

GLOSSARY (PART B)

ANIMAL WELFARE

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

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* 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 in a previously free country or zone, which includes including all suspected or confirmed *cases outbreaks* 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 eradicate, the *infection disease 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 in which a *disease* has been diagnosed.

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

PROTECTION ZONE

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

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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 country or zone of a different animal health status.

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 pathogenic agents ~~disease~~ to be controlled.

ZONE/REGION

means a clearly defined part of a territory of a 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~~.

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CHAPTER 4.3.

ZONING AND COMPARTMENTALISATION

Article 4.3.1.

Introduction

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, there may be benefits to a Member Country in establishing and maintaining a *subpopulation* with a 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 by the application of appropriate *biosecurity* management.

While zoning applies to an animal *subpopulation* defined primarily on a geographical basis, compartmentalisation applies to an animal *subpopulation* defined primarily by management and husbandry practices related to *biosecurity*. In practice, spatial considerations and appropriate management, including *biosecurity plans*, play important roles in the application of both concepts.

Zoning may encourage the more efficient use of resources within certain parts of a country and compartmentalisation may allow the functional separation of a *subpopulation* from other domestic or *wild animals* through *biosecurity*, which a *zone* 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. 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.

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

Article 4.3.2.

General considerations

The *Veterinary Services* of a Member Country that is establishing a *zone* or *compartment* within its territory should clearly define the *subpopulation* in accordance with the recommendations in the relevant chapters of the *Terrestrial Code*, including those on *surveillance*, and *animal identification* and *animal traceability*.

The procedures used to establish and maintain the specific *animal health status* of a *zone* or *compartment* depend on the epidemiology of the *disease*, including the presence and role of *vectors* and susceptible *wildlife* 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 established and should operate in accordance with Chapters 3.1. and 3.2., to provide confidence in the integrity of the *zone* or *compartment*. The final authority 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.

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In the context of maintaining the *animal health status* of a *population* or *subpopulation* of a country, *zone* or *compartment*, importations into the country as well as movements of *animals* and their products into the *zones* or *compartments* should be the subject of appropriate *sanitary measures* and *biosecurity*.

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

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.

Article 4.3.3.

Principles for defining and establishing a zone or compartment

The following principles 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 or legal boundaries, and made public through official channels.
- 2) 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 communicated to the relevant operators through official channels.
- 3) *Animals* and *herds* or *flocks* belonging to *subpopulations* of *zones* or *compartments* should be recognisable as such through a clear epidemiological separation from other *animals* and all factors presenting a *disease risk*. 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 specific *animal health status* of a *zone* or *compartment* should be appropriate to the particular circumstances, and depend on the epidemiology of the *disease*, environmental factors, the health status of *animals* in adjacent areas, applicable *biosecurity* (including movement controls, use of natural, artificial or legal boundaries, spatial separation of *animals*, control of fomites, and commercial management and husbandry practices), and *surveillance*.
- 4) Relevant *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* or individual animal level. Relevant animal movements into and out of the *zone* or *compartment* should be well documented and controlled. The existence of an *animal identification system* is a prerequisite to assess the integrity of the *zone* or *compartment*.
- 5) 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 standard operating procedures to provide clear evidence that the *surveillance* conducted, the *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*, 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 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 *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 *disease-specific* 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 the provisions for freedom of the relevant chapters of the *Terrestrial Code*.

An *infected zone* may be:

- a *zone* of a country where the *disease* is present and has not yet been eradicated, while other *zones* of the country may be free;
- a *zone* of a previously free country or *zone*, in which the *disease* 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 a *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 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 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;

Annex 22 (contd)

- 4) enhanced *biosecurity* including *disinfection* procedures for *vehicles/vessels*, vehicles for transportation of *commodities*, feed or fodder, and possible compulsory routes;
- 5) specific *surveillance* of susceptible *wildlife* and relevant *vectors*;
- 6) awareness campaigns aimed at the public or targeted at breeders, traders, hunters or *veterinarians*.

Measures, such as *vaccination*, implemented in a *protection zone* established in a free country or *zone* will not affect the status of the rest of the free country or *zone*, even if such measures make it necessary to distinguish the status of the *protection zone* from the rest of the country or *zone*.

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 *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 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*, 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 *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 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* demonstrates that this is the case.

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 or international trade. *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 compartmentalisation 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, to facilitate disease control and the continuation of trade, the use of 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. 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 22bis (contd)

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, and the animal identification and animal traceability of live animals. The Veterinary Services of an exporting country should be able to explain to the Veterinary Services of an importing country the basis for 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 of 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 disease surveillance and diagnosis.~~

~~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, and carry out documented periodic inspections of facilities, biosecurity, records and surveillance procedures. Veterinary Services should conduct or audit surveillance, reporting 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.~~

Annex 22bis (contd)

~~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 *animals* *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:~~

Annex 22bis (contd)

- 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.~~
- 24) 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 industry operators through official channels.
- 35) ~~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.~~
- 46) Relevant animals and animal products 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 or individual animal level. Relevant animal movements 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.
- 57) 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 animals and animal products 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 disease, 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 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 disease-specific 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 disease, 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 disease, infection or infestation has been diagnosed confirmed, or that does not meet disease freedom the provisions for freedom of the relevant chapters of the Terrestrial Code.

An infected zone may be:

- = a zone of a country where the disease has been is present and has not yet been eradicated, while other zones of the country are may be free;
- = a zone of a previously free country or zone, in which the disease 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 a 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 from by preventing the introduction of a pathogenic agent of a specific disease, infection or infestation from adjacent 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 an the adjacent 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;

Annex 22bis (contd)

- 3) specific procedures for sample handling, dispatching and testing;
- 4) enhanced biosecurity including disinfection procedures for vehicles/vessels, vehicles for transportation of commodities, feed or fodder, and possible compulsory routes;
- 5) specific surveillance of susceptible wildlife and relevant vectors;
- 6) awareness campaigns aimed at the public or targeted at breeders, traders, hunters or veterinarians.

Measures, such as vaccination, implemented in a protection zone established in a free country or zone will not affect the status of the rest of the free country or zone, even if such measures make it necessary to distinguish the status of the protection zone from the rest of the country or zone.

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 including includes:

- 1) appropriate control of movement of animals and other commodities upon notification 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) clear animal identification of the susceptible animal 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 evidence 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 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 last detected case.

OR

- b) the containment zone comprises an infected zone where outbreaks cases may continue to occur and a protection zone, where no outbreaks have occurred for at least two incubation periods, and which 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 of these areas may then be is reinstated.

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

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 *distinct specific animal health status* for the 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* certifies demonstrates that this is the case.

 — Text deleted.

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 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 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 *disease-specific chapters of the Terrestrial Code*;
- 4) the relevant general and specific recommendations for principles of veterinary vaccine production 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 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.

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

Annex 23 (contd)

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*, 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.

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 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 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 or emergence of *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;
- ~~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 or emergence of a *disease*;
- ~~3bis)~~ the zoonotic potential of the disease;
- 4) the density of the exposed susceptible animals population;

Annex 23 (contd)

- 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*;
- 8) the availability of an appropriate vaccine and 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* into or from a neighbouring country or *zone*.
- 4) **Targeted vaccination:** *vaccination* 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;
 - 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.

Annex 23 (contd)

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;
- effect on the ability to differentiate infected from vaccinated animals, at the individual or group level;
- suitability of vaccine formulation for species 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.

Article 4.X.Z6.

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.

1. Legal basis

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* 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.

32. Vaccination coverage

In practical terms, 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.

43. Stakeholder involvement

The *vaccination* programme should demonstrate good governance by the *Veterinary Services* ~~and~~ by clearly identifying the involvement of different stakeholders including other ~~government agencies~~ governmental organisations, farmers, 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.

54. 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.

65. Actions and timeline

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

76. Timing of vaccination campaigns

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

The objective of the *vaccination* campaign ~~is~~ should be to achieve the ~~necessary~~ 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;
- b) accessibility of the target population;
- c) animal handling facilities;
- d) animal body condition and physiological state;
- e) geographical factors;
- f) climate conditions;
- ~~fbs)~~ vector activity;
- g) awareness, acceptance and engagement of stakeholders;

Annex 23 (contd)

- h) types of production systems and animal movement patterns;
- i) timing of agricultural, social or cultural activities;
- j) availability of resources.

87. Auditing of the vaccination campaigns

The *vaccination* programme should include periodic auditing of all the participants in the 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 vaccination campaign 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;
- bis) 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 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.

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 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 ~~registration~~ should be obtained.

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

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 standard operating procedures 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;

~~ebis)~~ determine the disposition of partially used or unused containers of vaccine;

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

- f) identify vaccinated animals;
- g) ensure safety and welfare of animals and *vaccination* teams;
- h) record activities of vaccination teams;
- i) document *vaccinations*.

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 in accordance with Chapters 4.1. and 4.2.

Annex 23 (contd)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 *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 or emergence of the *disease*;

Annex 23 (contd)

- 3) reduction of the *incidence* or *prevalence* of the *disease* to a level where alternative measures such as *stamping-out* 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. 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. *Disease-specific* chapters of the *Terrestrial Code* provide additional recommendations on the management of vaccinated animals.

Disease-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 *disease-specific* chapters, *vaccination* of animals does not affect the *disease* status of the country or *zone*, and should not disrupt trade.

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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 morula¹ 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 ovaries² 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 24 (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~~s~~ 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.

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)ⁱ.

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 *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* 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*.

Annex 24 (contd)

- 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 an *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 an *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 an *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 ~~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.

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.

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.

Annex 24 (contd)

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 Manual¹ 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 Manual¹.
- 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 Manual¹.

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 Manual¹. 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 Manual¹;
 - 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 an 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 Manual¹.
 - b) ~~The frozen oocytes and embryos should if possible, depending on the species, be frozen in fresh liquid nitrogen or other cryoprotectant and then stored in fresh cryoprotectant liquid phase nitrogen or in the vapour phase of liquid nitrogen~~ cleaned and 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 Manual¹.
 - b) The fresh or chilled oocytes and embryos should be stored under strict hygienic conditions in portable incubators disinfected in accordance with the IETS Manual¹ 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.~~
- 45) Oocytes and embryos ~~Embryos~~ should not be exported until the appropriate veterinary certificates are completed.

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.

 — Text deleted.

¹ Manual of the International Embryo Transfer Society.

[Clean text]

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 *zoonoses*) and food safety, 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, including *veterinarians*, other relevant professionals and stakeholders, is critical for the effective operation of the food safety system.

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 public 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), 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.

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 potential risks associated with each stage of the food chain, i.e. primary production, transport, processing and distribution, and integrate risk management responses to such risks at the most appropriate points along the food chain. 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 25 (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 assessment. 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.

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 foodborne disease outbreak response, 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 non-compliance, appropriate corrective actions and sanctions should be applied.

Article 6.1.4.

The roles and responsibilities of Veterinary Services in a food safety system1. 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 that they delegate 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 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 the 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 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 risk of non-compliant 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*.

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 essential role in overseeing assurance schemes and 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, 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 25 (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.

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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 zoonoses) and food safety, which makes them uniquely equipped to play a central role in ensuring food safety, especially the safety of foods of animal origin. Close cooperation and effective communication between all actors, 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. 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 Chapters 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 25bis (contd)

Article 6.1.3.

Characteristics of a food safety system1. 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 potential risks associated with each component stage of the food chain, namely i.e. primary production, transport, processing 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 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 international trade, a risk based approach to food safety systems contributes to the determination of equivalence between trading partners.

3. Primary 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 Authority Authorities 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 non-compliance, appropriate corrective actions and sanctions should be applied.

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 foods 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 delegate 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.~~

~~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 training in food safety systems and ongoing professional development.~~

Annex 25bis (contd)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 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 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 of non-compliant levels of veterinary drug residues developing antimicrobial resistance and unsafe levels of veterinary drug residues in foods 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 foods 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.~~

Annex 25bis (contd)

~~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 foods 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 role in overseeing assurance schemes and certifying that foods of animal origin complies with animal health and food safety standards.

Other Competent Authorities may also be involved in providing assurances and certification of foods 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, 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*.~~

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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,
 - 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** cooperation between all Member Countries conducting antimicrobial resistance surveillance **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 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.

Annex 26 (contd)

Surveillance or 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.

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

- 1a) statistically based surveys;
- 2b) sampling and testing of food producing animals on the farm, at live animal markets or at *slaughter*;
- 3e) an organised sentinel programme, for example targeted sampling of food producing animals, *herds*, *flocks*, and *vectors* (e.g. birds, rodents);
- 4d) analysis of veterinary practice and diagnostic *laboratory* records;
- 5e) 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.Sampling12. 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 such as targeted, systematic random, non-random;
 - type of sample (e.g. such as faecal, faeces, carcass, food product);
 - sample size.

23. Sample size

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

The sample should avoid bias and provide a representative sample whilst taking into account 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

34. 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*.

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 and the prevalence of resistant bacteria.

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.

45. 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.

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*.

Annex 26 (contd)

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
	Faeces	Prevalence of resistant bacteria originating from animals at slaughter	
Abattoir	Caeca or intestines	As above	
	Carcass	Hygiene, contamination during slaughter	
Processing, packing	Food products	Hygiene, 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:

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

ai) 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.

bii) 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.

ciii) 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

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

2b) Zoonotic bacteria

a) *Salmonella*

Salmonella should be sampled from animal feed, food producing animals and animal-derived food products. 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*.

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. The inclusion of other relevant serovars will depend on the epidemiological situation in each country.

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

Annex 26 (contd)**bii)** *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.

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

Other emerging bacteria, 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.

3e) 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

1a) 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.

2b) 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.

Annex 26 (contd)

3e) 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 recorded quantitatively:

a) as distributions of MICs in micrograms per millilitre;

b) or inhibition zone diameters in millimetres.

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

a) sampling programme;

b) sampling date;

c) animal species and production type;

d) type of sample;

e) purpose of sampling;

f) type of antimicrobial susceptibility testing method used;

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

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

i) exposure of animals to antimicrobial agents;

j) bacterial recovery isolation rate.

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

a) identity of *laboratory*,

b) isolation date,

c) reporting date,

d) bacterial species,

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

e) serotype or serovar,

f) phage type,

g) antimicrobial susceptibility result or resistance phenotype,

h) genotype.

6f) 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.

7g) 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.

Annex 26 (contd)

- 8h)** The bacterial isolation methods, antimicrobial susceptibility testing methods, standards and guidelines used should be recorded.
- 9i)** 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.
- 10j)** Ideally, data should be collected at the individual isolate level, allowing antimicrobial resistance patterns over time to be recorded, along with relevant data on usage and management practices.

Article 6.7.9.~~10.~~ **Reference laboratory and annual reports**

- 1a)** Member Countries should designate a national reference centre that assumes the responsibility to:
- a)** coordinate the activities related to the antimicrobial resistance surveillance and monitoring programmes;
 - b)** coordinate and collect information from participating surveillance laboratories within the country;
 - c)** produce an annual report on the antimicrobial resistance situation in the country.
- 2b)** The national reference centre should have access to the:
- a)** raw data;
 - b)** complete results of quality assurance and inter-laboratory calibration activities;
 - c)** inter-laboratory proficiency testing results;
 - d)** information on the structure of the surveillance or monitoring system;
 - e)** information on the chosen laboratory methods.

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CHAPTER 7.1.

**INTRODUCTION TO THE
RECOMMENDATIONS FOR ANIMAL WELFARE**

Article 7.1.X.

Guiding principles for the use of animal-based measures to assess animal welfare

- 1) For the OIE animal welfare standards to be applicable globally, they should put more emphasis on good outcomes for the animals rather than on prescribe specific conditions of the animals' environment and management. Outcomes are generally measured assessed by assessing animals' enjoyment of the "five freedoms" described in Article 7.1.2. animal-based measures such as low mortality rate, low prevalence of injuries, ability to move freely, positive human-animal relationship, and a low incidence of aggression and stereotyped behaviour.
- 2) For each principle listed in Article 7.1.4., the most relevant measures criteria, ideally animal-based measures, should be included in the standard. Any given animal-based measure may be linked to more than one principle.
- 3) End 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.
- 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 available relevant science and experience of experts. To guide end users, Competent Authorities should collect data that can be used to set locally relevant target values.
- 5) In addition to animal-based measures, resource-based measures and management-based measures can should be defined on the basis of science and expert experience in cases where a showing that a welfare outcome is clearly linked to a resource such as adequate space, or to a management procedure such as pain mitigation.

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DRAFT CHAPTER 7.X.

ANIMAL WELFARE AND PIG PRODUCTION SYSTEMS

Article 7.X.1.

Definitions

'Pig production systems' are defined as all commercial systems in which the purpose of the operation includes some or all of the breeding, rearing and management of pigs (*Sus scrofa*) intended for production of *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 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 behavior, 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 of the animal (Newberry, 1995).

For the purposes of this chapter stereotypy is as a sequence of abnormal, repetitive and unvarying behaviours caused by known factors such as frustration, coping attempts, or dysfunction of the central nervous system. Some stereotypies commonly observed in pigs include sham chewing, stone chewing, tongue rolling, teeth grinding, bar biting and floor licking (NFACC, 2014; Tuytens, 2007; Mason and Latham, 2004).

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 domestic pig production systems. ~~However,~~ Captive wild pigs are not considered.

Article 7.X.3.

Commercial pig production systems

Commercial pig production systems include:

Annex 28 (contd)1. Indoors

These are systems in which pigs are kept indoors, and are fully dependent on humans to provide for basic animal needs such as ~~feed~~ 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

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 ~~feed~~ 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 tool 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* problem. These include changes of in feed and water intake, altered locomotory behaviour ~~and or~~ posture, altered lying time, 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 behaviour 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 infectious 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/abattoirs, 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 performance 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 welfare include:

- body condition,
- 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).

Annex 28 (contd)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 include:

- evidence of poor human-animal relationship, such as marked avoidance of handlers and 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 ~~feed~~ 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 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 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 and distress,
- 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.26. provide recommendations for measures applied to pigs.

Each recommendation includes a list of relevant 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.7.

Training of 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-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.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 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 animals, pigs and piglets showing increased abnormal behaviours such as tail nibbling.

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 28 (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. 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 or ~~and genital anogenital~~ region.

Exposure of pigs to sudden movement 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-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.98.

Painful procedures

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

These procedures are painful or have the potential to cause pain and thus should be performed only when necessary and in such a way as to minimise any pain and distress to the animal, e.g. using anaesthesia or analgesia 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 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 of ~~and~~ anaesthesia under the recommendation of a veterinarian) (Bonastre *et al.*, 2016 and Hansson *et al.*, 2011).

Outcome-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.99.

Feeding and provision of watering 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.
- ~~avoid metabolic and nutritional disorders.~~

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

Annex 28 (contd)

~~Pigs should be fed a diet with sufficient fibrous feedstuffs in order to reduce as much as possible the occurrence of gastric ulcers (Hedde *et al.*, 1985).~~

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-based criteria (or measurables): changes in body weight and body condition, physical appearance (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.1044.

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/ or chewing), reduce abnormal behaviour (e.g. tail, ear, leg and flank biting and apathetic behaviour) and improve biological function (Dudnik *et al.*, 2006; Elmore *et al.*, 2011; 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); novelty is another aspect that is very important in so as to maintaining interest in the provided material(s) (Trickett *et al.*, 2009; Abou-Ismaail 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 pats, rubs and talking when the opportunity arises) (Hemsworth and Coleman, 2011; Hemsworth and Coleman, 1994).

