will periodically identify suspected *cases* that require follow-up and investigation to confirm or exclude whether the cause of the condition is bluetongue. The rate at which such suspected *cases* are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. All suspected *cases* of bluetongue should be investigated immediately and samples should be taken and submitted to a *laboratory*. This requires that sampling kits and other equipment be available for those responsible for *surveillance*;

AND

b) conduct random or targeted serological and virological *surveillance* appropriate to the status of the country or *zone*.

Article 8.3.16.

Surveillance strategies

The target population for *surveillance* aimed at identification of *disease* or *infection* should cover susceptible domestic ruminants and camelids, and other susceptible herbivores of epidemiological significance within the country or *zone*. Active and passive *surveillance* for bluetongue should be ongoing as epidemiologically appropriate. *Surveillance* should be composed of random or targeted approaches using virological, serological and clinical methods appropriate for the status of the country or *zone*.

It may be appropriate to focus *surveillance* in an area adjacent to a border of an infected country or ~~*infected*~~ *zone* for up to 100 kilometres, taking into account relevant ecological or geographical features likely to interrupt the transmission of BTV or the presence in the bordering infected country or ~~*infected*~~ *zone* of a bluetongue *surveillance* programme (in accordance with Articles 8.3.14. to 8.3.17.) that supports a lesser distance.

A Member Country should justify the *surveillance* strategy chosen as being adequate to detect the presence of *infection* with BTV in accordance with Chapter 1.4. and the prevailing epidemiological situation. It may, for example, be appropriate to target clinical *surveillance* at particular species likely to exhibit clinical signs (e.g. sheep).

Similarly, virological and serological testing may be targeted to species that rarely show clinical signs (e.g. bovines ~~cattle~~).

In vaccinated populations, serological and virological *surveillance* is necessary to detect the BTV types circulating to ensure that all circulating types are included in the *vaccination* programme.

If a Member Country wishes to declare freedom from bluetongue in a specific *zone*, the design of the *surveillance* strategy should be aimed at the population within the *zone*.

For random surveys, the design of the sampling strategy should incorporate epidemiologically appropriate design prevalence. The sample size selected for testing should be large enough to detect evidence of *infection* if it were to occur at a predetermined minimum rate. The sample size and expected prevalence determine the level of confidence in the results of the survey. The Member Country should justify the choice of design *prevalence* and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design *prevalence* in particular should be based on the prevailing or historical epidemiological situation.

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

Irrespective of the testing system employed, *surveillance* system design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There should be an effective procedure for following up positive

reactions to ultimately determine with a high level of confidence, whether they are indicative of *infection* or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as those which may be epidemiologically linked to it.

The principles involved in *surveillance* for disease or *infection* are technically well defined. The design of *surveillance* programmes to prove the absence of *infection* with and transmission of, BTV should be carefully followed to avoid producing results that are either insufficiently reliable to be accepted by international trading partners, or excessively costly and logistically complicated.

1. Clinical surveillance

   Clinical *surveillance* aims to detect clinical signs of bluetongue at the *flock* or *herd* level, particularly during a newly introduced *infection*. In sheep and occasionally goats, clinical signs may include oedema, hyperaemia of mucosal membranes, coronitis and cyanotic tongue.

   Suspected *cases* of bluetongue detected by clinical *surveillance* should always be confirmed by *laboratory* testing.

2. Serological surveillance

   An active programme of *surveillance* of host populations to detect evidence of transmission of BTV is essential to establish the bluetongue status of a country or *zone*. Serological testing of ruminants is one of the most effective methods of detecting the presence of BTV. The species tested should reflect the epidemiology of bluetongue. Bovines ~~Cattle~~ are usually the most sensitive indicator species. Management variables that may influence likelihood of *infection*, such as the use of insecticides and animal housing, should be considered.

   Samples should be examined for antibodies against BTV. Positive test results can have four possible causes:

   a) natural *infection*,

   b) *vaccination*,

   c) maternal antibodies,

   d) the lack of specificity of the test.

   It may be possible to use sera collected for other survey purposes for bluetongue *surveillance*. However, the principles of survey design described in these recommendations and the requirements for a statistically valid survey for the presence of *infection* with BTV should not be compromised.

   The results of random or targeted serological surveys are important in providing reliable evidence that no *infection* with BTV is present in a country or *zone*. It is, therefore, essential that the survey is thoroughly documented. It is critical to interpret the results in light of the movement history of the animals being sampled.