Outcome-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.1142.

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.

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 that may reduce their 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 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.

Annex 28 (contd)

- 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 in accessing the feeding area (Bench *et al.*, 2013; Leeb *et al.*, 2001; Rizvi *et al.*, 1998).

Outcome-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.612.**Housing (including outdoor production systems)**

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~~ 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 must 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 theseat outcomes.

~~Pigs~~ Sows and gilts 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-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.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 (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.

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

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

Outcome-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 must~~ should 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-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, gestation and insemination stalls and farrowing crates. Stalls should must~~ be sized appropriately to allow pigs to ~~be able 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.

Outcome-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).

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.

Annex 28 (contd)

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-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, and diseases 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-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-based criteria (or measurables): behaviour (feed and water intake, respiratory rate, panting, agonistic behaviour), physical appearance (presence of faeces on the skin), 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 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-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, exposure of pigs to sudden or loud noises should be minimised 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-based criteria (or measurables): behaviour (e.g. fleeing and 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-based criteria (or measurables): behaviour (locomotive behaviour), morbidity rates, reproductive efficiency, physical appearance (injuries) and changes in body weight and body condition.

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 where possible some days before farrowing (Yun *et al.*, 2014). 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-based criteria (or measurables): mortality and culling rates (piglets), morbidity rates (metritis and mastitis), behaviour (~~stereotypes~~ restlessness and savaging), reproductive efficiency, physical appearance (injuries).

Annex 28 (contd)

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.

An average Piglet should be weaned at an age of at three weeks or older is recommended (Hameister *et al.*, 2010; Smith *et al.*, 2010; Gonyou *et al.*, 1998; Worobec *et al.*, 1999).

Delaying weaning to the age of four weeks or more may produce benefits such as improved bowel gut immunity and reduced less diarrhoea and less preventive 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-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-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).

Outcome-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.

Pigs should also be protected from pests such as excessive numbers of flies and mosquitoes.

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

Article 7.X.24.

Biosecurity and animal health1. 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*.

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 animals~~ 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.~~

Annex 28 (contd)

Outcome-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~~ health and welfare of the pig ~~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 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 rate 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 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* 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* 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-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.

Contingency ~~Emergency~~ plans

Where the failure of power, water ~~and or~~ feed supply systems could compromise *animal welfare*, pig producers should have contingency plans ~~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 H~~umane *killing* procedures for of~~ sick or injured pigs should be part of the disaster management plan.

Reference to emergency 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 for on-farm humane *killing*. Staff should be trained in the humane *killing* procedures appropriate for each class of pig.

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,~~
- ~~compound fracture,~~
- ~~spinal injury,~~
- ~~central nervous system disease,~~
- multiple joint *infections* with chronic weight loss,

Annex 28 (contd)

- 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.~~

- Text deleted.

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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 samples 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 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) 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 29 (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

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* demonstrates no evidence either of transmission of BTV or of adult *Culicoides* for part of a year.

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*.

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:

- 1) at least 28 days before the earliest date that historical data show transmission of BTV may recommence; or
- 2) immediately if current climatic data or data from a *surveillance* programme indicate an earlier resurgence of activity of adult *Culicoides*.

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 bluetongueFor 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;
 - 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.;
 - c) were identified as having been vaccinated;
 - d) remained in the free country or *zone* 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* 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 zones seasonally free from bluetongueFor ruminants and camelids

Annex 29 (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 *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 *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 *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 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 were identified as having been vaccinated and remained in the seasonally free ~~country or zone~~ 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* 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 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 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

Annex 29 (contd)

- 4) were protected from attacks from *Culicoides* 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 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.; 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 bluetongueFor 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 *zone* during the ~~seasonally free~~ season ~~period~~ for at least 60 days before commencement of, and during, collection of the semen; or
 - ~~b_e) 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 BTVFor 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 *vector-protected establishment* 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

Annex 29 (contd)

- 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 8.3.11.

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 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.:
- ~~e) 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* 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;

Annex 29 (contd)

- 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.

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.

Annex 29 (contd)

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*.

Annex 29 (contd)

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.

Annex 29 (contd)

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*.

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.

Annex 29 (contd)

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.

 — Text deleted.

CHAPTER 8.8.

INFECTION WITH FOOT AND MOUTH DISEASE
VIRUS

Article 8.8.1.

- 1) Many different species belonging to diverse taxonomic orders are known to be susceptible to *infection* with foot and mouth disease virus (FMDV). Their epidemiological significance depends upon the degree of susceptibility, the husbandry system, the density and extent of populations and the contacts between them. Amongst *Camelidae*, only Bactrian camels (*Camelus bactrianus*) are sufficiently susceptible to have potential for epidemiological significance. Dromedaries (*Camelus dromedarius*) are not susceptible to *infection* with FMDV while South American camelids are not considered to be of epidemiological significance.
- 2) For the purposes of the *Terrestrial Code*, foot and mouth disease (FMD) is defined as an *infection* of animals of the suborder *ruminantia* and of the family *suidae* of the order *Artiodactyla*, and *Camelus bactrianus* with FMDV.
- 3) The following defines the occurrence of *infection* with FMDV:
 - a) FMDV has been isolated from a sample from an animal listed in point 2; or
 - b) ~~viral~~ antigen or ~~viral~~ ribonucleic acid specific to FMDV has been identified in a sample from an animal listed in point 2, showing clinical signs consistent with FMD, or epidemiologically linked to a suspected or confirmed *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV; or
 - c) antibodies to structural or nonstructural proteins of FMDV, that are not a consequence of *vaccination*, have been identified in a sample from an animal listed in point 2, showing clinical signs consistent with FMD, or epidemiologically linked to a suspected or confirmed *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV.
- 4) Transmission of FMDV in a vaccinated population is demonstrated by change in virological or serological evidence indicative of recent *infection*, even in the absence of clinical signs.
- 5) For the purposes of the *Terrestrial Code*, the *incubation period* of FMD shall be 14 days.
- 6) *Infection* with FMDV can give rise to *disease* of variable severity and to ~~FMDV transmission of FMDV~~. FMDV may persist in the pharynx and associated lymph nodes of ruminants for a variable but limited period of time beyond 28 days. Such animals have been termed carriers. **However, the only persistently infected species from which transmission of FMDV has been proven is the African buffalo (*Syncerus caffer*). However, transmission to domestic livestock is rare.**
- 7) This chapter deals not only with the occurrence of clinical signs caused by FMDV, but also with the presence of *infection* with ~~FMDV~~ and transmission of FMDV in the absence of clinical signs.
- 8) Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 8.8.2.

FMD-free Country or zone free from FMD where vaccination is not practised

In defining a *zone* where *vaccination* is not practised the principles of Chapter 4.3. should be followed.

Susceptible animals in the ~~FMD-free country or zone free from FMD~~, where *vaccination* is not practised should be protected by the application of *biosecurity measures* that prevents the entry of FMDV into the free country or *zone*.

Annex 30 (contd)

Taking into consideration physical or geographical barriers with any neighbouring infected country or *zone*, these measures may include a *protection zone*.

To qualify for inclusion in the list of ~~FMD-free~~ countries or *zones* free from FMD, where *vaccination* is not practised, a Member Country should:

- 1) have a record of regular and prompt animal *disease* reporting;
- 2) send a declaration to the OIE stating that during the past 12 months, within the proposed ~~FMD~~ free country or *zone*:
 - a) there has been no *case* of FMD;
 - b) no *vaccination* against FMD has been carried out;
- 3) supply documented evidence that for the past 12 months:
 - a) *surveillance* in accordance with Articles 8.8.40. to 8.8.42. has been implemented to detect clinical signs of FMD and demonstrate no evidence of:
 - i) *infection* with FMDV in unvaccinated animals;
 - ii) ~~FMDV~~ transmission of FMDV in previously vaccinated animals when the ~~FMD~~ free country or *zone* where *vaccination* is practised is seeking to become one where *vaccination* is not practised;
 - b) regulatory measures for the prevention and early detection of FMD have been implemented;
- 4) describe in detail and provide ~~supply~~ documented evidence that for the past 12 months ~~the following have been properly implemented and supervised~~:
 - a) ~~in the case of a FMD free zone~~, the boundaries of the any proposed ~~FMD~~ free *zone* have been established and effectively supervised;
 - b) the boundaries and biosecurity measures of a any *protection zone*, ~~if applicable~~ have been established and effectively supervised;
 - c) the system for preventing the entry of FMDV into the proposed ~~FMD~~ free country or *zone* has been established and effectively supervised;
 - d) the control of the movement of susceptible animals, their *meat* and other products into the proposed ~~FMD~~ free country or *zone*, in particular the measures described in Articles 8.8.8., 8.8.9. and to 8.8.12. has been effectively implemented and supervised;
 - e) measures to prevent the introduction of ~~no~~ vaccinated animals has been introduced, except in accordance with Articles 8.8.8. and 8.8.9., 8.8.9bis., 8.8.11. and 8.8.11bis. have been effectively implemented and supervised. Any animals introduced for slaughter were subjected to ante- and post-mortem inspections in accordance with Chapter 6.2. with favourable results. For ruminants the head, including the pharynx, tongue and associated lymph nodes, was either destroyed or treated in accordance with Article 8.8.31.

The Member Country or the proposed free *zone* will be included in the list of ~~FMD-free~~ countries or *zones* free from FMD, where *vaccination* is not practised only after the submitted evidence, based on the provisions of Article 1.6.6., has been accepted by the OIE.

Retention on the list requires that the information in points 2, 3 and 4 above be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported to the OIE in accordance with the requirements in Chapter 1.1.

A country or zone free from FMD may maintain its free status despite an incursion of potentially infected African buffaloes provided that the surveillance programme substantiates the absence of transmission of FMDV.

Provided the conditions of points 1 to 4 are fulfilled, the status of a country or zone will not be affected by applying official emergency vaccination to FMD susceptible animals in zoological collections in the face of a FMD threat identified by the *Veterinary Authorities*, provided that the following conditions are met:

- the zoological collection has the primary purpose of exhibiting animals or preserving rare species, has been identified, including the boundaries of the facility, and is included in the country's contingency plan for FMD;
- appropriate *biosecurity* measures are in place, including effective separation from other susceptible domestic populations or *wildlife*;
- the animals are identified as belonging to the collection and any movements can be traced;
- the vaccine used complies with the standards described in the *Terrestrial Manual*;
- *vaccination* is conducted under the supervision of the *Veterinary Authority*;
- the zoological collection is placed under *surveillance* for at least 12 months after *vaccination*.

In the event of the application for the status of a new FMD-free zone where vaccination is not practised to be assigned to a new zone being adjacent to another FMD free zone of the same status where vaccination is not practised, it should be stated if the new zone is being merged with the adjacent zone to become one enlarged zone. If the two zones remain separate, details should be provided on the control measures to be applied for the maintenance of the status of the separate zones and particularly on the identification and the control of the movement of animals between the zones of the same status in accordance with Chapter 4.3.

A protection zone used to preserve the status of a free country or zone from a newly identified likelihood of introduction of FMDV should comply with Article 4.3.6. If vaccination is implemented in the protection zone, this will not affect the freedom of the rest of the country or zone.

Article 8.8.3.

FMD-free Country or zone free from FMD where vaccination is practised

In defining a zone where *vaccination* is practised the principles of Chapter 4.3. should be followed.

Susceptible animals in the FMD-free country or zone free from FMD where *vaccination* is practised should be protected by the application of *biosecurity* measures that prevent the entry of FMDV into the free country or zone. Taking into consideration physical or geographical barriers with any neighbouring infected country or zone, these measures may include a *protection zone*.

Based on the epidemiology of FMD in the country, it may be decided to vaccinate only a defined *subpopulation* comprised of certain species or other subsets of the total susceptible population.

To qualify for inclusion in the list of FMD-free countries or zones free from FMD where *vaccination* is practised, a Member Country should:

- 1) have a record of regular and prompt animal *disease* reporting;
- 2) send a declaration to the OIE stating that, based on the *surveillance* described in point 3, within the proposed FMD free country or zone:
 - a) there has been no case of FMD during the past two years;
 - b) there has been no evidence of FMDV transmission of FMDV during the past 12 months;

Annex 30 (contd)

3) supply documented evidence that:

- a) *surveillance* in accordance with Articles 8.8.40. to 8.8.42. has been implemented to detect clinical signs of FMD for the past two years and demonstrate no evidence of:
 - i) *infection* with FMDV in unvaccinated animals for the past two years;
 - ii) ~~FMDV~~ transmission of FMDV in vaccinated animals for the past 12 months;
 - b) regulatory measures for the prevention and early detection of FMD have been implemented for the past 12 months;
 - c) compulsory systematic *vaccination* in the target population has been carried out to achieve adequate *vaccination coverage* and population immunity for the past two years;
 - d) *vaccination* has been carried out following appropriate vaccine strain selection for the past two years;
- 4) describe in detail and ~~supply~~ provide documented evidence that for the past 12 months ~~the following have been properly implemented and supervised:~~
- a) ~~in case of FMD free zone,~~ the boundaries of the proposed FMD free zone have been established and effectively supervised;
 - b) the boundaries and biosecurity measures of any protection zone, if applicable have been established and effectively supervised;
 - c) the system for preventing the entry of FMDV into the proposed FMD free country or zone, in particular the measures described in Articles 8.8.8., 8.8.9. and 8.8.12. has been established and effectively supervised;
 - d) the control of the movement of susceptible animals and their products into the proposed FMD free country or zone has been effectively implemented and supervised.

The Member Country or the proposed free zone will be included in the list of ~~FMD free~~ countries or zones free from FMD where *vaccination* is practised only after the submitted evidence, based on the provisions of Article 1.6.6., has been accepted by the OIE.

Retention on the list requires that the information in points 2, 3 and 4 above be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported to the OIE in accordance with the requirements in Chapter 1.1.

If a Member Country that meets the requirements of a ~~FMD free~~ country or zone free from FMD where *vaccination* is practised wishes to change its status to ~~FMD free~~ country or zone free from FMD where *vaccination* is not practised, it should notify the OIE in advance of the intended date of cessation of *vaccination* and apply for the new status within 24 months of the cessation. The status of this country or zone remains unchanged until compliance with Article 8.8.2. is approved by the OIE. If the dossier for the new status is not provided within 24 months then the status of the country or zone as being free with *vaccination* will be suspended. If the country does not comply with requirements of Article 8.8.2., evidence should be provided within three months that it complies with Article 8.8.3. Otherwise the status will be withdrawn.

If a Member Country that meets the requirements of a country or zone free from FMD where *vaccination* is not practised wishes to change its status to country or zone free from FMD where *vaccination* is practised, it should provide the OIE with a plan following the structure of the Questionnaire of Article 1.6.6., indicating the intended date of beginning of *vaccination*. The status of this country or zone remains unchanged until approved by the OIE. As soon as recognised free with *vaccination* the country or zone will begin the *vaccination*. The Member Country should provide evidence within six months that it complies with Article 8.8.3. for this time period. Otherwise the status will be withdrawn.

If a country needs to define a *protection zone* in accordance with Article 4.3.6. in response to an increased risk, including by the application of *vaccination*, once the *protection zone* has been approved by the OIE, the freedom of the rest of the country or zone remains unchanged.

In the event of the application for the status of a new FMD free free zone where vaccination is practised to be assigned to a new zone being adjacent to another FMD free zone of the same status where vaccination is practised, it should be stated if the new zone is being merged with the adjacent zone to become one enlarged zone. If the two zones remain separate, details should be provided on the control measures to be applied for the maintenance of the status of the separate zones and particularly on the identification and the control of the movement of animals between the zones of the same status in accordance with Chapter 4.3.

Article 8.8.4.

FMD free Compartment free from FMD where vaccination is not practised

A FMD free compartment free from FMD where vaccination is not practised can be established in either a FMD free country or zone or in an infected country or zone. In defining such a compartment the principles of Chapters 4.3. and 4.4. should be followed. Susceptible animals in the FMD free compartment should be separated from any other susceptible animals by the application of an effective biosecurity plan management system.

A Member Country wishing to establish a FMD free compartment free from FMD where vaccination is not practised should:

- 1) have a record of regular and prompt animal *disease* reporting and, if not FMD free, have an *official control programme* and a *surveillance* system for FMD in place in accordance with Articles 8.8.40. to 8.8.42. that allows knowledge of the prevalence, distribution and characteristics of FMD in the country or zone;
- 2) declare for the FMD free compartment that:
 - a) there has been no case of FMD during the past 12 months;
 - b) no evidence of *infection* with FMDV has been found during the past 12 months;
 - c) *vaccination* against FMD is prohibited;
 - d) no animal vaccinated against FMD within the past 12 months is in the *compartment*;
 - e) animals, semen, embryos and animal products may only enter the *compartment* in accordance with relevant articles in this chapter;
 - f) documented evidence shows that *surveillance* in accordance with Articles 8.8.40. to 8.8.42. is in operation;
 - g) an *animal identification* and *traceability* system in accordance with Chapters 4.1. and 4.2. is in place;
- 3) describe in detail:
 - a) the animal *subpopulation* in the *compartment*;
 - b) the *biosecurity plan* to mitigate the risks identified by the *surveillance* carried out in accordance with point 1.

Annex 30 (contd)

The *compartment* should be approved by the *Veterinary Authority*. The **first** approval should only be granted when no case of FMD has occurred within a 10-kilometre radius of the *compartment* during the **past** three months prior to the effective establishment of the *biosecurity plan*.

Article 8.8.4bis.Compartment free from FMD where vaccination is practised

A *compartment* free from FMD where *vaccination* is practised can be established in either a free country or *zone* where *vaccination* is practised or in an infected country or *zone*. In defining such a *compartment* the principles of Chapters 4.3. and 4.4. should be followed. Susceptible animals in the free *compartment* should be separated from any other susceptible animals by the application of an effective *biosecurity plan*.

A Member Country wishing to establish a *compartment* free from FMD where *vaccination* is practised should:

- 1) have a record of regular and prompt animal *disease* reporting and, if not free, have an *official control programme* and a *surveillance* system for FMD in place in accordance with Articles 8.8.40. to 8.8.42. that allows knowledge of the prevalence, distribution and characteristics of FMD in the country or *zone*;
- 2) declare for the free *compartment* where *vaccination* is practised that:
 - a) there has been no case of FMD during the past 12 months;
 - b) no evidence of *infection* with FMDV has been found during the past 12 months;
 - c) compulsory systematic *vaccination* is carried out using a vaccine that complies with the standards described in the *Terrestrial Manual*, including appropriate vaccine strain selection. The *vaccination coverage* and *population immunity* are closely monitored;
 - d) animals, semen, embryos and animal products may only enter the *compartment* in accordance with relevant articles in this chapter;
 - e) documented evidence shows that regular clinical, serological and virological *surveillance* in accordance with Articles 8.8.40. to 8.8.42. is in operation, so as to detect *infection* at an early stage with a high level of confidence;
 - f) an *animal identification* and *traceability* system in accordance with Chapters 4.1. and 4.2. is in place;
- 3) describe in detail:
 - a) the animal *subpopulation* in the *compartment*;
 - b) the *biosecurity plan* to mitigate the risks identified by the *surveillance* carried out according to point 1) and the *vaccination plan*;
 - c) implementation of points 2c), 2e) and 2f).

The *compartment* should be approved by the *Veterinary Authority*. The approval should only be granted when no case of FMD has occurred within a 10-kilometre radius of the *compartment* during the three months prior to the effective establishment of the *biosecurity plan*.

Article 8.8.5.

FMD-infected Country or zone infected with FMDV

For the purposes of this chapter, a ~~FMD-infected~~ country or *zone* infected with FMDV is one that does not fulfil the requirements to qualify as either ~~FMD~~ free where *vaccination* is not practised or ~~FMD~~ free where *vaccination* is practised.

Article 8.8.6.

Establishment of a containment zone within a ~~FMD-free~~ country or zone free from FMD

In the event of limited *outbreaks* within a ~~FMD-free~~ country or zone previously free from FMD, including within a *protection zone*, with or without *vaccination*, a single *containment zone*, which includes all *outbreaks*, may be established for the purpose of minimising the impact on the entire country or *zone*.

For this to be achieved and for the Member Country to take full advantage of this process, the *Veterinary Authority* should submit as soon as possible to the OIE, in support of the application, documented evidence that:

- 1) on suspicion, a strict standstill has been imposed on the suspected *establishments* and in the country or *zone* animal movement control has been imposed and effective controls on the movement of other *commodities* mentioned in this chapter are in place;
- 2) on confirmation, an additional standstill of susceptible animals has been imposed in the entire *containment zone* and the movement controls described in point 1 have been reinforced;
- 3) the definitive boundaries of the *containment zone* have been established after an epidemiological investigation (trace-back, trace-forward) has demonstrated that the *outbreaks* are epidemiologically related and limited in number and geographic distribution;
- 4) investigations into the likely source of the *outbreaks* have been carried out;
- 5) a *stamping-out policy*, with or without the use of emergency *vaccination*, has been applied;
- 6) no new cases have been found in the *containment zone* within a minimum of two *incubation periods* as defined in Article 8.8.1. after the application of a *stamping-out policy* to the last detected case;
- 7) the susceptible domestic and *captive wild* animal populations within the *containment zone* are clearly identified as belonging to the *containment zone*;
- 8) *surveillance* in accordance with Articles 8.8.40. to 8.8.42. is in place in the *containment zone* and in the rest of the country or *zone*;
- 9) measures that prevent the spread of FMDV to the rest of the country or *zone*, taking into consideration physical and geographical barriers, are in place.

The free status of the areas outside the *containment zone* is suspended while the *containment zone* is being established. The free status of these areas may be reinstated irrespective of the provisions of Article 8.8.7., once the *containment zone* has been approved by the OIE as complying with points 1 to 9 above. *Commodities* from susceptible animals for *international trade* should be identified as to their origin, either from inside or outside the *containment zone*.

In the event of recurrence of *infection* with FMDV in unvaccinated animals or ~~FMDV~~ transmission of FMDV in vaccinated animals in the *containment zone*, the approval of the *containment zone* is withdrawn and the FMD status of the whole country or *zone* is suspended until the relevant requirements of Article 8.8.7. are fulfilled.

The recovery of the ~~FMD~~ free status of the *containment zone* should be achieved within 12 months of its approval and follow the provisions of Article 8.8.7.

Article 8.8.7.

Recovery of free status (see Figures 1 and 2)

- 1) When a FMD case occurs in a ~~FMD-free~~ country or *zone* previously free from FMD where *vaccination* is not practised, one of the following waiting periods is required to regain this free status:

Annex 30 (contd)

- a) three months after the disposal of the last animal killed where a *stamping-out policy*, without emergency *vaccination*, and *surveillance* are applied in accordance with Articles 8.8.40. to 8.8.42.; or
- b) three months after the disposal of the last animal killed or the *slaughter* of all vaccinated animals, whichever occurred last, where a *stamping-out policy*, emergency *vaccination* and *surveillance* in accordance with Articles 8.8.40. to 8.8.42. are applied; or
- c) six months after the disposal of the last animal killed or the last *vaccination*, whichever occurred last, where a *stamping-out policy*, emergency *vaccination* not followed by the slaughtering of all vaccinated animals, and *surveillance* in accordance with Articles 8.8.40. to 8.8.42. are applied. However, this requires a serological survey based on the detection of antibodies to nonstructural proteins of FMDV to demonstrate no evidence of *infection* in the remaining vaccinated population. This period can be reduced to three months if effectiveness of vaccination is demonstrated by a serological survey and serological surveillance for antibodies to nonstructural proteins is carried out in all vaccinated herds by sampling all vaccinated ruminants and their unvaccinated offspring, and a representative number of FMD susceptible animals of other species.

The country or *zone* will regain the its free status of FMD free country or zone where vaccination is not practised only after the submitted evidence, based on the provisions of Article 1.6.6., has been accepted by the OIE.

The time periods in points 1a) to 1c) are not affected if official emergency *vaccination* of zoological collections has been carried out following the relevant provisions of Article 8.8.2.

Where a *stamping-out policy* is not practised, the above waiting periods do not apply, and Article 8.8.2. applies.

- 2) When a ~~FMD~~ case of FMD occurs in a ~~FMD free~~ country or *zone* previously free from FMD where *vaccination* is not practised, the following waiting period is required to gain the status of ~~FMD free~~ country or *zone* free from FMD where *vaccination* is practised: six months after the disposal of the last animal killed where a *stamping-out policy* has been applied and a continued *vaccination* policy has been adopted, provided that *surveillance* is applied in accordance with Articles 8.8.40. to 8.8.42., and a serological survey based on the detection of antibodies to nonstructural proteins of FMDV demonstrates no evidence of ~~FMDV~~ transmission of FMDV.

The country or *zone* can gain the status of ~~FMD free country or zone~~ from FMD where *vaccination* is practised only after the submitted evidence, based on the provisions of Article 1.6.6., has been accepted by the OIE.

Where a *stamping-out policy* is not practised, the above waiting periods do not apply, and Article 8.8.3. applies.

- 3) When a case of infection with FMDV occurs in a ~~FMD free~~ country or *zone* previously free from FMD where *vaccination* is practised, one of the following waiting periods is required to regain this free status:
 - a) six months after the disposal of the last animal killed where a *stamping-out policy*, with emergency *vaccination*, and *surveillance* in accordance with Articles 8.8.40. to 8.8.42. are applied, provided that serological *surveillance* based on the detection of antibodies to nonstructural proteins of FMDV demonstrates no evidence of ~~virus~~ transmission of FMDV; or
 - b) 12 months after the detection of the last case where a *stamping-out policy* is not applied, but where emergency *vaccination* and *surveillance* in accordance with Articles 8.8.40. to 8.8.42. are applied, provided that serological *surveillance* based on the detection of antibodies to nonstructural proteins of FMDV demonstrates no evidence of ~~virus~~ transmission of FMDV.

The country or zone will regain its free status only after the submitted evidence, based on the provisions of Article 1.6.6., has been accepted by the OIE.

Annex 30 (contd)

When ~~re~~ emergency *vaccination* is not applied, the above waiting periods do not apply, and Article 8.8.3. applies.

~~The country or zone will regain the status of FMD free country or zone where vaccination is practised only after the submitted evidence, based on the provisions of Article 1.6.6., has been accepted by the OIE.~~

- 4) When a ~~FMD~~ case of infection with FMDV occurs in a ~~FMD free compartment free from FMD,~~ Article 8.8.4. or Article 8.8.4bis. applies.
- 5) Member Countries applying for the recovery of status should do so only when the respective requirements for the recovery of status are met. When a *containment zone* has been established, the restrictions within the *containment zone* should be lifted in accordance with the requirements of this article only when ~~the disease~~ FMD has been successfully eradicated within the *containment zone*.

For Member Countries not applying for recovery within 24 months after suspension, the provisions of Article 8.8.2., Article 8.8.3. or Article 8.8.4. apply.

Article 8.8.8.

Direct transfer of FMD susceptible animals from an infected zone for slaughter in a free zone (whether vaccination is practised or not)

In order not to jeopardise the status of a free *zone*, FMD susceptible animals should only leave the infected *zone* if transported directly ~~to~~ for *slaughter* in the nearest designated *slaughterhouse/abattoir* under the following conditions:

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

The animals should have been subjected to ante- and post-mortem inspection within 24 hours before and after *slaughter* with no evidence of FMD, and the *meat* derived from them treated in accordance with point 2 of Article 8.8.22. or Article 8.8.23. Other products obtained from the animals and any products coming into contact with them should be treated in accordance with Articles 8.8.31. to 8.8.38. in order to destroy any FMDV potentially present.

Article 8.8.9.

Direct transfer of FMD susceptible animals from a containment zone for slaughter in a free zone (whether vaccination is practised or not)

In order not to jeopardise the status of a free *zone*, FMD susceptible animals should only leave the *containment zone* if transported directly ~~to~~ for *slaughter* in the nearest designated *slaughterhouse/abattoir* under the following conditions:

Annex 30 (contd)

- 1) the *containment zone* has been officially established in accordance with the requirements in Article 8.8.6.;
- 2) the animals ~~should be~~ are transported under the supervision of the *Veterinary Authority* in a *vehicle*, which was cleansed and disinfected before *loading*, directly from the *establishment* of origin to the *slaughterhouse/abattoir* without coming into contact with other susceptible animals;
- 3) such an *slaughterhouse/abattoir* is not approved for the export of *fresh meat* during the time it is handling the *meat* of animals from the *containment zone*;
- 4) *vehicles* and the *slaughterhouse/abattoir* ~~should be~~ are subjected to thorough cleansing and *disinfection* immediately after use.

The animals should have been subjected to ante- and post-mortem inspection within 24 hours before and after *slaughter* with no evidence of FMD and the *meat* derived from them treated in accordance with point 2 of Article 8.8.22. or Article 8.8.23. Other products obtained from the animals and any products coming into contact with them should be treated in accordance with Articles 8.8.31. to 8.8.38. in order to destroy any FMDV potentially present.

Article 8.8.9bis.Direct transfer of FMD vaccinated animals from a free zone where vaccination is practised or not for slaughter in a free zone where vaccination is not practised

In order not to jeopardise the status of a free zone where vaccination is not practised, FMD vaccinated animals should only leave the free zone if transported directly for slaughter in the nearest designated slaughterhouse/abattoir under the following conditions:

- 1) no animal in the establishment of origin has shown clinical signs of FMD for at least 30 days prior to movement;
- 2) the animals were kept in the country or zone of origin for at least three months prior to movement;
- 3) the animals are transported under the supervision of the Veterinary Authority in a vehicle, directly from the establishment of origin to the slaughterhouse/abattoir;
- 4) if transiting an infected zone, were not exposed to any source of FMDV during transportation to the place of shipment.

Article 8.8.10.

Recommendations for importation from FMD-free countries, or zones or compartments free from FMD where vaccination is not practised or FMD-free compartments free from FMDFor FMD susceptible animals

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

- 1) showed no clinical sign of FMD on the day of shipment;
- 2) were kept since birth or for at least the past three months in a ~~FMD-free~~ country or zone free from FMD where *vaccination* is not practised or a ~~FMD-free~~ compartment free from FMD;
- 3) if transiting an infected zone, were not exposed to any source of FMDV during transportation to the *place of shipment*;
- 4) if previously vaccinated, comply with point 4 of Article 8.8.11.

Article 8.8.11.

Recommendations for importation from ~~FMD-free countries~~, ~~or~~ zones or compartments free from FMD where vaccination is practised

For domestic ruminants and pigs

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

- 1) showed no clinical sign of FMD on the day of shipment;
- 2) were kept since birth or for at least the past three months in a ~~FMD-free~~ country or zone free from FMD where *vaccination* is practised;
- 3) if not vaccinated were subjected to a virological and serological tests for FMD with negative results;
- 4) if vaccinated were subjected to virological and NSP serological tests for FMD with negative results:
- 5) if transiting an infected zone, were not exposed to any source of FMDV during transportation to the *place of shipment*.

Article 8.8.11bis.

Recommendations for the importation from a free country, zone or compartment where vaccination is practised

For vaccinated animals destined for slaughter

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

- 1) no animal in the establishment of origin has shown clinical signs of FMD for at least 30 days prior to shipment;
- 2) the animals were kept in the country, zone or compartment of origin since birth or for at least three months prior to shipment;
- 3) the animals were transported under the supervision of the *Veterinary Authority* directly from the establishment of origin in sealed vehicles/vessels;
- 4) if transiting an infected zone, were not exposed to any source of FMDV during transportation to the place of shipment.

Article 8.8.12.

Recommendations for importation from ~~FMD-infected~~ countries or zones infected with FMDV, where an official control programme exists

For domestic ruminants and pigs

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

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

Annex 30 (contd)

- 2) pigs have not been fed swill not complying with Article 8.8.31bis.;
- 32) prior to isolation, the animals were kept in the *establishment* of origin:
- a) for 30 days, or since birth if younger than 30 days, if a *stamping-out policy* is applied to control FMD in the *exporting country or zone*, or
 - b) for three months, or since birth if younger than three months if a *stamping-out policy* is not applied to control FMD in the *exporting country or zone*;
- 43) the establishment of origin is covered by the official control programme and FMD has not occurred within it the establishment of origin for the relevant period as defined in points 2a) and 2b) above;
- 54) the animals were isolated in an *establishment* for the 30 days prior to shipment, and all animals in isolation were subjected to diagnostic virological and serological tests for evidence of FMDV with negative results on samples collected at least 28 days after the start of isolation period, and that FMD did not occur within a 10 kilometre radius of the *establishment* during that period, or the *establishment* is a *quarantine station*;
- 65) the animals were not exposed to any source of FMDV during their transportation from the *establishment* to the *place of shipment*.

Article 8.8.13.

Recommendations for importation from ~~FMD-free~~ countries or zones free from FMD where vaccination is not practised or ~~FMD-free~~ compartments free from FMD

For fresh semen of domestic ruminants and pigs

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

- 1) the donor males:
 - a) showed no clinical sign of FMD on the day of collection of the semen;
 - b) were kept for at least three months prior to collection in a ~~FMD-free~~ country or zone free from FMD where *vaccination* is not practised or ~~FMD-free~~ compartments free from FMD;
 - c) were kept in an *artificial insemination centre* where none of the animals had a history of *infection* with FMDV;
- 2) the semen was collected, processed and stored in accordance with Chapters 4.5. and 4.6.

Article 8.8.14.

Recommendations for importation from ~~FMD-free~~ countries or zones free from FMD where vaccination is not practised or ~~FMD-free~~ compartments free from FMD

For frozen semen of domestic ruminants and pigs

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

Annex 30 (contd)

- 1) the donor males:
 - a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;
 - b) were kept for at least three months prior to collection in a ~~FMD-free~~ country or zone free from FMD where *vaccination* is not practised or ~~FMD-free compartments~~ free from FMD;
- 2) the semen was collected, processed and stored in accordance with Chapters 4.5. and 4.6.

Article 8.8.15.

Recommendations for importation from ~~FMD-free~~ countries or zones free from FMD where *vaccination* is practised

For frozen semen of domestic ruminants and pigs

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

- 1) the donor males:
 - a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;
 - b) were kept for at least three months prior to collection in a ~~FMD-free~~ country or zone free from FMD where *vaccination* is practised;
 - c) either
 - i) have been vaccinated at least twice, with the last *vaccination* not ~~less~~ more than ~~one~~ six months ~~and not more than six months prior to collection~~, unless protective immunity has been demonstrated for more than six months, and not less than one month prior to collection;
 - or
 - ii) were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMDV, with negative results;
- 2) the semen:
 - a) was collected, processed and stored in accordance with Chapters 4.5. and 4.6.;
 - b) was stored in the country of origin for a period of at least one month following collection, and during this period no animal on the *establishment* where the donor ~~animals~~ males were kept showed any sign of FMD.

Article 8.8.16.

Recommendations for importation from ~~FMD-infected~~ countries or zones infected with FMDV

For frozen semen of domestic ruminants and pigs

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

- 1) the donor males:
 - a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;
 - b) were kept in an *artificial insemination centre* ~~where to which~~ no animal had been added in the 30 days before collection, and within a 10 kilometre radius of which, ~~that~~ FMD has not occurred ~~within a 10 kilometre radius of the artificial insemination centre for~~ in the 30 days before and after collection;

Annex 30 (contd)

- c) either
- i) have been vaccinated at least twice, with the last *vaccination* not ~~less~~ more than ~~one~~ six months ~~and not more than six months prior to collection~~, unless protective immunity has been demonstrated for more than six months, and not less than one month prior to collection;
- or
- ii) were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMDV, with negative results;
- 2) the semen:
- a) was collected, processed and stored in accordance with Chapters 4.5. and 4.6.;
 - b) was subjected, with negative results, to a test for evidence of FMDV if the donor male has been vaccinated within the 12 months prior to collection;
 - c) was stored in the country of origin for a period of at least one month following collection, and that during this period no animal on the *establishment* where the donor males were kept showed any sign of FMD.

Article 8.8.17.

Recommendations for the importation of *in vivo* derived embryos of bovines cattle

Irrespective of the FMD status of the *exporting country, zone or compartment*, *Veterinary Authorities* should authorise without restriction on account of FMD the import or transit through their territory of *in vivo* derived embryos of bovines cattle—subject to the presentation of an *international veterinary certificate* attesting that the embryos were collected, processed and stored in accordance with the relevant provisions of Chapters 4.7. and 4.9., as relevant.

Article 8.8.18.

Recommendations for importation from ~~FMD-free~~ countries or zones free from FMD where vaccination is not practised or ~~FMD-free~~ compartments free from FMD

For *in vitro* produced embryos of bovines cattle

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

- 1) the donor females:
 - a) showed no clinical sign of FMD at the time of collection of the oocytes;
 - b) were kept for at least three months prior to collection in a ~~FMD-free~~ country or zone free from FMD where *vaccination* is not practised or ~~FMD-free~~ compartments free from FMD;
- 2) fertilisation was achieved with semen meeting the conditions referred to in Articles 8.8.13., 8.8.14., 8.8.15. or 8.8.16., as relevant;
- 3) the oocytes were collected, and the embryos were processed and stored in accordance with Chapters 4.8. and 4.9., as relevant.

Article 8.8.19.

Recommendations for importation from ~~FMD-free~~ countries or zones free from FMD where vaccination is practisedFor *in vitro* produced embryos of **bovines cattle**

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

- 1) the donor females:
 - a) showed no clinical sign of FMD at the time of collection of the oocytes;
 - b) were kept for at least three months prior to collection in a ~~FMD-free~~ country or zone free from FMD where *vaccination* is practised;
 - c) either
 - i) have been vaccinated at least twice, with the last *vaccination* not ~~less~~ more than ~~one~~ six months ~~and not more than six months prior to collection~~, unless protective immunity has been demonstrated for more than six months, and not less than one month prior to collection;
 - or
 - ii) were subjected, not less than 21 days after collection, to tests for antibodies against FMDV, with negative results;
- 2) fertilisation was achieved with semen meeting the conditions referred to in Articles 8.8.13., 8.8.14., 8.8.15. or 8.8.16., as relevant;
- 3) the oocytes were collected, and the embryos were processed and stored in accordance with Chapters 4.8. and 4.9., as relevant.

Article 8.8.20.

Recommendations for importation from ~~FMD-free~~ countries or zones free from FMD where vaccination is not practised or ~~FMD-free~~ compartments free from FMDFor fresh meat or meat products of FMD susceptible animals

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

- 1) have been kept in a ~~FMD-free~~ country or zone free from FMD, where *vaccination* is not practised or ~~FMD free compartment free from FMD~~, or ~~which~~ have been imported in accordance with Article 8.8.10., Article 8.8.11. or Article 8.8.12.;
- 2) have been slaughtered in an approved *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections with favourable results.