   Serological *surveillance* in a free *zone* should target those areas that are at highest *risk* of transmission of BTV, based on the results of previous *surveillance* and other information. This will usually be towards the boundaries of the free *zone*. In view of the epidemiology of bluetongue, either random or targeted sampling is suitable to select *herds* or animals for testing.

   Serological *surveillance* in *infected zones* will identify changes in the boundary of the *zone*, and can also be used to identify the BTV types circulating. In view of the epidemiology of bluetongue, either random or targeted sampling is suitable.

3. Virological surveillance

   Isolation and genetic analysis of BTV from a proportion of infected animals provides information on serotype and genetic characteristics of the viruses concerned.

   Virological *surveillance* can be conducted:

a) to identify virus transmission in at risk populations,

b) to confirm clinically suspected *cases*,

c) to follow up positive serological results,

d) to better characterise the genotype of circulating virus in a country or *zone*.

4. Sentinel animals

Sentinel animals are a form of targeted *surveillance* with a prospective study design. They are the preferred strategy for bluetongue *surveillance*. They comprise groups of unexposed animals that have not been vaccinated and are managed at fixed locations and sampled regularly to detect new *infections* with BTV.

The primary purpose of a sentinel animal programme is to detect *infections* with BTV occurring at a particular place, for instance sentinel groups may be located on the usual boundaries of *infected zones* to detect changes in distribution of BTV. In addition, sentinel animal programmes allow the timing and dynamics of *infections* to be observed.

A sentinel animal programme should use animals of known source and history of exposure, control management variables such as use of insecticides and animal housing (depending on the epidemiology of bluetongue in the area under consideration), and be flexible in its design in terms of sampling frequency and choice of tests.

Care is necessary in choosing the sites for the sentinel groups. The aim is to maximise the chance of detecting transmission of BTV at the geographical location for which the sentinel site acts as a sampling point. The effect of secondary factors that may influence events at each location, such as climate, may also be analysed. To avoid bias, sentinel groups should comprise animals selected to be of similar age and susceptibility to *infection* with BTV. Bovines ~~Cattle~~ are the most appropriate sentinels but other domestic ruminant species may be used. The only feature distinguishing groups of sentinels should be their geographical location.

Sera from sentinel animal programmes should be stored methodically in a serum bank to allow retrospective studies to be conducted in the event of new serotypes being isolated.

The frequency of sampling will depend on the reason for choosing the sampling site. In endemic areas, virus isolation will allow monitoring of the serotypes and genotypes of BTV circulating during each time period. The borders between infected and uninfected areas can be defined by serological detection of *infective period*. Monthly sampling intervals are frequently used. Sentinels in declared free *zones* add to confidence that *infection* with BTV is not occurring unobserved. In such cases, sampling prior to and after the possible period of transmission is sufficient.

Definitive information on the presence of BTV in a country or *zone* is provided by isolation and identification of the viruses. If virus isolation is required, sentinels should be sampled at sufficiently frequent intervals to ensure that samples are collected during the period of viraemia.

5. Vector surveillance

BTV is transmitted between ruminant hosts by species of *Culicoides* which vary around the world. It is therefore important to be able to identify potential *vector* species accurately although many such species are closely related and difficult to differentiate with certainty.

Vector surveillance aims to demonstrate the absence of *vectors* or to determine areas of different levels of *risk* and local details of seasonality by determining the various *vector* species present in an area, their respective seasonal occurrence, and abundance. *Vector surveillance* has particular relevance to potential areas of spread.

Long term *surveillance* can also be used to assess *vector* abatement measures or to confirm continued absence of *vectors*.

Annex 20 (contd)

The most effective way of gathering this information should take account of the biology and behavioural characteristics of the local *vector* species of *Culicoides* and may include the use of Onderstepoort-type light

traps or similar, operated from dusk to dawn in locations adjacent to domestic ruminants, or the use of drop traps over ruminants.

Vector surveillance should be based on scientific sampling techniques. The choice of the number and type of traps to be used and the frequency of their use should take into account the size and ecological characteristics of the area to be surveyed.

The operation of *vector surveillance* sites at the same locations as sentinel animals is advisable.

The use of a *vector surveillance* system to detect the presence of circulating virus is not recommended as a routine procedure as the typically low *vector infection* rates mean that such detections can be rare.

Animal-based *surveillance* strategies are preferred to detect virus transmission.