Article 8.8.21.

Recommendations for importation from ~~FMD-free~~ countries or zones free from FMD where vaccination is practisedFor fresh meat and meat products of ruminants and pigs

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

Annex 30 (contd)

- 1) have been kept in the ~~FMD-free~~ country or zone free from FMD where *vaccination* is practised, or which have been imported in accordance with Article 8.8.10., Article 8.8.11. or Article 8.8.12.;
- 2) have been slaughtered in an approved *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections ~~for FMD~~ with favourable results;
- 3) for ruminants the head, including the pharynx, tongue and associated lymph nodes, has been excluded from the shipment.

Article 8.8.22.

Recommendations for importation from ~~FMD-infected~~ countries or zones infected with FMDV, where an official control programme exists

For fresh meat of bovines cattle and water buffaloes (*Bubalus bubalis*) (excluding feet, head and viscera)

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

- 1) comes from animals which:
 - a) have remained, for at least three months prior to *slaughter*, in a *zone* of the *exporting country* where bovines cattle and water buffaloes are regularly vaccinated against FMD and where an *official control programme* is in operation;
 - b) have been vaccinated at least twice with the last *vaccination* not more than six months, unless protective immunity has been demonstrated for more than six months, and not less than one month prior to *slaughter*;
 - c) were kept for the past 30 days in:
 - = a quarantine station; or in
 - = an establishment, within a ten-kilometre radius of which ~~and that FMD has not occurred within a 40 kilometre radius of the establishment during that period, or the establishment is a quarantine station;~~
 - d) have been transported, in a *vehicle* which was cleansed and disinfected before the bovines cattle and water buffaloes were loaded, directly from the *establishment* of origin or *quarantine station* to the approved *slaughterhouse/abattoir* without coming into contact with other FMD susceptible animals which do not fulfil the required conditions for export;
 - e) have been slaughtered in an approved *slaughterhouse/abattoir*.
 - i) which is officially designated for export;
 - ii) in which no FMD has been detected during the period between the last *disinfection* carried out before *slaughter* and the shipment for export has been dispatched;
 - f) were subjected to ante- and post-mortem inspections in accordance with Chapter 6.2., with favourable results have been subjected, with favourable results, to ante mortem inspection within 24 hours of slaughter and to post mortem inspections within 24 hours before and after slaughter with no evidence of FMD;

- 2) comes from deboned carcasses:
 - a) from which the major lymphatic nodes have been removed;
 - b) which, prior to deboning, have been submitted to maturation at a temperature greater than + 2°C for a minimum period of 24 hours following *slaughter* and in which the pH value was less than 6.0 when tested in the middle of both the longissimus dorsi muscle.

Article 8.8.22bis.

Recommendations for importation from countries or zones infected with FMDV, where an official control programme exists

For fresh meat of domestic pigs

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

- 1) the *meat* comes from animals complying with points 1 to 6 of Article 8.8.12.;
- 2) the animals were transported, in a *vehicle* which was cleaned and disinfected before the pigs were loaded, directly from the *establishment* of origin or *quarantine station* to the approved *slaughterhouse/abattoir* without coming into contact with other FMD susceptible animals that do not fulfil the conditions required for export, either during transport or at the *slaughterhouse/abattoir*;
- 3) the animals were slaughtered in an approved *slaughterhouse/abattoir*.
 - a) which is officially designated for export;
 - b) in which no FMD has been detected during the period between the last *disinfection* carried out before *slaughter* and the shipment for export has been dispatched;
- 4) the animals were subjected to ante- and post-mortem inspections in accordance with Chapter 6.2., with favourable results;
- 5) the carcasses were not released earlier than 24 hours after *slaughter* and not before *Veterinary Authorities* have confirmed that FMD has not occurred in the *establishment* of origin.

Article 8.8.23.

Recommendations for importation from ~~FMD-infected~~ countries or zones infected with FMDV

For meat products of FMD susceptible animals

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

- 1) the entire consignment of *meat products* come from animals which have been slaughtered in an approved *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections ~~for FMD~~ with favourable results;
- 2) the *meat products* have been processed to ensure the destruction of FMDV in accordance with one of the procedures in Article 8.8.31.;
- 3) the necessary precautions were taken after processing to avoid contact of the *meat products* with any potential source of FMDV.

Annex 30 (contd)

Article 8.8.24.

Recommendations for importation from ~~FMD-free~~ countries or zones free from FMD where whether vaccination ~~either is practised or is not practised~~ or ~~FMD-free~~ compartments free from FMD

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

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products come from animals which have been kept in a ~~FMD-free~~ country, zone or compartment free from FMD, or which have been imported in accordance with Article 8.8.10., Article 8.8.11. or Article 8.8.12.

Article 8.8.25.

Recommendations for importation from ~~FMD-infected~~ countries or zones infected with FMDV, where an official control programme exists

For milk and milk products

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

- 1) these products:
 - a) originate from *establishments* which were not infected or suspected of being infected with FMD at the time of *milk* collection;
 - b) have been processed to ensure the destruction of FMDV in accordance with one of the procedures in Article 8.8.35. and in Article 8.8.36.;
- 2) the necessary precautions were taken after processing to avoid contact of the products with any potential source of FMDV.

Article 8.8.26.

Recommendations for importation from ~~FMD-infected~~ countries or zones infected with FMDV

For blood-meal and meat-meals from FMD susceptible animals

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

- 1) the manufacturing method for these products included heating to a minimum core temperature of 70°C for at least 30 minutes;
- 2) the necessary precautions were taken after processing to avoid contact of the products with any potential source of FMDV.

Article 8.8.27.

Recommendations for importation from ~~FMD-infected~~ countries or zones infected with FMDV

For wool, hair, bristles, raw hides and skins from FMD susceptible animals

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

- 1) these products have been processed to ensure the destruction of FMDV in accordance with one of the procedures in Articles 8.8.32., 8.8.33. and 8.8.34.;
- 2) the necessary precautions were taken after collection or processing to avoid contact of the products with any potential source of FMDV.

Annex 30 (contd)

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

Article 8.8.28.

Recommendations for importation from ~~FMD-infected~~ countries or zones infected with FMDV

For straw and forage

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

- 1) are free of grossly identified contamination with material of animal origin;
- 2) have been subjected to one of the following treatments, which, in the case of material sent in bales, has been shown to penetrate to the centre of the bale:
 - a) either to the action of steam in a closed chamber such that the centre of the bales has reached a minimum temperature of 80°C for at least ~~ten~~ 10 minutes,
 - b) or to the action of formalin fumes (formaldehyde gas) produced by its commercial solution at 35-40% in a chamber kept closed for at least eight hours and at a minimum temperature of 19°C;

OR

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

Article 8.8.29.

Recommendations for importation from ~~FMD-free~~ countries or zones free from FMD, where whether vaccination either is practised or is not practised

For skins and trophies derived from FMD susceptible wildlife

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products are derived from animals that have been killed in ~~such~~ a country or zone free from FMD or which have been imported from a country, zone or compartment free from FMD.

Article 8.8.30.

Recommendations for importation from ~~FMD-infected~~ countries or zones infected with FMDV

For skins and trophies derived from FMD susceptible wildlife

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products have been processed to ensure the destruction of FMDV in accordance with the procedures in Article 8.8.37.

Article 8.8.31.

Procedures for the inactivation of FMDV in meat and meat products

For the inactivation of FMDV present in *meat* and *meat products*, one of the following procedures should be used:

Annex 30 (contd)1. Canning

Meat and *meat products* are subjected to heat treatment in a hermetically sealed container to reach an internal core temperature of at least 70°C for a minimum of 30 minutes or to any equivalent treatment which has been demonstrated to inactivate FMDV.

2. Thorough cooking

Meat, previously deboned and defatted, and *meat products* are subjected to a heat treatment that results in a core temperature of at least 70°C for a minimum of 30 minutes.

After cooking, they should be packed and handled in such a way they are not exposed to a source of FMDV.

3. Drying after salting

When *rigor mortis* is complete, the *meat* is deboned, treated with salt (NaCl) and 'completely dried'. It should not deteriorate at ambient temperature.

'Completely dried' is defined as a moisture protein ratio that is not greater than 2.25:1 or a water activity (Aw) that is not greater than 0.85.

Article 8.8.31bis.**Procedures for the inactivation of FMDV in swill**

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

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

Article 8.8.32.

Procedures for the inactivation of FMDV in wool and hair

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

- 1) for wool, industrial washing, which consists of the immersion of the wool in a series of baths of water, soap and sodium hydroxide (~~soda~~ NaOH) or potassium hydroxide (~~potash~~ KOH);
- 2) chemical depilation by means of slaked lime or sodium sulphide;
- 3) fumigation with formaldehyde in a hermetically sealed chamber for at least 24 hours;
- 4) for wool, industrial scouring which consists of the immersion of wool in a water-soluble detergent held at 60-70°C;
- 5) for wool, storage of wool at 4°C for four months, 18°C for four weeks or 37°C for eight days.

Article 8.8.33.

Procedures for the inactivation of FMDV in bristles

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

Annex 30 (contd)

- 1) boiling for at least one hour; or
- 2) immersion for at least 24 hours in a 1% aqueous solution of formaldehyde.

Article 8.8.34.

Procedures for the inactivation of FMDV in raw hides and skins

For the inactivation of FMDV present in raw hides and skins for industrial use, the following procedure should be used: treatment for at least 28 days with salt (NaCl) containing 2% sodium carbonate (Na₂CO₃).

Article 8.8.35.

Procedures for the inactivation of FMDV in milk and cream for human consumption

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

- 1) a process applying a minimum temperature of 132°C for at least one second (ultra-high temperature [UHT])⁷² or
- 2) if the *milk* has a pH less than 7.0, a process applying a minimum temperature of 72°C for at least 15 seconds (high temperature - short time pasteurisation [HTST])⁷³ or
- 3) if the *milk* has a pH of 7.0 or greater, the HTST process applied twice.

Article 8.8.36.

Procedures for the inactivation of FMDV in milk for animal consumption

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

- 1) the HTST process applied twice; or
- 2) HTST combined with another physical treatment, e.g. maintaining a pH 6 for at least one hour or additional heating to at least 72°C combined with desiccation; or
- 3) UHT combined with another physical treatment referred to in point 2 above.

Article 8.8.37.

Procedures for the inactivation of FMDV in skins and trophies from susceptible wildlife ~~susceptible to the disease~~

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

- 1) boiling in water for an appropriate time so as to ensure that any matter other than bone, horns, hooves, claws, antlers or teeth is removed; or
- 2) gamma irradiation at a dose of at least 20 kiloGray at room temperature (20°C or higher); or
- 3) soaking, with agitation, in a 4% (weight/volume) solution of sodium carbonate (Na₂CO₃) maintained at pH 11.5 or greater for at least 48 hours; or
- 4) soaking, with agitation, in a formic acid solution (100 kg salt [NaCl] and 12 kg formic acid per 1,000 litres water) maintained at pH less than 3.0 for at least 48 hours; wetting and dressing agents may be added; or
- 5) in the case of raw hides, treating for at least 28 days with salt (NaCl) containing 2% sodium carbonate (Na₂CO₃).

Annex 30 (contd)

Article 8.8.38.

Procedures for the inactivation of FMDV in casings of ruminants and pigs

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

Article 8.8.39.

OIE endorsed official control programme for FMD

The overall objective of an OIE endorsed *official control programme* for FMD is for countries to progressively improve the situation and eventually attain FMD free status. The *official control programme* should be applicable to the entire country even if certain measures are directed towards defined *subpopulations* only.

Member Countries may, on a voluntary basis, apply for endorsement of their *official control programme* for FMD when they have implemented measures in accordance with this article.

For a Member Country's *official control programme* for FMD to be endorsed by the OIE, the Member Country should:

- 1) have a record of regular and prompt animal *disease* reporting in accordance with the requirements in Chapter 1.1.;
- 2) submit documented evidence of the capacity of the *Veterinary Services* to control FMD; one way of providing this evidence is through the OIE PVS Pathway;
- 3) submit a detailed plan of the programme to control and eventually eradicate FMD in the country or *zone* including:
 - a) the timeline;
 - b) the performance indicators for assessing the efficacy of the control measures to be implemented;
 - c) documentation indicating that the *official control programme* for FMD is applicable to the entire country;
- 4) submit a dossier on the epidemiology of FMD in the country describing the following:
 - a) the general epidemiology in the country highlighting the current knowledge and gaps and the progress that has been made in controlling FMD;
 - b) the measures implemented to prevent introduction of *infection*, the rapid detection of, and response to, all FMD *outbreaks* in order to reduce the incidence of FMD *outbreaks* and to eliminate ~~FMDV~~ transmission of FMDV in at least one *zone* in the country;
 - c) the main livestock production systems and movement patterns of FMD susceptible animals and their products within and into the country;
- 5) submit evidence that ~~FMD surveillance is in place~~:
 - a) FMD surveillance is in place, taking into account provisions in accordance with Chapter 1.4. and the provisions on *surveillance* of this chapter;
 - b) ~~it has~~ it has diagnostic capability and procedures, including regular submission of samples to a *laboratory* that carries out diagnosis and further characterisation of strains;

- 6) where *vaccination* is practised as a part of the *official control programme* for FMD, provide:
- a) evidence (such as copies of legislation) that *vaccination* of selected populations is compulsory;
 - b) detailed information on *vaccination* campaigns, in particular on:
 - i) target populations for *vaccination*;
 - ii) monitoring of *vaccination* coverage, including serological monitoring of population immunity;
 - iii) technical specification of the vaccines used, including matching with the circulating FMDV strains, and description of the licensing procedures in place;
 - iv) the proposed timeline for the transition to the use of vaccines fully compliant with the standards and methods described in the *Terrestrial Manual*;
- 7) provide an emergency preparedness and response plan to be implemented in case of *outbreaks*.

The Member Country's *official control programme* for FMD will be included in the list of programmes endorsed by the OIE only after the submitted evidence, based on the provisions of Article 1.6.11., has been accepted by the OIE. Retention on the list requires an annual update on the progress of the *official control programme* and information on significant changes concerning the points above. Changes in the epidemiological situation and other significant events should be reported to the OIE in accordance with the requirements in Chapter 1.1.

The OIE may withdraw the endorsement of the *official control programme* if there is evidence of:

- non-compliance with the timelines or performance indicators of the programme; or
- significant problems with the performance of the *Veterinary Services*; or
- an increase in the incidence or an extension of the distribution of FMD that cannot be addressed by the programme.

Article 8.8.40.

General principles of surveillance

Articles 8.8.40. to 8.8.42. define the principles and provide a guide for the *surveillance* of FMD in accordance with Chapter 1.4. applicable to Member Countries seeking establishment, maintenance or recovery of freedom from FMD at the country, *zone* or *compartment* level or seeking endorsement by the OIE of their *official control programme* for FMD, in accordance with Article 8.8.39. *Surveillance* aimed at identifying *disease* and FMDV infection with or transmission of FMDV should cover domestic and, where appropriate, *wildlife* species as indicated in point 2 of Article 8.8.1.

1. Early detection

A *surveillance* system in accordance with Chapter 1.4. should be the responsibility of the *Veterinary Authority* and should provide an early warning system to report suspected *cases* throughout the entire production, marketing and processing chain. A procedure should be in place for the rapid collection and transport of samples to a *laboratory* for FMD diagnosis. This requires that sampling kits and other equipment be available to those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to seek assistance from a team with expertise in FMD diagnosis and control.

Annex 30 (contd)2. Demonstration of freedom

The impact and epidemiology of FMD widely differ in different regions of the world and therefore it is inappropriate to provide specific recommendations for all situations. *Surveillance* strategies employed for demonstrating freedom from FMD in the country, *zone* or *compartment* at an acceptable level of confidence should be adapted to the local situation. For example, the approach to demonstrating freedom from FMD following an *outbreak* caused by a pig-adapted strain of FMDV should differ significantly from an approach designed to demonstrate freedom from FMD in a country or *zone* where African buffaloes (*Syncerus caffer*) provide a potential reservoir of *infection*.

Surveillance for FMD should be in the form of a continuing programme. Programmes to demonstrate no evidence of *infection with FMDV* and transmission of FMDV should be carefully designed and implemented to avoid producing results that are insufficient to be accepted by the OIE or trading partners, or being excessively costly and logistically complicated.

The strategy and design of the *surveillance* programme will depend on the historical epidemiological circumstances including whether ~~or not~~ *vaccination* has been used practised or not.

A Member Country wishing to substantiate FMD freedom where *vaccination* is not practised should demonstrate no evidence of *infection with FMDV*.

A Member Country wishing to substantiate FMD freedom where *vaccination* is practised should demonstrate that FMDV has not been transmitted in any susceptible populations. Within vaccinated populations, serological surveys to demonstrate no evidence of ~~FMDV~~ transmission of FMDV should target animals that are less likely to show vaccine-derived antibodies to nonstructural proteins, such as young animals vaccinated a limited number of times, or unvaccinated animals. In any unvaccinated *subpopulation*, *surveillance* should demonstrate no evidence of *infection with FMDV*.

Surveillance strategies employed for establishing and maintaining a *compartment* should identify the prevalence, distribution and characteristics of FMD outside the *compartment*.

3. OIE endorsed official control programme

Surveillance strategies employed in support of an OIE endorsed *official control programme* should demonstrate evidence of the effectiveness of any *vaccination* used and of the ability to rapidly detect all FMD *outbreaks*.

Therefore considerable latitude is available to Member Countries to design and implement *surveillance* to establish that the whole territory or part of it is free from ~~FMDV~~ *infection with*, and transmission of FMDV and to understand the epidemiology of FMD as part of the *official control programme*.

The Member Country should submit a dossier to the OIE in support of its application that not only explains the epidemiology of FMD in the region concerned but also demonstrates how all the risk factors, including the role of *wildlife*, if appropriate, are identified and managed. This should include provision of scientifically based supporting data.

4. Surveillance strategies

The strategy employed to establish the prevalence of *infection with FMDV* or to substantiate freedom from ~~FMDV~~ *infection with*, or transmission of FMDV may be based on randomised or targeted clinical investigation or sampling at an acceptable level of statistical confidence, as described in Articles 1.4.4. and 1.4.5. If an increased likelihood of *infection* in particular localities or species can be identified, targeted sampling may be appropriate. Clinical inspection may be targeted at particular species likely to exhibit clear clinical signs (e.g. **bovines** **cattle** and pigs). The Member Country should justify the *surveillance* strategy chosen and the frequency of sampling as adequate to detect the presence of ~~FMDV~~ *infection with*, or transmission of FMDV in accordance with Chapter 1.4. and the epidemiological situation.

The design of the sampling strategy should incorporate an epidemiologically appropriate design prevalence. The sample size selected for testing should be adequate to detect *infection* or transmission if it were to occur at a predetermined minimum rate. The sample size and expected *disease* prevalence determine the level of confidence in the results of the survey. The Member Country should justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the prevailing or historical epidemiological situation, in accordance with Chapter 1.4.

5. Follow-up of suspected cases and interpretation of results

An effective *surveillance* system will identify suspected cases that require immediate follow-up and investigation to confirm or exclude that the cause of the condition is FMDV. Samples should be taken and submitted for diagnostic testing, unless the suspected case can be confirmed or ruled out by epidemiological and clinical investigation. 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 animals concerned were subjected during the investigation.

The sensitivity and specificity of the diagnostic tests employed, including the performance of confirmatory tests, are key factors in the design, sample size determination and interpretation of the results obtained. The sensitivity and specificity of the tests used should be validated for the *vaccination* or *infection* history and production class of animals in the target population.

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

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

- characterisation of the existing production systems;
- results of clinical *surveillance* of the suspects and their cohorts;
- description of number of, and protocol for, *vaccinations* performed in the area under assessment;
- *biosecurity* and history of the *establishments* with reactors;
- identification and traceability of animals and control of their movements;
- other parameters of regional significance in historic FMDV transmission of FMDV.

6. Demonstration of population immunity

Following routine *vaccination*, evidence should be provided to demonstrate the effectiveness of the *vaccination* programme such as adequate *vaccination* coverage and population immunity. This can help to reduce reliance on post-*vaccination* surveys for residual *infection* and transmission.

In designing serological surveys to estimate population immunity, blood sample collection should be stratified by age to take account of the number of *vaccinations* the animals have received. The interval between last *vaccination* and sampling depends upon the intended purpose. Sampling at one or two months after *vaccination* provides information on the efficiency of the *vaccination* programme, while sampling before or at the time of revaccination provides information on the duration of immunity. When multivalent vaccines are used, tests should be carried out to determine the antibody level at least for each serotype, if not for each antigen blended into the vaccine. The test cut-off for an acceptable level of antibody should be selected with reference to protective levels demonstrated by vaccine-challenge test results for the antigen concerned. Where the threat from circulating virus has been characterised as resulting from a field virus with significantly different antigenic properties from the vaccine virus, this should be taken into account when interpreting the protective effect of population immunity. Figures for population immunity should be quoted with reference to the total of susceptible animals in a given *subpopulation* and in relation to the subset of vaccinated animals.

Annex 30 (contd)

The entire investigative process should be documented within the *surveillance* programme.

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

Article 8.8.41.

Methods of surveillance1. Clinical surveillance

Farmers and workers who have day-to-day contact with livestock, as well as *veterinary para-professionals*, *veterinarians* and diagnosticians, should report promptly any suspicion of FMD. The *Veterinary Services Authority* should implement programmes to raise awareness among them.

Clinical *surveillance* requires the physical examination of susceptible animals. Although significant emphasis is placed on the diagnostic value of mass serological screening, *surveillance* based on clinical inspection may provide a high level of confidence of detection of *disease* if a sufficient number of clinically susceptible animals is examined at an appropriate frequency and investigations are recorded and quantified.

Clinical examination and diagnostic testing should be applied to clarify the status of suspected cases. Diagnostic testing may confirm clinical suspicion, while clinical *surveillance* may contribute to confirmation of positive laboratory test results. Clinical *surveillance* may be insufficient in *wildlife* and domestic species that usually do not show clinical signs or husbandry systems that do not permit sufficient observations. In such situations, serological *surveillance* should be used. Hunting, capture and non-invasive sampling and observation methods can be used to obtain information and diagnostic samples from *wildlife* species.

2. Virological surveillance

Establishment of the molecular, antigenic and other biological characteristics of the causative virus, as well as its source, is mostly dependent upon clinical *surveillance* to provide samples. FMDV isolates should be sent regularly to an OIE Reference Laboratory.

Virological *surveillance* aims to:

- a) confirm clinically suspected cases;
- b) follow up positive serological results;
- c) characterise isolates for epidemiological studies and vaccine matching;
- d) monitor populations at risk for the presence and transmission of the virus.

3. Serological surveillance

Serological *surveillance* aims to detect antibodies resulting from *infection* or *vaccination* using nonstructural protein tests or structural protein tests.

Serological *surveillance* may be used to:

- a) estimate the prevalence or substantiate freedom from ~~FMDV infection~~ with, or transmission of, FMDV;
- b) monitor population immunity.

Serum collected for other purposes can be used for FMD *surveillance*, provided the principles of survey design described in this chapter are met.

The results of random or targeted serological surveys are important in providing reliable evidence of the FMD situation in a country, *zone* or *compartment*. It is therefore essential that the survey be thoroughly documented.

Article 8.8.42.

The use and interpretation of serological tests (see Figure 3)

The selection and interpretation of serological tests should be considered in the context of the epidemiological situation. Test protocols, reagents, performance characteristics and validation of all tests used should be known. Where combinations of tests are used, the overall test system performance characteristics should also be known.

Animals infected with FMDV produce antibodies to both the structural proteins and the nonstructural proteins of the virus. Vaccinated animals produce antibodies mainly or entirely to the structural proteins of the virus depending upon vaccine purity. The structural protein tests are serotype specific and for optimal sensitivity one should select an antigen or virus closely related to the field strain expected. In unvaccinated populations, structural protein tests may be used to screen sera for evidence of FMDV infection with, or transmission of FMDV or to detect the introduction of vaccinated animals. In vaccinated populations, structural protein tests may be used to monitor the serological response to the *vaccination*.

Nonstructural protein tests may be used to screen sera for evidence of *infection* or transmission of all serotypes of FMDV regardless of the *vaccination* status of the animals provided the vaccines comply with the standards of the *Terrestrial Manual* with respect to purity. However, although animals vaccinated and subsequently infected with FMDV develop antibodies to nonstructural proteins, the levels may be lower than those found in infected animals that have not been vaccinated. To ensure that all animals that had contact with FMDV have seroconverted, it is recommended that for each *vaccination* area samples for nonstructural protein antibody testing are taken not earlier than 30 days after the last case and in any case not earlier than 30 days after the last *vaccination*.

Positive FMDV antibody test results can have four possible causes:

- *infection* with FMDV;
- *vaccination* against FMD;
- maternal antibodies (maternal antibodies in **bovines cattle** are usually found only up to six months of age but in some individuals and in some other species, maternal antibodies can be detected for longer periods);
- non-specific reactivity of the serum in the tests used.

1. Procedure in case of positive test results

The proportion and strength of seropositive reactors should be taken into account when deciding if they are *laboratory* confirmed reactors or further investigation and testing are required.

When false positive results are suspected, seropositive reactors should be retested in the *laboratory* using repeat and confirmatory tests. Tests used for confirmation should be of high diagnostic specificity to minimise false positive test results. The diagnostic sensitivity of the confirmatory test should approach that of the screening test.

All *herds* with at least one ~~laboratory confirmed~~ reactor that has been confirmed in a laboratory should be investigated. The investigation should examine all evidence, which may include the results **of virological tests and** of any further serological tests **that might used to** confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were due to FMDV transmission of FMDV, as well as of virological tests. This investigation should document the status for each positive *herd*. Epidemiological investigation should be continued concurrently.

Clustering of seropositive results within *herds* or within a region should be investigated as it may reflect any of a series of events, including the demographics of the population sampled, vaccinal exposure or the presence of *infection* or transmission. As clustering may signal *infection* or transmission, the investigation of all instances should be incorporated in the survey design.

Paired serology can be used to identify FMDV transmission of FMDV by demonstrating an increase in the number of seropositive animals or an increase in antibody titre at the second sampling.

Annex 30 (contd)

The investigation should include the reactor animals, susceptible animals of the same *epidemiological unit* and susceptible animals that have been in contact or otherwise epidemiologically associated with the reactor animals. The animals sampled should be identified as such and remain in the *establishment* pending test results, should be clearly identified, accessible and should not be vaccinated during the investigations, so that they can be retested after an appropriate period of time. Following clinical examination, a second sample should be taken, after an appropriate time has lapsed, from the animals tested in the initial survey with emphasis on animals in direct contact with the reactors. If the animals are not individually identified, a new serological survey should be carried out in the *establishments* after an appropriate time, repeating the application of the primary survey design. If FMDV is not circulating, the magnitude and prevalence of antibody reactivity observed should not differ in a statistically significant manner from that of the primary sample.

In some circumstances, unvaccinated sentinel animals may also be used. These can be young animals from unvaccinated dams or animals in which maternally conferred immunity has lapsed and preferably of the same species as in the positive sampling units. If other susceptible, unvaccinated animals are present, they could act as sentinels to provide additional serological evidence. The sentinels should be kept in close contact with the animals of the *epidemiological unit* under investigation for at least two *incubation periods*, and if there is no transmission of FMDV, they should will remain serologically negative if FMDV is not circulating.

2. Follow-up of field and laboratory findings

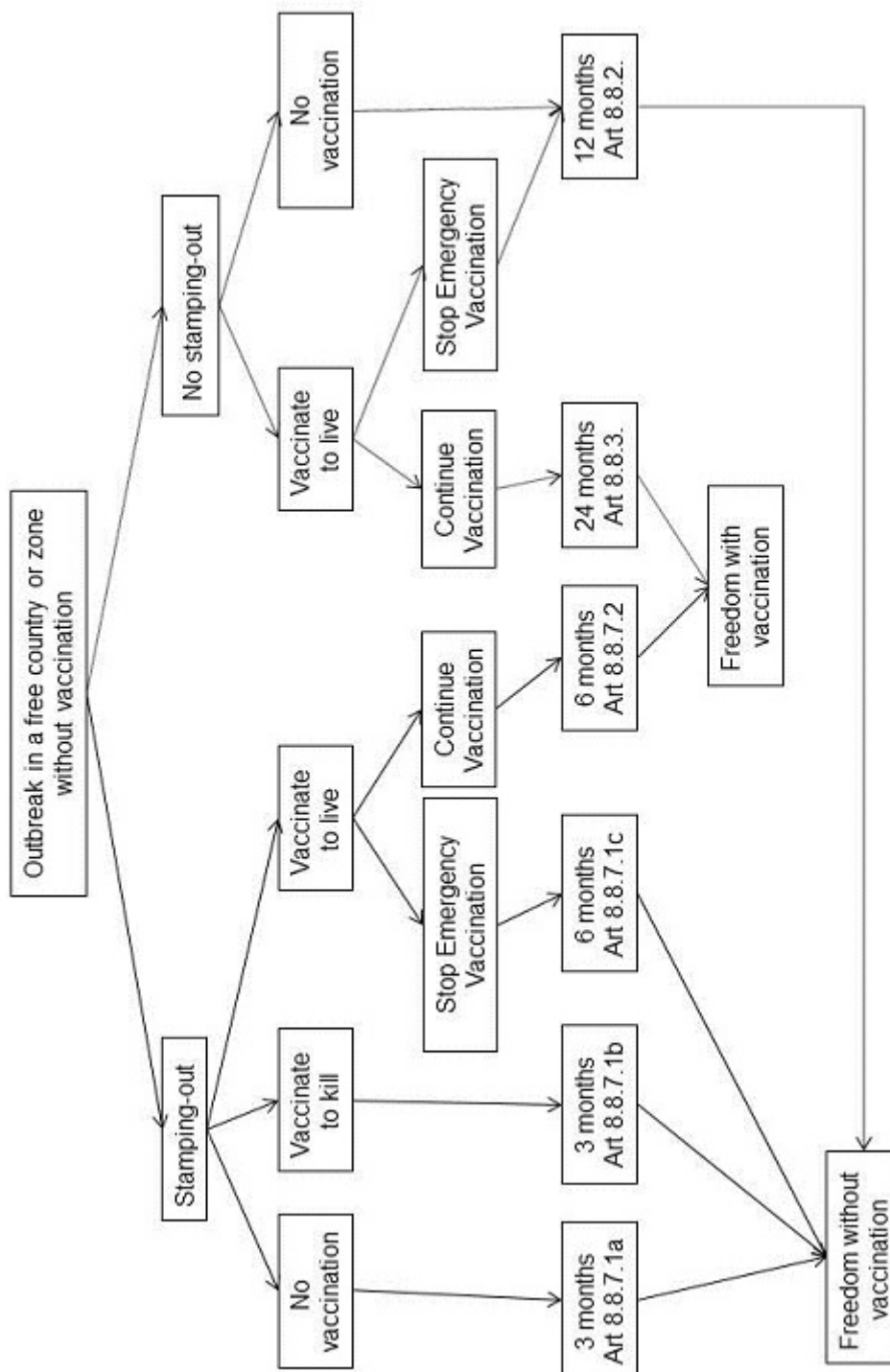
If transmission is demonstrated, an *outbreak* is declared.

It is difficult to determine The significance of small numbers of seropositive animals in the absence of current FMDV transmission is difficult to determine. Such findings may be an indication of past *infection* followed by recovery or by the development of a carrier state, in ruminants, or due to non-specific serological reactions. Antibodies to nonstructural proteins may be induced by repeated *vaccination* with vaccines that do not comply with the requirements for purity. However, the use of such vaccines is not permissible in countries or zones applying for an official status. In the absence of evidence of FMDV infection with, and transmission of, FMDV, such findings do not warrant the declaration of a new *outbreak* and the follow-up investigations may be considered complete.

However, if the number of seropositive animals is greater than the number of false positive results expected from the specificity of the diagnostic tests used, susceptible animals that have been in contact or otherwise epidemiologically associated with the reactor animals should be investigated further.

Abbreviations and acronyms:	
ELISA	Enzyme-linked immunosorbent assay
VNT	Virus neutralisation test
NSP	Nonstructural protein(s) of foot and mouth disease virus (FMDV)
3ABC	NSP antibody test
SP	Structural protein of foot and mouth disease virus

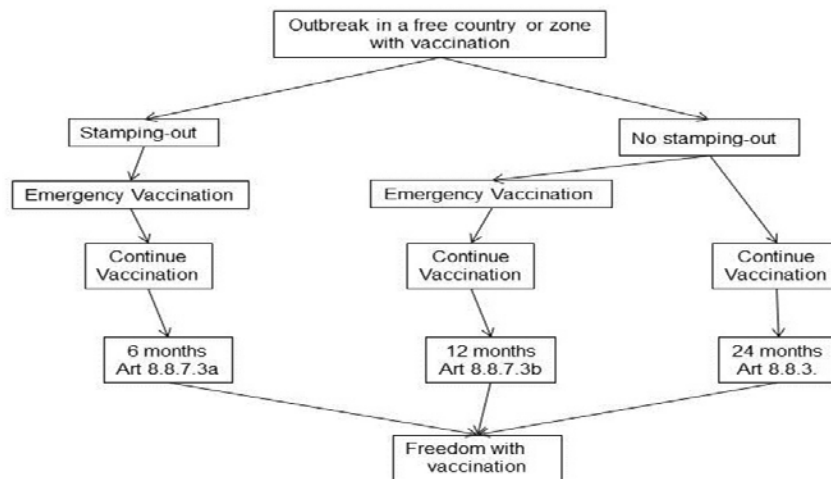
Fig. 1. Schematic representation of the minimum waiting periods and pathways for recovery of FMD free status after an outbreak of FMD in a previously free country or zone where vaccination is not practised



Waiting periods are minima depending upon outcome of *surveillance* specified in respective articles. If there are multiple waiting periods because of different control measures, the longest applies.

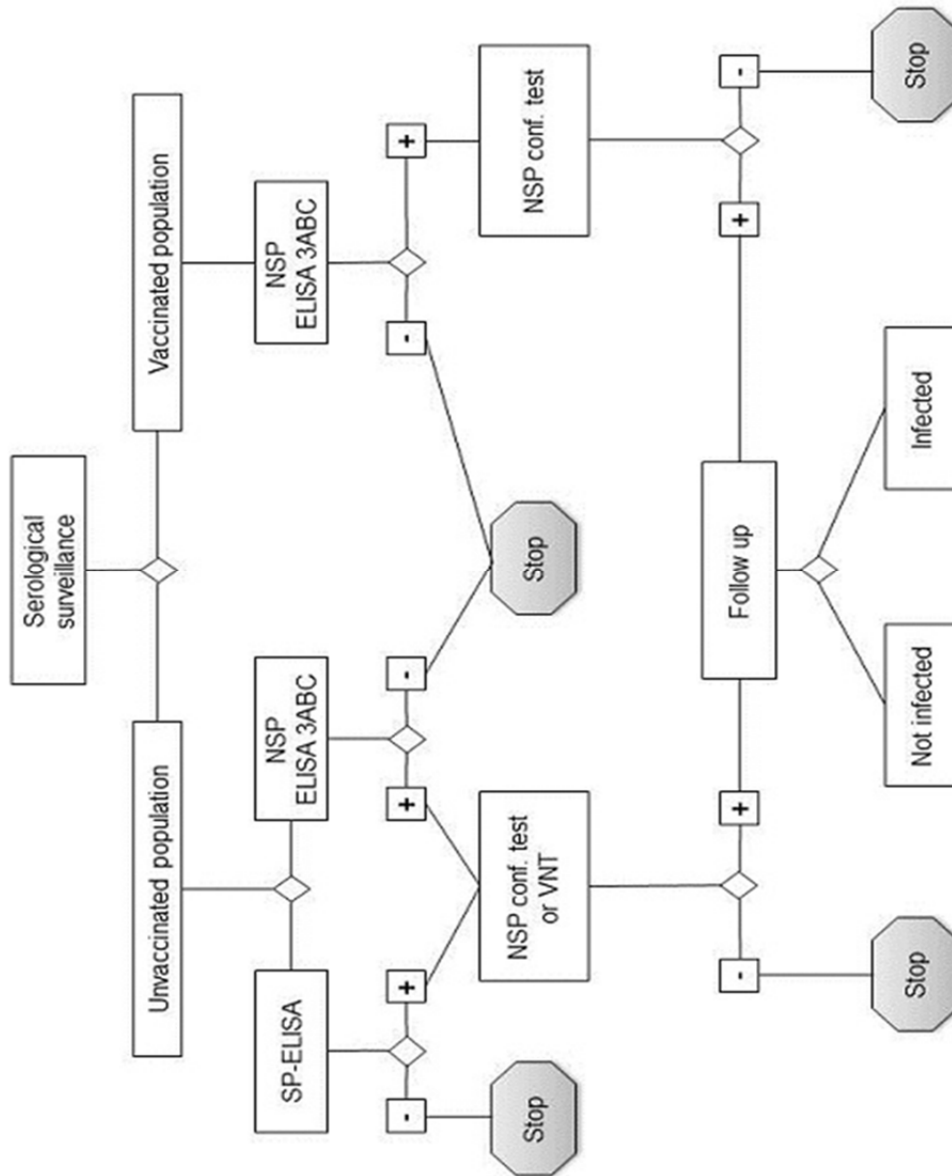
Annex 30 (contd)

Fig. 2. Schematic representation of the minimum waiting periods and pathways for recovery of FMD free status after an outbreak of FMD in a previously free country or zone where vaccination is practised



Waiting periods are minima depending upon outcome of *surveillance* specified in respective articles. If there are multiple waiting periods because of different control measures, the longest applies.

Fig. 3. Schematic representation of laboratory tests for determining evidence of infection with FMDV by means of serological surveys



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SECTION 6. VETERINARY PUBLIC HEALTH

CHAPTER 6.Z.

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 includes all actions directly or indirectly linked with *animals*, their products and by-products, so long as they contribute to protect and improve 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, prevention, control and eradication of *zoonoses*, *animal welfare* and biomedical research.

Veterinary Services play a key role in preventing, mitigating and controlling risks to public health at origin or sources of infection. In particular, *Veterinary Services* contribute to public health in several areas such as 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 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 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 and animal health, including domestic *animals* and *wildlife*, and biodiversity.