Article 8.3.17.

Documentation of bluetongue free status

1. Additional surveillance requirements for Member Countries declaring freedom from bluetongue

In addition to the general requirements described above, a Member Country declaring freedom from bluetongue for the entire country or a *zone* should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances and should be planned and implemented in accordance with general conditions and methods described in this chapter, to demonstrate absence of *infection* with BTV during the preceding 24 months in susceptible domestic ruminant populations. This requires the support of a *laboratory* able to undertake identification of *infection* with BTV through virus detection and antibody tests. This *surveillance* should be targeted to unvaccinated animals. Clinical *surveillance* may be effective in sheep while serological *surveillance* is more appropriate in bovines ~~cattle~~.

2. Additional requirements for countries or zones that practise vaccination

Vaccination to prevent the transmission of BTV may be part of a disease control programme. The level of *flock* or *herd* immunity required to prevent transmission will depend on the *flock* or *herd* size, composition (e.g. species) and density of the susceptible population. It is therefore impossible to be prescriptive. The vaccine should also comply with the provisions stipulated for BTV vaccines in the *Terrestrial Manual*. Based on the epidemiology of bluetongue in the country or *zone*, it may be decided to vaccinate only certain species or other *subpopulations*.

In countries or *zones* that practise *vaccination*, virological and serological tests should be carried out to ensure the absence of virus transmission. These tests should be performed on unvaccinated *subpopulations* or on sentinels. The tests should be repeated at appropriate intervals in accordance with the purpose of the *surveillance* programme. For example, longer intervals may be adequate to confirm endemicity, while shorter intervals may allow on-going demonstration of absence of transmission.

Annex 21

CHAPTER 8.4.

INFECTION WITH *BRUCELLA ABORTUS*, *B. MELITENSIS* AND *B.SUIS*

[...]

Article 8.4.10.

Herd or flock free from infection with *Brucella* in bovids, sheep and goats, camelids or cervids without vaccination

1) To qualify as free from *infection* with *Brucella* without *vaccination*, a *herd* or *flock* of bovids, sheep and goats, camelids or cervids should satisfy the following requirements:

a) the *herd* or *flock* is in a country or *zone* free from *infection* with *Brucella* without *vaccination* in the relevant animal category and is certified free without *vaccination* by the *Veterinary Authority*;

OR

b) the *herd* or *flock* is in a country or *zone* free from *infection* with *Brucella* with *vaccination* in the relevant animal category and is certified free without *vaccination* by the *Veterinary Authority*; and no animal of the *herd* or *flock* has been vaccinated in the past three years;

OR

c) the *herd* or *flock* met the following conditions:

i) *infection* with *Brucella* in animals is a *notifiable disease* in the entire country;

ii) no animal of the relevant category of the *herd* or *flock* has been vaccinated in the past three years;

iii) no *case* has been detected in the *herd* or *flock* for at least the past year;

iv) animals showing clinical signs consistent with *infection* with *Brucella* such as abortions have been subjected to the necessary diagnostic tests with negative results;

v) for at least the past year, there has been no evidence of *infection* with *Brucella* in other *herds* or *flocks* of the same *establishment*, or measures have been implemented to prevent any transmission of the *infection* with *Brucella* from these other *herds* or *flocks*;

vi) two tests have been performed with negative results on all sexually mature animals, i.e. except castrated males, present in the *herd* at the time of testing, the first test being performed not before ~~3~~ three months after the *slaughter* of the last case and the second test at an interval of more than ~~6~~ six and less than 12 months.

2) To maintain the free status, the following conditions should be met:

a) the requirements in points 1*a)* or 1*b)* or 1*c) i)* to *v)* above are met;

b) regular tests, at a frequency depending on the prevalence of *herd* or *flock infection* in the country or *zone*, demonstrate the continuing absence of *infection* with *Brucella*;

Annex 21 (contd)

c) animals of the relevant category introduced into the *herd* or *flock* are accompanied by a certificate from an *Official Veterinarian* attesting that they come from:

i) a country or *zone* free from *infection* with *Brucella* in the relevant category without *vaccination*;

OR

ii) a country or *zone* free from *infection* with *Brucella* with *vaccination* and the animals of the relevant category have not been vaccinated in the past three years;

OR

iii) a *herd* or *flock* free from *infection* with *Brucella* with or without *vaccination* and that the animals have not been vaccinated in the past three years and were tested for *infection* with *Brucella* within 30 days prior to shipment with negative results; in the case of post-parturient females, the test is carried out at least 30 days after giving birth. This test is not required for sexually immature animals.