Veterinary training and education should take into account the development of these capabilities in the local, regional and global context.

CHAPTER 4.Y.

MANAGEMENT OF OUTBREAKS OF LISTED DISEASES

Article 4.Y.1.

Introduction

When an OIE *listed disease* occurs in a country, *Veterinary Services* should implement a response proportionate to the likely impact of the *disease* and as a result of a *risk analysis*, in order to minimise its spread and consequences and, if possible, eradicate it.

The purpose of this chapter is to provide recommendations to prepare, develop and implement control plans in response to *outbreaks of listed diseases*, including zoonoses. It is not aimed at giving ready-made fit-for-all solutions, but rather at outlining principles to follow when combating animal *diseases* through organised control plans.

Disease control plans should be prepared in advance by the *Veterinary Authority* and *Veterinary Services* disposing of the necessary regulatory, technical and financial tools.

Control plans should be justified by rationales considering animal health, public health, socio-economic, *animal welfare* and environmental aspects.

Control plans should be developed with the aim of achieving defined measurable objectives, in response to a situation in which purely private action is not sufficient. Depending on the prevailing epidemiological, environmental and socio-economic situation, the goal may vary from the reduction of impact to the eradication of a given *disease*.

In any case, the components of plans for management of *outbreaks* are an *early detection system* (including a warning procedure) and quick and effective action. Learning from past *outbreaks* and reviewing the response sequence are critical for better performance in future situations. Plans should be tested regularly to ensure that they are fit-for-purpose, practical, feasible and well-understood and that field staff are trained and other stakeholders fully aware of their role in implementing the response.

Article 4.Y.2.

Legal framework and regulatory environment

- 1) In order to be able to effectively control *listed diseases*, the *Veterinary Authority* should ensure that:
 - the *Veterinary Services* comply with the principles of Chapter 3.1., especially the services dealing with the prevention and control of contagious animal *diseases*, including zoonoses;
 - the *veterinary legislation* complies with the principles of Chapter 3.4.
- 2) In particular, in order for the *Veterinary Services* to be the most effective when combatting animal *disease outbreaks*, the following should be addressed in the *veterinary legislation*:
 - legal powers and structure of command and responsibilities, including responsible officials with defined powers; especially a right of entry to *establishments* or other related enterprises such as live *animal* markets, *slaughterhouses/abattoirs* and animal products processing plants, for regulated purposes of *surveillance* and *disease* control actions, with the possibility of obliging owners to assist;
 - sources of financing for epidemiological enquiries, laboratory diagnostic, disinfectants, insecticides, vaccines and other critical supplies;

Annex 32 (contd)

- sources of financing and compensation policy for livestock and property that may be destroyed as part of *disease control programmes*;
 - coordination with other authorities, especially law enforcement and public health authorities.
- 3) Furthermore, the specific regulations on *disease control policies* should include the following:
- *risk analysis* to identify and prioritise potential *disease risks*, including a regularly updated list of *notifiable diseases*;
 - definitions and procedures for the reporting and management of a suspected case, case, *establishment* suspected of being infected, infected *establishment*, contact *establishment*;
 - definitions and procedures for the declaration and management of *infected zones* and other *zones*, such as *free zones*, *protection zones*, *containment zones*, or less specific ones such as *zones of intensified surveillance*;
 - procedures for the collection, transport and testing of animal samples;
 - procedures for the identification of *animals*;
 - procedures for the restrictions of movements, including possible standstill or compulsory veterinary certification, of relevant *animals* and animal products within, to, or from given *zones* or *establishments* or other related enterprises;
 - procedures for the destruction or *slaughter* and safe disposal or processing of infected or potentially infected *animals*, including relevant *wildlife*, and contaminated or potentially contaminated products and materials;
 - procedures for compensation for the owners of *animals* or animal products, including defined standards and means of implementing such compensation;
 - procedures for cleaning, *disinfection* and disinsection of *establishments* and related premises, *vehicles* or equipment;
 - procedures for the compulsory emergency *vaccination* or treatment of *animals*, as relevant, and for any other necessary *disease control actions*.

Article 4.Y.3.

Preparedness

The *Veterinary Authority* should integrate preparedness planning and practice as one of its core functions. Rapid, effective response to a new occurrence or emergence of contagious *diseases* is dependent on the level of preparedness.

Preparedness should be justified by *risk analysis*, should be planned, and should include training, capacity building and simulation exercises.

1. Risk analysis

Risk analysis, including import *risk analysis*, in accordance with Chapter 2.1., should be used to determine which *diseases* require preparedness planning and to what extent.

A *risk analysis* identifies the pathogenic agents that present the greatest risk and for which preparedness is most important and therefore helps to prioritise the range of *disease* threats and categorise the consequent actions. It also helps to define the best strategies and control options.

The *risk analysis* should be updated regularly to detect changes (e.g. new pathogenic agents, or changes in distribution and virulence of pathogenic agents previously identified as presenting the major *risk* and changes in possible pathways).

2. Planning

Four kinds of plans, describing what governmental or local authorities and all stakeholders should do, comprise any comprehensive preparedness and response system:

- a) a preparedness plan, which outlines what should be done before an *outbreak* of a *notifiable disease* occurs;
- b) a response or contingency plan, which details what should be done in the event of an occurrence of a *notifiable disease*, beginning from the point when a suspected *case* is reported;
- c) a comprehensive set of instructions for field staff and other stakeholders on how to undertake specific tasks required by the response or contingency plan;
- d) a recovery plan for the safe restoration of normal activities, possibly including procedures and practices modified in light of the experience gained during the management of the *outbreak*.

3. Simulation exercises

The *Veterinary Services* and all stakeholders should be made aware of the sequence of measures to be taken in the framework of a contingency plan through the organisation of simulation exercises, mobilising a sufficient number of staff and stakeholders to evaluate the level of preparedness and fill possible gaps in the plan or in staff capacity.

Article 4.Y.4.

Early detection system

- 1) Depending on the priorities identified by the *Veterinary Authority*, *Veterinary Services* should implement adequate *surveillance* for *listed diseases* in accordance with Chapter 1.4. or *disease-specific* chapters, in order to detect suspected *cases* and either rule them out or confirm them. The *surveillance* should be adapted to the epidemiological and environmental situation. *Vector surveillance* should be conducted in accordance with Chapter 1.5.
- 2) In order to implement adequate *surveillance*, the *Veterinary Authority* should have access to good diagnostic capacity. This means that the *veterinarians* and other relevant personnel of the *Veterinary Services* have adequate knowledge of the *disease*, its clinical and pathological manifestation and its epidemiology, and that laboratories approved for the testing of animal samples for the relevant *diseases* are available.
- 3) Suspected *cases* of *notifiable diseases* should be reported without delay to the *Veterinary Authority*, ideally with the following information:
 - the *disease* or pathogenic agent suspected, with brief descriptions of clinical signs or lesions observed, or laboratory test results as relevant;
 - the date when the signs were first noticed at the initial site and any subsequent sites;
 - the names and addresses or geographical locations of *establishments* suspected of being infected or premises;
 - the animal species affected, including possible human cases, and the approximate numbers of sick and dead *animals*;
 - initial actions taken, including *biosecurity* and precautionary movement restrictions of *animals*, products, staff, vehicles and equipment.

Annex 32 (contd)

- 4) Immediately following the report of a suspected case, investigation should be conducted by the *Veterinary Services*, taking into account the following:
- *biosecurity* to be observed when entering and leaving the *establishment*, premises or locality;
 - clinical examinations to be undertaken (number and types of *animals*);
 - samples to be taken from *animals* showing signs or not (number and types of *animals*), with specified sampling and sample handling equipment and sample handling procedures, including for the safety of the investigator and animal owners;
 - procedure for submitting samples for testing;
 - size of the affected *establishment*, premises or locality and possible entry pathways;
 - investigation of the approximate numbers of similar or possibly susceptible *animals* in the *establishment* and its surroundings;
 - details of any recent movements of possibly susceptible *animals* or *vehicles* or people to or from the affected *establishments*, premises or locality;
 - any other relevant epidemiological information, such as presence of the suspected *disease* in *wildlife* or abnormal *vector* activity;

A procedure should be in place for reporting findings to the *Veterinary Authority* and for record keeping.

- 5) All suspected case investigations should provide a result, either positive or negative. Criteria should be established in advance for a case definition. Confirmation can be made on clinical and post-mortem grounds, epidemiological information, laboratory test results or a combination of these, in accordance with relevant articles of the *Terrestrial Code* or *Terrestrial Manual*. Strong suspicion based on supportive, but not definitive, findings should lead to the implementation of local control measures as a precaution. When a case is confirmed, full *sanitary measures* should be implemented as planned.
- 6) When a case of a *listed disease* is detected, *notification* shall be made to the OIE in accordance with Chapter 1.1.

Article 4.Y.5.

General considerations when managing an outbreak

Once an *outbreak* is confirmed, effective *risk management* depends on the application of a combination of measures that are operating at the same time or consecutively, aimed at:

- 1) eliminating the source of pathogenic agent, through:
 - the *killing* or *slaughter* of *animals* infected or suspected of being infected, and safe disposal of dead *animals* and potentially contaminated products;
 - the cleaning, *disinfection* and, if relevant, disinsection of premises and equipment;
- 2) stopping the spread of *infection*, through:
 - movement restrictions on *animals*, *vehicles* and equipment;
 - *biosecurity*;
 - *vaccination*, treatment or culling of *animals* at risk;
 - communication and public awareness.

Different strategies may be chosen depending on the epidemiological, environmental, economic and social situation. The *Veterinary Authority* should assess the situation beforehand and at the time of the *outbreak* detection. For example, the wider the spread of the *disease* and the more locations affected at the beginning of the implementation of the measures, the less likely it will be that culling as a main eradication tool will be effective, and the more likely it will be that other control tools such as *vaccination* or treatment, either in conjunction with culling or alone, will be needed. The involvement of *vectors* or *wildlife* will also have a major influence on the control strategy and different options chosen.

In any case, the management plan should consider the costs of the measures in relation to the benefits expected, and should at least integrate the compensation of owners for losses incurred by the measures.

Article 4.Y.6.

Culling and disposal

Living infected *animals* are the greatest source of pathogenic agents. These *animals* may directly transmit the pathogenic agent to other *animals*, and also lead to indirect *infection* through the contamination of fomites, including breeding and handling equipment, bedding, vehicles, and people's clothing and footwear. Although carcasses may remain contaminated for a period after death, active shedding of the pathogenic agent effectively ceases when the *animal* is killed or slaughtered. Thus, culling of *animals* is often the preferred strategy for the control of contagious *diseases*.

Veterinary Services should adapt any culling strategy to the transmission pathways of the agent. Stamping-out should be the preferred strategy for highly contagious *diseases* and for situations where the country or *zone* was formerly free or freedom was impending, while other strategies, such as test and cull, are better suited to less contagious *diseases* and situations where the *disease* is endemic.

For control measures including destruction of *animals* or products to be most effective, *animal identification* and *animal traceability* should be in place, in accordance with Chapters 4.1. and 4.2.

The *slaughter* or *killing* of *animals* should be performed in accordance with Chapters 7.5. or 7.6., respectively.

The disposal of dead *animals* and their potentially contaminated products should be performed in accordance with Chapter 4.12.

1. Stamping-out

Stamping-out consists primarily in the *killing* of all the *animals* affected or suspected of being affected, including those which have been directly or indirectly exposed to the causal pathogenic agent. This strategy is used for the most contagious *diseases*.

Stamping-out can be limited to the affected *establishments* and, where appropriate, other *establishments* found to be epidemiologically linked with an affected *establishment*, or be broadened to include all *establishments* of a defined *zone*, when pre-emptive depopulation can be used to stop the transmission of a fast spreading pathogenic agent.

Killing should preferably be performed on site, and the carcasses disposed of on site or transported directly and safely to a rendering plant or other dedicated site for destruction. If to be killed outside of the *establishment* or slaughtered, the *animals* should be transported directly to a dedicated *approved* rendering plant or *slaughterhouse/abattoir* respectively, without any possible direct or indirect contacts with other *animals*. Slaughtered *animals* and their products should be processed separately from others.

Stamping-out can be applied to all the animal species present on affected premises, or to all susceptible species, or only to the same species as the affected *animals*.

Annex 32 (contd)

Products originating from killed or slaughtered *animals* (from carcasses, *meat*, *milk* or genetic material to slurry) should be destroyed or processed in a way that inactivates the pathogenic agent. The inactivating process should be carried out in accordance with the relevant articles of the *disease-specific* chapters.

Stamping-out procedures systematically include the cleaning and *disinfection* of *establishments* and *vehicles* used for the transport of *animals*, carcasses or products, as well as of any equipment and material that has been in direct or indirect contact with the *animals*. The procedures may include *disinsection* or *disinfestation* in the case of *vector-borne disease* or parasitic *infestation*. These procedures should be conducted in accordance with the relevant articles of Chapter 4.13.

2. Test and cull

This strategy consists of finding the proven infected *animals* in order to remove them from the population and either *slaughter* or kill and dispose of them. It should be used for less contagious or slow-spreading *diseases*.

Apart from the selection of *animals* to be culled, the same principles apply as for stamping-out in terms of processing, treatment and disposal of dead or slaughtered *animals* and their products.

Article 4.Y.7.

Movement control

Disease spread due to the movement of live *animals*, animal products and contaminated material should be controlled by movement restrictions that are adequately enforced.

These restrictions can be applied to one or more animal species, and to people, vehicles and equipment. They may vary from pre-movement certification to total standstill, and be limited to one or more *establishments*, or cover specific *zones*, or the entire country. The restrictions can include the complete isolation of individual *animals* or group of *animals*, and specific rules applied to movements, such as protection from *vectors*.

Specific rules covering movement controls should apply to each of any defined *zones*. Physical barriers should be installed as needed, to ensure the effective application of movement restrictions.

Movement controls should be in place until the end of other *disease* control operations, e.g. stamping-out, and after *surveillance* has demonstrated they are no longer needed.

Veterinary Services should coordinate their movement control actions with other relevant authorities such as local authorities, law enforcement agencies and communication media, as well as with neighbouring countries in the case of transboundary *diseases*.

Article 4.Y.8.

Biosecurity

In order to avoid the spread of the pathogenic agent outside of the affected *establishments* or *infected zones*, and in addition to the management measures described in Articles 4.Y.5. to 4.Y.7., *biosecurity* should be applied, in particular measures to avoid the contamination of people's clothes and shoes, of *vehicles* and of the environment.

Specific disinfectant solutions should be used for footbaths or disinfectant baths for vehicles' wheels; single use material and clothes should be used for the handling of *animals* and animal products; protection of premises from *wildlife* should be ensured; wastes, waste-water and other effluents should be collected and treated appropriately.

Article 4.Y.9.

Vaccination and treatment

Vaccination in response to a contagious *disease outbreak* should be conducted in accordance with Chapter 4.X.

Annex 32 (contd)

Vaccination in response to an *outbreak* requires previous planning to identify potential sources of vaccine, including vaccine banks, and to plan the possible strategies for application, such as emergency *vaccination* or ring *vaccination*.

The properties of the vaccines should be well understood, especially the level of protection against *infection* or *disease* and the possibility to differentiate the immune response produced by the vaccine from that produced by *infection* with the pathogenic agent.

Although *vaccination* may hide ongoing *infection* or agent transmission, it can be used to decrease the shedding of the pathogenic agent, hence reduce the reproductive rate of the *infection*. In particular, when stamping-out is not feasible, *vaccination* can be used to reduce the circulation of the *infection* until levels are low enough for a test and cull strategy.

Whenever *vaccination* is to be used as a tool to control *outbreaks* or spread of *disease*, the control plan should include an exit strategy, i.e. when and how to stop the *vaccination* or whether *vaccination* should become routine.

Article 4.Y.10.

Zoning

The *Veterinary Authority* should use the tool of zoning in accordance with Chapter 4.3.

The use of zoning for *disease* control is inherently linked with measures of killing, movement control, *vaccination* and *surveillance*, which apply differently according to the *zones*. In particular, efforts should be concentrated on those parts of a territory affected by the *disease*, to prevent the spread of the pathogenic agent and to preserve the status of the parts of the territory not affected by the *disease*.

Zones defined may be *infected zones*, *protection zones*, *containment zones*, or other types of *zones*, e.g. *zones* of intensified *surveillance*, *zones* of intensified *vaccination*.

Article 4.Y.11.

Communication in outbreak management

For the best implementation of *disease* control measures, *Veterinary Services* should ensure good communication with all concerned stakeholders, including the general public. This should be carried out, among others, through awareness campaigns targeted at breeders, *veterinarians*, local authorities, consumers and general public.

Veterinary Services should communicate before, during and after *outbreaks*, in accordance with Chapter 3.3.

Article 4.Y.12.

Specific post-control surveillance

Specific *surveillance* should be applied in order to monitor the effectiveness of the control plan, and assess the status of the remaining *animal populations* in the different *zones* established by the *Veterinary Services*.

The results of this *surveillance* should be used to reassess the measures applied, including reshaping of the *zones* and re-evaluation of the culling or *vaccination* strategies, and for the eventual recovery of free status.

This *surveillance* should be conducted in accordance with Chapter 1.4. and with the relevant articles of the *disease-specific* chapters.

Annex 32 (contd)

Article 4.Y.13.

Further outbreak investigation, monitoring, evaluation and review

In order to gather information required for any management information system, *Veterinary Services* should conduct an in-depth epidemiological investigation of each *outbreak* to build up a detailed first-hand, field-based knowledge of how the *disease* is transmitted, and inform further *disease* control plans. This requires staff who have been trained in the way to conduct it and the use of the standardised data collection forms.

Information gathered and experience gained should be used to monitor, evaluate and review *disease* control plans.

CHAPTER 8.4.

**INFECTION WITH *BRUCELLA ABORTUS*,
B. MELITENSIS AND *B. SUIIS***

[...]

Article 8.4.10.

Herd or flock free from infection with *Brucella* in bovinds, sheep and goats, camelids or cervids without vaccination

- 1) To qualify as free from *infection* with *Brucella* without *vaccination*, a *herd* or *flock* of bovinds, 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, except castrated males, present in the *herd* at the time of testing, the first test being performed not before 3 months after the *slaughter* of the last case and the second test at an interval of more than 6 and less than 12 months.

- 2) To maintain the free status, the following conditions should be met:
 - a) the requirements in points 1a) or 1b) or 1c) 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 33 (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.

[...]

— Text deleted.

CHAPTER 8.15.

INFECTION WITH RINDERPEST VIRUS

Article 8.15.1.

[...]

Article 8.15.2.

Definitions and general provisionsFor 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; 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 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 incorporated 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 at 56°C for at least 2 hours, or shown to be free from RPV genome sequences by a validated RT-PCR assay;
- 3) ban on *vaccination* against rinderpest means a ban on administering any vaccine containing RPV or RPV components 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.

[...]

— Text deleted.

CHAPTER 15.2.

INFECTION WITH CLASSICAL SWINE FEVER VIRUS

Article 15.2.1.

General provisions

The pig (*Sus scrofa*, both domestic and wild) is the only natural host for classical swine fever virus (CSFV). For the purposes of this chapter, a distinction is made between:

- = domestic and captive wild pigs, whether permanently housed or free ranging, used for the production of meat, or other commercial products or use, or for breeding; and
- = wild and feral pigs.