[…]

Annex 22

CHAPTER 8.15.

INFECTION WITH RINDERPEST VIRUS

Article 8.15.1.

[…]

Article 8.15.2.

Definitions and general provisions

For the purpose of the *Terrestrial Code*:

1) RPV-containing material means field and laboratory strains of RPV; vaccine strains of RPV including valid and expired vaccine stocks; tissues, sera and other ~~clinical~~ *pathological material* ~~from animals known or suspected to be infected~~; laboratory-generated ~~diagnostic~~ material containing ~~or encoding~~ live virus, recombinant morbilliviruses (segmented or nonsegmented) containing unique RPV nucleic acid or amino acid sequences, and full length genomic material including virus ~~ribonucleic acid (~~RNA~~)~~ and its cDNA copies ~~of virus RNA~~;

2) subgenomic fragments of RPV genome (either as plasmid or incorporated into ~~other~~ recombinant viruses) ~~morbillivirus nucleic acid~~ that ~~are not capable of being~~ cannot be incorporated into ~~in~~ a replicating morbillivirus or morbillivirus-like virus are not considered ~~as~~ to be RPV-containing material~~;~~, neither are sera that have been either heat-treated to at least 56˚C for at least ~~2~~ two hours, or shown to be free from RPV genome sequences by a validated RT-PCR assay;

3) a ban on *vaccination* against rinderpest means a ban on administering any vaccine containing RPV or ~~RPV~~ any components derived from RPV to any *animal*;

4) the *incubation period* for rinderpest shall be 21 days;

5) a *case* is defined as an *animal* infected with RPV whether or not showing clinical signs; and

6) for the purpose of this chapter, 'susceptible *animals*' means domestic, *feral* and *wild* artiodactyls.

[…]

Annex 23

CHAPTER 12.10.

INFECTION WITH *BURKHOLDERIA MALLEI* (GLANDERS)

Article 12.10.1.

General provisions

~~Most glanders susceptible animals are equids.~~ Equids are the major hosts and reservoirs of glanders although s~~S~~cientific data are not available ~~for~~ on the occurrence of *infection* in zebras. Camelids, goats and various carnivores including bears, canids and felids can also be infected but play no significant ~~epidemiological~~ role in the epidemiology of the *disease*. Glanders is a ~~significant and~~ rare but potentially fatal zoonotic disease ~~with fatal outcome if not treated in a timely manner~~.

For the purposes of the *Terrestrial Code*, glanders is defined as an *infection* of equids with *Burkholderia mallei* ~~in an equid~~ with or without the presence of clinical signs.

~~The chapter deals not only with the occurrence of clinical signs caused by *B. mallei*, but also with the presence of *infection* with *B. mallei* in the absence of clinical signs.~~

The following defines the occurrence of ~~an~~ *infection* with *B. mallei*:

1) *B. mallei* has been isolated from a sample from an equid; or

2) antigen or genetic material specific to *B. mallei* has been identified in a sample from an equid showing clinical or pathological signs consistent with glanders, or epidemiologically linked to a confirmed or suspected *outbreak* of glanders, or giving cause for suspicion of previous contact with *B. mallei*; or

3) antibodies specific to *B. mallei* have been identified by a testing regime appropriate to the species in a sample from an equid showing clinical or pathological signs consistent with glanders, or epidemiologically linked to a confirmed or suspected *outbreak* of glanders, or giving cause for suspicion of previous contact with *B. mallei.*

For the purposes of the *Terrestrial Code*, the *infective period* of *B. mallei* in equids is lifelong and the *incubation period* ~~is~~ shall be six months.

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

Article 12.10.2.

Country or zone free from infection with *B. mallei* ~~infection~~

A country or a *zone* that does not comply with the point 1 *a)* of Article 1.4.6. may be considered free from *infection* with *B. mallei* when:

1) ~~glanders~~ *infection* with *B. mallei* ~~is~~ has been a *notifiable disease* in the entire country for at least the past three years;

2) ~~either:~~

~~a)~~ there has been no *case* ~~*outbreak* and no evidence~~ of *infection* with *B. mallei* ~~in equids~~ during the past three years. ~~following the destruction of the last *case*; or~~

3~~b~~) ~~no evidence of *infection* with *B. mallei* has been found during the past six months following the destruction of the last *case*; and there is~~ a *surveillance* programme ~~in place demonstrating the absence of *infection*~~ in accordance with Article 12.10.8. has demonstrated no evidence of *infection* with *B. mallei* in the past ~~six~~ 12 months;

~~AND~~

4~~3~~) imports of equids and their germplasm into the country or *zone* are carried out in accordance with this chapter.