For the purposes of the *Terrestrial Code*, classical swine fever (CSF) is defined as an *infection* of pigs with classical swine fever virus (CSFV).

The following defines the occurrence of infection with CSFV:

- 1) a strain of CSFV (excluding vaccine strains) has been isolated from samples from a pig;

OR

- 2) ~~viral antigen or nucleic acid specific to CSFV~~ (excluding vaccine strains) has been ~~identified detected, or viral ribonucleic acid (RNA) specific to a strain of CSFV has been demonstrated to be present,~~ in samples from ~~one or more~~ a pigs showing clinical signs or pathological lesions suggestive of CSF, or epidemiologically linked to a suspected or confirmed or suspected outbreak case of CSF, or giving cause for suspicion of previous association or contact with CSFV, ~~with or without clinical signs consistent with CSF;~~

OR

- 3) ~~virus specific~~ antibodies specific to CSFV that are not a consequence of *vaccination* or *infection* with other pestiviruses, have been identified in samples from ~~one or more~~ a pigs in a herd showing clinical signs or pathological lesions consistent with CSF, or epidemiologically linked to a suspected or confirmed or suspected outbreak case of CSF, or giving cause for suspicion of previous association or contact with CSFV.

~~The pig is the only natural host for CSFV. The definition of pig includes all varieties of *Sus scrofa*, both domestic and wild. For the purposes of this chapter, a distinction is made between:~~

- ~~– domestic and captive wild pigs, permanently captive or farmed free range, used for the production of meat, or other commercial products or use, or for breeding these categories of pigs;~~
- ~~– wild and feral pigs.~~

~~For the purposes of the *Terrestrial Code*, the incubation period shall be 14 days. Pigs exposed to CSFV prenatally may not show clinical signs at birth and be persistently infected throughout life and may have an incubation period of several months before showing signs of disease. Pigs exposed postnatally have an incubation period of 2-14 days, and are usually infective between post infection days 5 and 14, but up to 3 months in cases of chronic infections.~~

~~A Member Country should not impose bans on the trade in commodities of domestic and captive wild pigs in response to a notification of infection with CSFV in wild and feral pigs provided that Article 15.2.2. is implemented.~~

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 Article 15.2.2, even if they notify infection with CSFV in wild or feral pigs.

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

Annex 35 (contd)

Article 15.2.2.

General criteria for the determination of the ~~classical swine fever~~ CSF status of a country, zone or compartment

- 1) CSF ~~should be~~ is notifiable in the whole territory, and all pigs showing clinical signs or pathological lesions suggestive of CSF ~~should be~~ are subjected to appropriate field or *laboratory* investigations;
- 2) an on-going awareness programme ~~should be~~ is in place to encourage reporting of all cases suggestive of CSF;
- 3) the *Veterinary Authority* ~~should have~~ has current knowledge of, and authority over, all domestic and *captive wild pig herds* in the country, *zone* or *compartment*;
- 4) the *Veterinary Authority* ~~should have~~ has current knowledge about of the population distribution and habitat of *wild* and *feral* pigs in the country or *zone*;
- 5) for domestic and *captive wild* pigs, appropriate *surveillance* in accordance with Articles 15.2.26. to 15.2.32. is in place;
- 6) for *wild* and *feral* pigs, if present in the country or *zone*, a *surveillance* programme is in place according to Article 15.2.31., taking into account the presence of natural and artificial boundaries, the ecology of the *wild* and *feral* pig population, and an assessment of the *risks* of *disease* spread;
- 7) based on the assessed *risk* of spread within the *wild* and *feral* pig population, and according to Article 15.2.29., the domestic and *captive wild* pig population ~~should be~~ is separated from the *wild* and *feral* pig population by appropriate measures.

Article 15.2.3.

Country or zone free from CSF ~~Classical swine fever free country or zone~~

A country or *zone* may be considered free from CSF when Article 15.2.2. is complied with, and when:

- 1) *surveillance* in accordance with Articles 15.2.26. to 15.2.32. has been in place for at least 12 months;
- 2) there has been no *outbreak* of CSF in domestic and *captive wild* pigs during the past 12 months;
- 3) no evidence of *infection* with CSFV has been found in domestic and *captive wild* pigs during the past 12 months;
- 4) no *vaccination* against CSF has been carried out in domestic and *captive wild* pigs during the past 12 months unless there are means, validated according to Chapter 2.8.3. of the *Terrestrial Manual*, of distinguishing between vaccinated and infected pigs;
- 5) imported pigs and pig *commodities* comply with the requirements in Articles 15.2.7. to 15.2.14bis.

The proposed free country or ~~the proposed free~~ *zone* will be included in the list of CSF free countries or *zones* only after the submitted evidence, based on the provisions of Article 1.6.9., has been accepted by the OIE.

Retention on the list requires that the information in points 1 to 5 above be re-submitted annually and changes in the epidemiological situation or other significant events should be reported to the OIE according to the requirements in Chapter 1.1.

Article 15.2.4.

Compartment free from CSF ~~Classical swine fever free compartment~~

The bilateral recognition of a compartment free from CSF ~~free compartment~~ should follow the relevant requirements of this chapter and the principles laid down in Chapters 4.3. and 4.4. Pigs in the compartment free from CSF should be separated from any other pigs by the application of effective biosecurity.

Article 15.2.5.

Establishment of a containment zone within a ~~classical swine fever free country or zone~~ free from CSF

In the event of limited *outbreaks* or cases of CSF within a ~~CSF free country or zone~~ free from CSF, including within a *protection zone*, a *containment zone*, which includes all *outbreaks*, can be established for the purpose of minimising the impact on the entire country or zone.

For this to be achieved and for the Member Country to take full advantage of this process, the *Veterinary Authority* should submit documented evidence as soon as possible to the OIE.

In addition to the requirements for the establishment of a *containment zone* outlined in point 3 of Article 4.3.3., the *surveillance* programme should take into consideration the involvement of *wild* and *feral* pigs and measures to avoid their dispersion.

The free status of the areas outside the *containment zone* is suspended while the *containment zone* is being established. The free status of these areas may be reinstated irrespective of the provisions of Article 15.2.6., once the *containment zone* is clearly established. It should be demonstrated that *commodities* for *international trade* have originated outside the *containment zone*.

In the event of the recurrence of CSF in the *containment zone*, the approval of the *containment zone* is withdrawn ~~and the free status of the country or zone is suspended until the relevant requirements of Article 15.2.3. have been fulfilled.~~

The recovery of the CSF free status of the *containment zone* should follow the provisions of Article 15.2.6 and be achieved within 12 months of its approval.

Article 15.2.6.

Recovery of free status

Should an outbreak of CSF occur in a previously a CSF outbreak occur in a free country or zone, the free its status may be restored where *surveillance* in accordance with Articles 15.2.2630- to 15.2.32. has been carried out with negative results either:

1) three months after the last case where a *stamping-out policy* without *vaccination* is practised;

OR

2) where a *stamping-out policy* with emergency *vaccination* is practised:

a) three months after the last case and the *slaughter* of all vaccinated *animals*, or

b) three months after the last case without the *slaughter* of vaccinated *animals* where there are means, validated according to Chapter 2.8.3. of the *Terrestrial Manual*, of distinguishing between vaccinated and infected pigs;

OR

3) where a *stamping-out policy* is not practised, the provisions of Article 15.2.3. should be followed.

Annex 35 (contd)

The country or *zone* will regain CSF free status only after the submitted evidence, based on the provisions of Article 1.6.9., has been accepted by the OIE.

The country or *zone* will regain CSF free status only after the submitted evidence, based on the provisions of Article 1.6.10., has been accepted by the OIE.

Article 15.2.6bis.**Direct transfer of pigs within a country from an infected zone to a free zone for slaughter**

In order not to jeopardise the status of a free zone, pigs should only leave the infected zone if transported by mechanised vehicle directly for slaughter in the nearest designated slaughterhouse/abattoir under the following conditions:

- 1) no pig has been introduced into the establishment of origin and no pig in the establishment of origin has shown clinical signs of CSF for at least 30 days prior to slaughter.
- 2) the pigs were kept in the establishment of origin for at least three months prior to movement for slaughter.
- 3) CSF has not occurred within a 10-kilometre radius of the establishment of origin for at least three months prior to movement;
- 4) the pigs should be transported under the supervision of the Veterinary Services in a vehicle, which was cleaned and disinfected before loading, directly from the establishment of origin to the slaughterhouse/abattoir without coming into contact with other pigs;
- 5) such a slaughterhouse/abattoir is not approved for the export of fresh meat during the time it is handling the meat of pigs from the infected zone;
- 6) vehicles and the slaughterhouse/abattoir should be subjected to disinfection immediately after use.

The pigs should be subjected to ante- and post-mortem inspections in accordance with Chapter 6.2. with favourable results and the meat should be treated according to Article 15.2.23.

Any other products obtained from the pigs, and any products coming into contact with them, should be considered contaminated and treated in accordance with Article 15.2.22. or Articles 15.2.24. to 15.2.25.ter to destroy any residual virus.

Article 15.2.6ter.**Direct transfer of pigs within a country from a containment zone to a free zone for slaughter**

In order not to jeopardise the status of a free zone, pigs should only leave the containment zone if transported by mechanised vehicle directly to slaughter in the nearest designated slaughterhouse/abattoir under the following conditions:

- 1) the containment zone has been officially established according to the requirements in Article 15.2.5.;
- 2) the pigs should be transported under the supervision of the Veterinary Services in a vehicle, which was cleaned and disinfected before loading, directly from the establishment of origin to the slaughterhouse/abattoir without coming into contact with other pigs;
- 3) such a slaughterhouse/abattoir is not approved for the export of fresh meat during the time it is handling the meat of pigs from the containment zone;
- 4) vehicles and the slaughterhouse/abattoir should be subjected to disinfection immediately after use.

The pigs should be subjected to ante- and post-mortem inspections in accordance with Chapter 6.2. with favourable results and the *meat* should be treated according to Article 15.2.23.

Any other products obtained from the pigs, and any products coming into contact with them, should be considered contaminated and treated in accordance with Article 15.2.22. or Articles 15.2.24. to 15.2.25ter. to destroy any residual virus.

Article 15.2.7.

Recommendations for importation from countries, zones or compartments free from ~~classical swine fever~~ CSF

For domestic and captive wild pigs

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

- 1) showed no clinical sign of CSF on the day of shipment;
- 2) ~~were kept in a country, zone or compartment free from CSF since birth or for at least the past three months~~ in a country, zone or compartment free from CSF;
- 3) ~~have were~~ not been vaccinated against CSF, nor are they the progeny of vaccinated sows, unless there are means, validated according to Chapter 2.8.3. of the *Terrestrial Manual*, of distinguishing between vaccinated and infected pigs.

Article 15.2.8.

Recommendations for importation from countries or zones ~~considered infected with classical swine fever virus~~ not free from CSF

For domestic and captive wild pigs

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

- 1) showed no clinical sign of CSF on the day of shipment;
- 2) and either:
 - a) were kept since birth or for the past three months in a CSF free compartment, or
 - b) were isolated for 28 days prior to shipment in a quarantine station, and were subjected to a virological test and a serological test performed on a sample collected at least 21 days after entry into the quarantine station, with negative results;
- 3) ~~have were~~ not been vaccinated against CSF, nor are they the progeny of vaccinated sows, unless there are means, validated according to Chapter 2.8.3. of the *Terrestrial Manual*, of distinguishing between vaccinated and infected pigs.

Article 15.2.9.

Recommendations for the importation of wild and feral pigs

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

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

Annex 35 (contd)

- 2) were ~~kept isolated in~~ a *quarantine station* for ~~40~~ 28 days prior to shipment, and were subjected to a virological test and a serological test performed on a sample collected at least 21 days after entry into the *quarantine station*, with negative results;
- 3) ~~have~~ were not ~~been~~ vaccinated against CSF, unless there are means, validated according to Chapter 2.8.3. of the *Terrestrial Manual*, of distinguishing between vaccinated and infected pigs.

Article 15.2.10.

Recommendations for importation from countries, zones or compartments free from classical swine fever CSF

For semen of domestic and captive wild pigs

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

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

Article 15.2.11.

Recommendations for importation from countries or zones ~~considered infected with classical swine fever virus~~ not free from CSF

For semen of domestic and captive wild pigs

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

- 1) the donor ~~animals~~ males:
 - a) were kept ~~in a compartment free from CSF~~ since birth or for at least three months prior to collection in an establishment in which surveillance, in accordance with Articles 15.2.26. to 15.2.32., demonstrated that no case of CSF occurred in the past 12 months;
 - b) showed no clinical sign of CSF on the day of collection of the semen ~~and for the following 40 days~~;
 - c) met one of the following conditions:
 - i) were subjected to a virological test performed on a blood sample taken on the day of collection, with negative results; or
 - ii) were not ~~been~~ vaccinated against CSF and were subjected to a serological test performed on a sample taken at least 21 days after collection, with negative results; or
 - iii) have been vaccinated against CSF and were subjected to a serological test performed on a sample taken at least 21 days after collection, which ~~and it has been conclusively demonstrated that any antibody is due to~~ was caused by the vaccine; ~~or~~
 - iiii) ~~have been vaccinated against CSF and were subjected to a virological test performed on a sample taken on the day of collection and it has been conclusively demonstrated that the boar is negative for virus genome~~;
- 2) the semen was collected, processed and stored in ~~conformity~~ accordance with the provisions of Chapters 4.5. and 4.6.

Article 15.2.12.

Recommendations for importation from countries, zones or compartments free from classical swine fever CSFFor in vivo derived embryos of domestic pigs

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

- 1) the donor females: ~~showed no clinical sign of CSF on the day of collection of the embryos;~~
 - a) were kept since birth or for at least three months prior to collection in a country, zone or compartment free from CSF;
 - b) showed no clinical sign of CSF on the day of collection of the embryos;
- 2) the semen used to fertilise the oocytes complied with the conditions in Articles 15.2.10. or Article 15.2.11., as relevant;
- 3) the embryos were collected, processed and stored in accordance with Chapters 4.7. and 4.9., as relevant.

Article 15.2.13.

Recommendations for importation from countries or zones ~~considered infected with classical swine fever virus~~ not free from CSFFor in vivo derived embryos of domestic pigs

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

- 1) the donor females:
 - a) ~~were kept in a compartment free from CSF since birth or for at least three months prior to collection in an establishment in which surveillance, in accordance with Articles 15.2.26. to 15.2.32., demonstrated that no case of CSF occurred in the past three months;~~
 - b) ~~showed no clinical sign of CSF on the day of collection of the embryos and for the following 40 days;~~
 - c) ~~and either met one of the following conditions:~~
 - i) were subjected to a virological test performed on a blood sample taken on the day of collection, with negative results; or
 - ii) ~~have~~ were not ~~been~~ vaccinated against CSF and were subjected, with negative results, to a serological test performed at least 21 days after collection; ~~or~~
 - iii) ~~have been~~ were vaccinated against CSF and were subjected to a serological test performed on a sample taken at least 21 days after collection, which ~~and it has been conclusively demonstrated by means, validated according to Chapter 2.8.3. of the Terrestrial Manual, that any antibody is due to~~ was caused by the vaccine;
- 2) the embryos were collected, processed and stored in accordance with Chapters 4.7. and 4.9., as relevant.

Annex 35 (contd)

Article 15.2.14.

Recommendations for importation from countries, zones or compartments free from ~~classical swine fever~~ CSFFor fresh meat of domestic and captive wild pigs

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

- 1) have been kept in a country, *zone* or *compartment* free from CSF, or which have been imported in accordance with Article 15.2.7. or Article 15.2.8.;
- 2) have been slaughtered in an approved *slaughterhouse/abattoir*, where they have been subjected to ante- and post-mortem inspections in accordance with Chapter 6.2. with favourable results ~~and have been found free from any sign suggestive of CSF.~~

Article 15. 2.14 bis.**Recommendations for importation from countries or zones not free from CSF, where an official control programme exists**For fresh meat of domestic pigs

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

- 1) the meat comes from pigs complying with Article 15.2.8.;
- 2) the pigs were transported under the supervision of the *Veterinary Services*, in a *vehicle* which was cleaned and disinfected before the pigs were loaded;
- 3) the pigs were transported directly to the approved *slaughterhouse/abattoir* without coming into contact either during transport or at the *slaughterhouse/abattoir* with other pigs which do not fulfil the conditions required for export;
- 4) the pigs were slaughtered in an approved *slaughterhouse/abattoir*.
 - a) which is officially designated for export;
 - b) in which no case of CSF was detected during the period between the last *disinfection* carried out before *slaughter* and the shipment for export has been dispatched;
- 5) the pigs were subjected to ante- and post-mortem inspections in accordance with Chapter 6.2. with favourable results;
- 6) appropriate precautions have been taken after *slaughter* to avoid contact of the *fresh meat* with any source of CSFV.

Article 15.2.15.

Recommendations for the importation of fresh meat of wild and feral pigs

Regardless of the CSF status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *fresh meat* comes from ~~animals~~ pigs:

- 1) which ~~have been~~ were subjected to a post-mortem inspection in accordance with Chapter 6.2. in an approved examination centre, with favourable results ~~and have been found free from any sign suggestive of CSF;~~

Annex 35 (contd)

- 2) from each of which a sample ~~has been~~ was collected and ~~has been~~ subjected to a virological test and a serological test for CSF, with negative results.

Article 15.2.16.

Recommendations for the importation of ~~meat and meat products of pigs intended for use in animal feeding, for agricultural or industrial use, or for pharmaceutical or surgical use~~

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

- 1) ~~have been~~ were prepared:
- a) exclusively from *fresh meat* meeting the conditions laid down in Articles 15.2.14., 15.2.14bis. or 15.2.15.;
 - b) in a processing establishment facility:
 - i) approved by the *Veterinary Authority* for export purposes;
 - ii) processing only *meat* meeting satisfying the conditions ~~laid down~~ in Articles 15.2.14., 15.2.14bis. or 15.2.15.;

OR

- 2) ~~have been~~ were processed in accordance with one of the processes in Article 15.2.23. in an establishment a facility approved by the *Veterinary Authority* for export purposes ~~so as to ensure the destruction of the CSFV in conformity with one of the procedures referred to in Article 15.2.23., and that the necessary appropriate~~ precautions were taken after processing to avoid contact of the product with any source of CSFV.

Article 15.2.17.

Recommendations for the importation of ~~pig products not derived from fresh meat intended for use in animal feeding~~

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

- 1-) ~~originated from domestic and captive wild pigs in a CSF free country, zone or compartment and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; or~~
- 2-) ~~have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSFV in accordance with Article 15.2.22., and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSFV.~~

Article 15.2.18.

Recommendations for the importation of ~~pig products not derived from fresh meat intended for agricultural or industrial use~~

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

- 1-) ~~originated from domestic and captive wild pigs in a CSF free country, zone or compartment and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; or~~
- 2-) ~~have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSFV, and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSFV.~~

Annex 35 (contd)

Article 15.2.19.

Recommendations for the importation of bristles

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

- 1) originated from domestic ~~and or~~ captive wild pigs in a CSF-free country, zone or compartment free from CSF and ~~have been~~ were prepared-processed in a processing-establishment facility approved by the *Veterinary Authority* for export purposes; or
- 2) ~~have been~~ were processed in accordance with one of the processes in Article 15.2.25bis in an establishment a facility approved by the *Veterinary Authority* for export purposes ~~so as to ensure the destruction of the CSFV~~, and that ~~the necessary~~ appropriate precautions were taken after processing to avoid contact of the product with any source of CSFV.