Article 12.10.3.

Recovery of free status

When a *case* is detected in a previously free country or *zone*, freedom from *infection* with *B. mallei* can be regained after the following:

1) a standstill of ~~movements of~~ equids and their germplasm from *establishments* affected ~~infected~~ or suspected of being affected ~~infected~~ has been imposed until the destruction of the last *case*;

2) an epidemiological investigation (trace-back, trace-forward), including ~~investigations~~ to determine the likely source of the *outbreak,* ~~have~~ has been carried out;

3) a *stamping-out policy,* which includes at least the destruction of all infected equids and ~~cleansing and~~ the *disinfection* of the affected ~~infected~~ *establishments,* has been applied;

4) ~~increased~~ *surveillance* in accordance with Article 12.10.8. has been carried out and has demonstrated ~~not detected any~~ no evidence of *infection* in the ~~six~~ 12 months after ~~*stamping-out*~~ *disinfection* of the last ~~infected~~ affected *establishment* and during that period measures have been in place to control the movement of equids.

~~5) measures are in place to control the movement of equids to prevent the spread of *B. mallei*.~~

When the measures above are not carried out, Article 12.10.2. applies.

Article 12.10.4.

Recommendations for importation of equids from countries or zones free from infection with *B. mallei* ~~infection~~

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

1) showed no clinical signs of ~~glanders~~ *infection* with *B. mallei* on the day of shipment;

2) either:

a) was kept for six months prior to shipment, or since birth, in a ~~the *exporting*~~ country or *zone* or countries or *zones* free from *infection* with *B. mallei*; or

b) if kept at any time in the past six months in a country or *zone* not free from *infection* with *B. mallei*, was imported in accordance with Article 12.10.5. into a country or *zone* free from *infection* with *B. mallei* ~~kept in an *establishment* in the *exporting country* for at least 30 days and~~ then ~~was subjected to a prescribed test with negative result on a sample taken during the 10 days prior to shipment~~.

Article 12.10.5.

Recommendations for importation of equids from countries or zones ~~considered infected~~ not free from infection with *B. mallei*

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

1) showed no clinical signs of ~~glanders~~ *infection* with *B. mallei* on the day of shipment;

2) was kept for six months prior to shipment, or since birth, in an *establishment* where no *case* of ~~glanders~~ *infection* with *B. mallei* was reported during the ~~six~~ 12 months prior to shipment;

3) was isolated and subjected to two ~~a prescribed~~ tests for *infection* with *B. mallei*, with negative results on ~~a~~ samples taken ~~during the~~ 21 to 30 days apart with the second sample taken within 10 days prior to shipment.

Article 12.10.6.

Recommendations for the importation of equine semen

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

1) on the day of collection, the donor males ~~animals~~:

a) showed no clinical signs of ~~glanders~~ *infection* with *B. mallei* ~~on the day of collection~~; ~~and for the following 21 days;~~

b) were examined clinically for signs of orchitis and cutaneous lesions of the penis, with negative results; ~~were kept continuously:~~

~~*i)* either for a period of at least 21 days prior to, and for until at least 21 days after, the collection in a country or a *zone* free from *infection* with *B. mallei*, or~~

~~*ii)* for at least six months prior to the collection of the semen and during the collection in an *establishment* or *artificial insemination centre* free from *infection* with *B. mallei* and were subjected to a prescribed test, with a negative result on a sample taken between 21 and 30 days before the collection, or in the case of frozen semen between 21 and 30 days after the collection;~~

2) the semen was collected, processed and stored in accordance with the relevant recommendations in Chapter 4.5. and in Articles 4.6.5. to 4.6.7.

Annex 23 (contd)

Article 12.10.7.

Recommendations for the importation of *in vivo* derived equine embryos

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

1) the donor females ~~animals:~~

   ~~*a)*~~ showed no clinical signs of ~~glanders~~ *infection* with *B. mallei* on the day of collection ~~and for the following 21 days~~;

   ~~*b)* were kept continuously:~~

      ~~*i)* either for a period of at least 21 days before, and for until at least 21 days after, the day of collection of the embryos in a country or a *zone* free from *infection* with *B. mallei*, or~~

      ~~*ii)* for at least six months prior to the collection and during the collection in an *establishment* free from *infection* with *B. mallei* and were subjected to a prescribed test, with a negative result on a sample taken between 21 and 30 days before the collection, or in the case of frozen embryos, between 21 and 30 days after the collection;~~

2) the embryos were collected, processed and stored in accordance with the relevant recommendations in Chapters 4.7. and 4.9.~~, as relevant~~;

3) the semen used for embryo production ~~to fertilise the oocytes~~ complies with ~~the recommendations in~~ Article 12.10.6.

Article 12.10.8.

General principles of surveillance

~~The purpose of *surveillance* is to determine the status of a country or a *zone* with respect to *infection* with *B. mallei*.~~

~~Populations of *captive wild*, *feral* and *wild* equids should be included in the *surveillance* programme, for example through roadkill or population control measures.~~

~~Clinical *surveillance* aims at detecting signs of glanders by close physical examination of susceptible animals. Clinical inspection is an important component of *surveillance* contributing to the desired level of confidence of detection of *disease*, if a sufficiently large number of clinically susceptible animals is examined.~~

~~Systematic pathological *surveillance* is an effective approach for glanders and should be conducted on dead equids on farm, at *slaughterhouses/abattoirs* and establishments for the disposal of carcasses of equids. Suspicious pathological findings should be confirmed by agent identification and isolates should be typed.~~

~~When conducting serological *surveillance* repeated testing of the equine population is necessary to reach an acceptable level of confidence.~~

~~Clinical examination and laboratory testing should be applied to clarify the status of suspects detected by either of these complementary diagnostic approaches. Laboratory testing and necropsy may contribute to confirm clinical suspicion, while clinical examination may contribute to confirmation of positive serology.~~

This article and Article 12.10.9. provide recommendations for *surveillance* for ~~glanders~~ *infection* with *B. mallei* and are complementary to Chapter 1.4. The impact and epidemiology of ~~glanders~~ *infection* with *B. mallei* vary in different regions of the world. The *surveillance* strategies employed ~~for determining glanders status~~ should be adapted to the respective epidemiological situation.

The *surveillance* ~~programme~~ systems should be designed:

- to demonstrate that ~~susceptible~~ equine populations in a country or *zone* show no evidence of *infection* with *B. mallei* or
- to detect its introduction into a free population or~~.~~
- ~~I~~if *B. mallei* is known to be present, ~~*surveillance* should~~ to allow the estimation of the *prevalence* and the determination of the distribution of the *infection*.

~~A~~ The *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority* and should have in place:

a) a ~~formal and ongoing~~ system for detecting and investigating *outbreaks* of *disease*;

b) a procedure for the ~~rapid~~ collection and transport of samples from suspected *cases* to a *laboratory* with appropriate testing capability for ~~glanders~~ diagnosis of *infection* with *B. mallei*;

c) a system for recording, managing and analysing diagnostic, epidemiological and surveillance data;

d) ~~established links~~ a procedure for confirmation of inconclusive tests in ~~with~~ an OIE Reference Laboratory ~~in case of need for confirmatory testing~~.

~~The glanders *surveillance* programme should include an *early detection system* for reporting suspected *cases*.~~ Diagnosticians and those with regular contact with ~~susceptible or infected~~ equids, including private *veterinarians*, *veterinary paraprofessionals* and *animal handlers* should report promptly any suspicion of ~~glanders~~ *infection* with *B. mallei*. ~~to the *Veterinary Authority*~~. The reporting system efficacy should be enhanced ~~under the *Veterinary Authority* should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary paraprofessionals*)~~ by ~~government~~ awareness programmes and *animal identification* of equids. ~~Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in glanders, epidemiological evaluation and control as part of their contingency plan.~~

The *Veterinary* ~~*Authority*~~ *Services* should implement, when relevant and according to the results of former *surveillance*, regular and frequent clinical inspections and ~~random or~~ targeted serological surveys ~~and laboratory testing~~ of high-risk ~~groups~~ *subpopulations* or those ~~adjacent to~~ neighbouring a country or *zone* infected with *B. mallei*.

An effective *surveillance* system is likely to identify suspected *cases* that require follow-up investigation to confirm or exclude that the cause of the condition is *B. mallei*. All suspected *cases* ~~of *infection* with *B. mallei*~~ should be investigated immediately and samples should be taken and submitted to a *laboratory*. This requires that sampling kits and other equipment be available to those responsible for the *surveillance*. Details of the occurrence of suspected *cases* and how they were investigated and dealt with should be documented. This should include the results of diagnostic testing and the control measures to which the equids concerned or affected *establishments* were subjected during the investigation (quarantine, movement control, euthanasia).

Susceptible *captive wild*, *feral* and *wild* equine *populations* should be included in the *surveillance* ~~programme~~.

Surveillance should address not only the occurrence of clinical signs caused by *B. mallei*, but also evidence of *infection* with *B. mallei* in the absence of clinical signs.

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Article 12.10.9.

Surveillance strategies

The strategy employed ~~may~~ should be based on ~~clinical investigation, or randomised or targeted sampling at an acceptable level of statistical confidence.~~ the current knowledge of the epidemiological situation, and the expected results of the *surveillance*, such as the demonstration of a supposed free status. The *populations* of equids subject to the *surveillance* can be covered by passive clinical *surveillance*, active investigation of suspected *cases*, or randomised or targeted sampling.

~~If glanders is present, it is usually~~ *Infection* with *B. mallei* usually occurs at a very low *prevalence* and randomised samples should be collected in high numbers. If an increased likelihood of *infection* in particular geographical locations or *subpopulations* can be identified, targeted sampling is appropriate.

~~To detect *infection* or to determine the distribution and estimate the *prevalence* of *infection* either at the level of the entire population or within targeted *subpopulations*, the design of the sampling strategy and frequency of testing should incorporate epidemiologically appropriate design *prevalence* for the selected populations. The sample size selected for testing should be statistically relevant to detect the presence of *infection* if it were to occur at a predetermined minimum rate. The design *prevalence* and confidence level should be consistent with the objectives of the *surveillance* and the epidemiological situation.~~

To substantiate freedom from *infection* in a country or *zone*, *surveillance* should be conducted in accordance with the relevant provisions of ~~Chapter 1.4.~~ Article 1.4.6. ~~Irrespective of the approach selected, the sensitivity and specificity of the diagnostic tests employed should be considered in the design and in the interpretation of the results obtained.~~ The relatively high rate of occurrence of false positive reactions to tests for *B. mallei* ~~has to~~ should be considered and the rate at which these false positives are likely to occur should be calculated in advance. Every positive result should be investigated to determine whether it is indicative of *infection* or not. This involves supplementary tests, trace-back and trace-forward, and inspection of individual *animals* and *herds* for clinical signs. ~~Laboratory results should be interpreted in the context of the epidemiological situation.~~

~~Methods should include c~~Clinical or pathological *surveillance* and laboratory testing are complementary diagnostic approaches that. ~~They~~ should always be applied in series to clarify the status of suspected *cases* ~~of glanders detected by either of these complementary diagnostic approaches~~. Agent identification should be carried out on any equid serologically positive or showing clinical signs. Any ~~*epidemiological unit* within which~~ suspected *cases* ~~are detected~~ should be considered infected until contrary evidence is produced.

1. Clinical surveillance

   Clinical *surveillance* aims at detecting clinical signs by close physical examination of equids. However, systematic clinical *surveillance* is of limited use only, as asymptomatic carrier animals are the main reservoir of the disease.

2. Pathological ~~and bacteriological~~ surveillance

   Systematic pathological *surveillance* is an effective approach for the detection of ~~glanders~~ *infection* with *B. mallei* and should be conducted on dead equids on farms, at *slaughterhouses/abattoirs* and facilities for the disposal of carcasses of equids. ~~Suspicious p~~Pathological findings indicating possible *infection* with *B. mallei* should be confirmed by agent identification and any isolate~~s~~ should be characterised.

3. Serological surveillance

   Serological *surveillance* for ~~glanders~~ *infection* with *B. mallei* is the preferred strategy. *Animal identification* and ~~R~~repeated testing of the ~~equid~~ *population* ~~with recommended tests is~~ are necessary to ~~reach an acceptable level of confidence~~ establish its *infection* status.

4. Malleinisation

Frequently used as a *surveillance* method, malleinisation demonstrates hypersensitivity to antigens of *B. mallei*. However, this method has shortcomings, such as low sensitivity, interference with other tests and *animal welfare* concerns ~~that should be considered when interpreting results~~.