Article 15.2.20.

Recommendations for the importation of litter and manure from pigs

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

- 1) originated from domestic ~~and or~~ captive wild pigs in a CSF-free country, zone or compartment free from CSF and ~~have been prepared~~ were processed in a processing-establishment facility approved by the *Veterinary Authority* for export purposes; or
- 2) ~~have been~~ were processed in accordance with one of the procedures in Article 15.2.25ter in an establishment a facility approved by the *Veterinary Authority* for export purposes ~~so as to ensure the destruction of the CSFV~~, and that ~~the necessary~~ appropriate precautions were taken after processing to avoid contact of the product with any source of CSFV.

Article 15.2.21.

Recommendations for the importation of skins and trophies from pigs

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

- 1) originated from domestic ~~and or~~ captive wild pigs in a CSF-free country, zone or compartment free from CSF and ~~have been prepared~~ were processed in a processing-establishment facility approved by the *Veterinary Authority* for export purposes; or
- 2) ~~have been~~ were processed in accordance with one of the procedures in Article 15.2.25 in an establishment a facility approved by the *Veterinary Authority* for export purposes ~~so as to ensure the destruction of the CSFV~~ in conformity with one of the procedures referred to in Article 15.2.25, and that ~~the necessary~~ appropriate precautions were taken after processing to avoid contact of the product with any source of CSFV.

Article 15.2.21bis.**Recommendations for the importation of other pig products**

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

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

Annex 35 (contd)

- 2) were processed in a manner to ensure the destruction of CSFV in a facility approved by the Veterinary Authority for export purposes, and that appropriate precautions were taken after processing to avoid contact of the product with any source of CSFV.

Article 15.2.22.

Procedures for the inactivation of ~~the classical swine fever virus~~ CSFV in swill

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

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

Article 15.2.23.

Procedures for the inactivation of ~~the classical swine fever virus~~ CSFV in meat

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

1. Heat treatment

Meat should be subjected to one of the following treatments:

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

2. Natural fermentation and maturation

The *meat* should be subjected to a treatment consisting of natural fermentation and maturation having the following characteristics:

- a) an Aw a_w value of not more than 0.93, or
- b) a pH value of not more than 6.0.

~~Hams should be subjected to a natural fermentation and maturation process for at least 190 days and loins for 140 days.~~

3. Dry cured ~~pork pig meat~~

- a) ~~Italian style hams with bone in should be cured with salt and dried for a minimum of 313 days.~~
- b) ~~Spanish style pork meat with bone in should be cured with salt and dried for a minimum of 252 days for Iberian hams, 140 days for Iberian shoulders, 126 days for Iberian loin, and 140 days for Serrano hams.~~

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

Annex 35 (contd)

Article 15.2.24.

Procedures for the inactivation of ~~the classical swine fever virus~~ CSFV in casings of pigs

For the inactivation of CSFV in casings of pigs, the following procedures should be used: ~~salting~~ treating for at least 30 days either with phosphate supplemented dry salt or saturated brine (A_w $a_w < 0.80$) containing 86.5% NaCl, 10.7% Na_2HPO_4 and 2.8% Na_3PO_4 (weight/weight/weight), ~~and kept~~ and at a temperature of greater than 20°C or above during this entire period.

Article 15.2.25.

Procedures for the inactivation of ~~the classical swine fever virus~~ CSFV in skins and trophies

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

- 1) boiling in water for an appropriate time so as to ensure that any matter other than bone, tusks or teeth is removed;
- 2) gamma irradiation at a dose of at least 20 kiloGray at room temperature (20°C or higher);
- 3) soaking, with agitation, in a 4 ~~percent~~ % (w/v) solution of washing soda (sodium carbonate [Na_2CO_3]) maintained at pH 11.5 or above for at least 48 hours;
- 4) soaking, with agitation, in a formic acid solution (100 kg salt [NaCl] and 12 kg formic acid per 1,000 litres water) maintained at below pH 3.0 for at least 48 hours; wetting and dressing agents may be added;
- 5) in the case of raw hides, salting for at least 28 days with sea salt containing 2 ~~percent~~ % washing soda (sodium carbonate [Na_2CO_3]).

Article 15.2.25bis.**Procedures for the inactivation of CSFV in bristles**

For the inactivation of CSFV in bristles for industrial use, they should be boiled for at least 30 minutes.

Article 15.2.25ter.**Procedures for the inactivation of CSFV in litter and manure from pigs**

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

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

Article 15.2.26.

Introduction to surveillance: introduction

Articles 15.2.26. to 15.2.32. define the principles and provide a guide on the *surveillance* for CSF, complementary to Chapter 1.4., applicable to Member Countries seeking the OIE recognition of CSF status. This may be for the entire country or a *zone*. Guidance is also provided for Member Countries seeking recovery of CSF status for the entire country or for a *zone* following an *outbreak* and for the maintenance of CSF status.

Annex 35 (contd)

The impact and epidemiology of CSF may vary in different regions of the world. The *surveillance* strategies employed for demonstrating freedom from CSF at an acceptable level of confidence should be adapted to the local situation. For example, the approach should be tailored in order to prove freedom from CSF for a country or *zone* where *wild* and *feral* pigs provide a potential reservoir of *infection*, or where CSF is present in adjacent countries. The method should examine the epidemiology of CSF in the region concerned and adapt to the specific risk factors encountered. This should include provision of scientifically based supporting data. There is, therefore, latitude available to Member Countries to provide a well-reasoned argument to prove that absence of *infection* with CSFV is assured at an acceptable level of confidence.

Surveillance for CSF should be in the form of a continuing programme designed to establish that susceptible populations in a country, *zone* or *compartment* are free from *infection* with CSFV or to detect the introduction of CSFV into a population already defined as free. Consideration should be given to the specific characteristics of CSF epidemiology which include:

- the role of swill feeding, the impact of different production systems and the role of *wild* and *feral* pigs on *disease* spread;
- the role of semen in transmission of the virus;
- the lack of pathognomonic gross lesions and clinical signs;
- the frequency of clinically inapparent *infections*;
- the occurrence of persistent and chronic *infections*;
- the genotypic, antigenic, and virulence variability exhibited by different strains of CSFV.

Article 15.2.27.

General conditions and methods for surveillance: ~~general conditions and methods~~

- 1) A *surveillance* system in accordance with Chapter 1.4. and under the responsibility of the *Veterinary Authority* should address the following aspects:
 - a) formal and ongoing system for detecting and investigating *outbreaks of disease* or CSFV *infection* should be in place;
 - b) a procedure should be in place for the rapid collection and transport of samples from suspected cases to a laboratory ~~for CSF diagnosis~~;
 - c) appropriate laboratory testing capability for CSF diagnosis;
 - ~~d)~~ a system for recording, managing and analysing diagnostic and *surveillance* data should be in place.
- 2) The CSF *surveillance* programme should:
 - a) include an ~~early warning~~ detection system throughout the production, marketing and processing chain for reporting suspected cases. Diagnosticians and those with regular contact with pigs should report promptly any suspicion of CSF to the *Veterinary Authority*. The ~~notification reporting~~ system under the *Veterinary Authority* should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary paraprofessionals*) by government information programmes. Since many strains of CSFV do not induce pathognomonic gross lesions or clinical signs, cases in which CSF cannot be ruled out should be immediately investigated. Other important *diseases* such as African swine fever should also be considered in any differential diagnosis. As part of the contingency plan, personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in CSF diagnosis, epidemiological evaluation, and control;
 - b) implement, when relevant, regular and frequent clinical inspections and laboratory testing of high-risk groups (for example, where swill feeding is practised), or those adjacent to a CSF infected country or *zone* (for example, bordering areas where infected *wild* and *feral* pigs are present).

Annex 35 (contd)

An effective *surveillance* system will periodically identify suspected cases that require follow-up and investigation to confirm or exclude *infection* with CSFV. The rate at which such suspected cases are likely to occur will differ between epidemiological situations and cannot, therefore, be reliably predicted. Applications for recognition of CSF status should, as a consequence, provide details in accordance with Article 1.6.10. of the occurrence of suspected cases and how they were investigated and dealt with.

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

- a) an emergence or an increase in the prevalence of CSF in countries or zones from which live pigs or products are imported;
- b) an increase in the prevalence of CSF in *wild* or *feral* pigs in the country or zone;
- c) an increase in the prevalence of CSF in adjacent countries or zones;
- d) an increased entry from, or exposure to, infected *wild* or *feral* pig populations of adjacent countries or zones.

Article 15.2.28.

Surveillance strategies

1. Introduction

The population covered by *surveillance* aimed at detecting *disease* and *infection* should include domestic and *wild* pig populations within the country or *zone* to be recognised as free from *infection* with CSFV.

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

- a) swill fed farms;
- b) pigs reared outdoors;
- c) specific high-risk *wild* and *feral* pig subpopulations and their proximity.

Risk factors may include, among others, temporal and spatial distribution of past *outbreaks*, pig movements and demographics, ~~etc~~ and types of production systems.

Serology in unvaccinated populations is often the most effective and efficient *surveillance* methodology, for reasons of cost, ~~persistence~~ extended duration of antibody levels and the existence of clinically inapparent *infections*. ~~serology in unvaccinated populations is often the most effective and efficient *surveillance* methodology~~. In some circumstances, such as differential diagnosis of other *diseases*, clinical and virological *surveillance* may also have value.

The *surveillance* strategy chosen should be justified as adequate to detect the presence of *infection* with CSFV in accordance with Chapter 1.4. and the epidemiological situation. Cumulative survey results in combination with the results of routine *surveillance*, over time, will increase the level of confidence in the *surveillance* strategy.

Annex 35 (contd)

When applying randomised sampling, either at the level of the entire population or within targeted sub-populations, the design of the sampling strategy should incorporate epidemiologically appropriate design prevalences for the selected populations. The sample size selected for testing should be large enough to detect *infection* if it were to occur at a predefined minimum rate. The choice of design prevalence and confidence level should be justified based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence in particular, needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the approach selected, the sensitivity and specificity of the diagnostic tests should be considered in the survey design, the sample size determination and the interpretation of the results obtained.

The *surveillance* system design should anticipate the occurrence of false positive reactions. This is especially true of the serological diagnosis of CSF because of the recognised cross-reactivity with ruminant pestiviruses, among other factors mentioned in point 4. There needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether or not they are indicative of *infection* with CSFV. This should involve confirmatory and differential tests for pestiviruses, as well as further investigations concerning the original sampling unit as well as *animals* which may be epidemiologically linked.

2. Clinical surveillance

Clinical *surveillance* continues to be the cornerstone of CSF detection. However, due to the low virulence of some CSFV strains and the spread of *diseases* such as African swine fever, and those associated with porcine circovirus 2 *infection*, clinical *surveillance* should be supplemented, as appropriate, by serological and virological *surveillance*.

Clinical signs and pathological findings are useful for early detection; in particular, any cases where clinical signs or lesions suggestive of CSF are accompanied by high morbidity or mortality, these should be investigated without delay. In CSFV *infections* involving low virulence strains, high mortality may only be seen in young *animals* and adults may not present clinical signs.

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

3. Virological surveillance

Virological *surveillance* should be conducted:

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

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

4. Serological surveillance

Serological *surveillance* aims at detecting antibodies against CSFV. Positive CSFV antibody test results can have five possible causes:

Annex 35 (contd)

- a) natural *infection* with CSFV;
- b) *vaccination* against CSF;
- c) maternal antibodies;
- d) cross-reactions with other pestiviruses;
- e) non-specific reactors.

The *infection* of pigs with other pestiviruses may complicate a *surveillance* strategy based on serology. Antibodies to bovine viral diarrhoea viruses (BVDV) and Border disease virus (BDV) can give positive results in serological tests for CSF, due to common antigens. Such samples will require differential tests to confirm their identity. One route by which ruminant pestiviruses can infect pigs is the use of vaccines contaminated with BVDV.

CSFV may lead to persistently infected, seronegative young animals, which continuously shed virus. CSFV *infection* may also lead to chronically infected pigs which may have undetectable or fluctuating antibody levels. Even though serological methods will not detect these animals, such animals are likely to be in a minority in a herd and would not confound a diagnosis based on serology as part of a *herd* investigation.

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

In countries or *zones* where *vaccination* has been recently discontinued, targeted serosurveillance of young unvaccinated animals can indicate the presence of *infection*. Maternal antibodies are usually found up to 8-10 weeks of age but may be occasionally last up to four and a half months and can interfere with the interpretation of serological results.

Marker vaccines and accompanying DIVA tests which fulfil the requirements of the *Terrestrial Manual* may allow discrimination between vaccinal antibody and that induced by natural *infection*. The serosurveillance results using DIVA techniques may be interpreted either at animal or *herd* level.

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

- ~~a) an emergence or an increase in the prevalence of CSF in countries or *zones* from which live pigs or products are imported;~~
- ~~b) an increase in the prevalence of CSF in wild or feral pigs in the country or *zone*;~~
- ~~c) an increase in the prevalence of CSF in adjacent countries or *zones*;~~
- ~~d) an increased entry from, or exposure to, infected wild or feral pig populations of adjacent countries or *zones*.~~

Article 15.2.29.

Additional surveillance procedures for Member Countries applying for OIE recognition of classical swine fever CSF free status

The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances in and around the country or *zone* and should be planned and implemented according to the conditions for status recognition described in Article 15.2.2. and 15.2.3. and methods described elsewhere in this chapter. The objective is to demonstrate the absence of *infection* with CSFV in domestic and *captive wild* pigs during the last 12 months and to assess the *infection* status in *wild* and *feral* pig populations as described in Article 15.2.31.

Article 15.2.30.

Additional surveillance procedures for recovery of free status

In addition to the general conditions described in this chapter, a Member Country seeking recovery of country or zone CSF free status, including a *containment zone*, should show evidence of an active *surveillance* programme to demonstrate absence of *infection* with CSFV.

Populations under this *surveillance* programme should include:

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

The domestic and *captive wild* pig populations should undergo regular clinical, pathological, virological and serological examinations, planned and implemented according to the general conditions and methods described in these recommendations. Epidemiological evidence of the *infection* status in *wild* and *feral* pigs should be compiled. To regain CSF free status, the *surveillance* approach should provide at least the same level of confidence as within the original application for recognition of freedom.

Article 15.2.31.

Surveillance for ~~classical swine fever virus~~ CSFV in wild and feral pigs

- 1) The objective of a *surveillance* programme is either to demonstrate that CSFV *infection* is not present in *wild* and *feral* pigs or, if known to be present, to estimate the distribution and prevalence of the *infection*. While the same principles apply, *surveillance* in *wild* and *feral* pigs presents additional challenges including:
 - a) determination of the distribution, size and movement patterns associated with the *wild* and *feral* pig population;
 - b) relevance and practicality of assessing the possible presence of CSFV *infection* within the population;
 - c) determination of the practicability of establishing a *zone* taking into account the degree of interaction with domestic and *captive wild* pigs within the proposed *zone*.

The geographic distribution and estimated size of *wild* and *feral* pig populations need to be assessed as a prerequisite for designing a monitoring system. Sources of information to aid in the design of a monitoring system may include governmental and non-governmental *wildlife* organisations such as hunter associations.

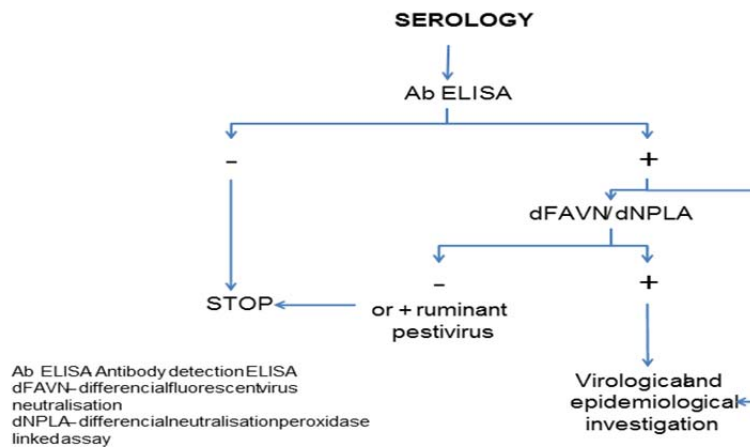
- 2) For implementation of the ~~monitoring~~ *surveillance* programme, ~~it will be necessary to define the limits of the area over which *wild* and *feral* pigs range should be defined, in order to delineate the epidemiological units within the monitoring programme. It is often difficult to define epidemiological units for *Subpopulations* of *wild* and *feral* pigs may be separated from each other by natural or~~ The most practical approach is based on natural and artificial barriers.
- 3) The ~~monitoring~~ *surveillance* programme should involve serological and virological testing, including ~~animals~~ *pigs* found dead, road kills, ~~animals~~ *pigs* showing abnormal behaviour or exhibiting gross lesions during dressing.

Annex 35 (contd)

- 4) There may be situations where a more targeted *surveillance* programme can provide additional assurance. The criteria to define high risk areas for targeted *surveillance* include:
- a) areas with past history of CSF;
 - b) subregions with large populations of *wild* and *feral* pigs;
 - c) border regions with CSF affected countries or zones;
 - d) interface between *wild* and *feral* pig populations, and domestic and *captive wild* pig populations;
 - e) areas with farms with free-ranging and outdoor pigs;
 - f) areas with a high level of hunting activity, where animal dispersion and feeding as well as inappropriate disposal of waste can occur;
 - gf) other risk areas determined by the *Veterinary Authority* such as ports, airports, garbage dumps and picnic and camping areas.

Article 15.2.32.

The use and interpretation of diagnostic tests in surveillance



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CHAPTER 7.1.

INTRODUCTION TO THE RECOMMENDATIONS FOR ANIMAL WELFARE

Article 7.1.1.

Definition-General considerations

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

An animal is in a good state of welfare if (as indicated by scientific evidence) it is healthy, comfortable, well nourished, safe, 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 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, shelter, management and nutrition, 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.

[...]

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**WORK PROGRAMME FOR
THE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION**

Subject	Issue (By priority order, reason for new work)	Status and Action (Start date, # of rounds for comments)
Restructuring of the Code	1) Work with AAHSC towards harmonisation, as appropriate, of the horizontal parts of the <i>Codes</i> , notably Glossary, User's Guide and Section 4 on disease control and Section 6 on Veterinary Public Health (Member Countries comments)	Ongoing
	2) Work with BSC for accurate disease description and diagnostic in the <i>Manual</i> and case definitions in the <i>Code</i> and names of diseases and country and zone disease status (Member Countries comments)	Ongoing
	3) Revision and formatting of chapters (articles numbering, tables and figures) (Member Countries comments and to improve consistency)	Ongoing
	4) Revision of the Users' guide to address the precedence of chapters (Member Countries comments)	Preliminary discussion
Glossary	1) Global revision of glossary for consistency throughout the Code (Member Countries comments and to improve consistency)	Ongoing and proposed some editorial changes & deletions sent for comments (FEB 2016 / 3 rd)
	2) Vaccination, zone, free zone, infected zone, containment zone, protection zone (Member Countries comments and to improve consistency)	Revised definitions for comments in parallel with revision of CH 4.3. and new CH 4.X. on vaccination sent for comments (FEB 2016 / 3 rd)
	3) Pathogenic agent, disease, infection and infestation (To improve consistency)	New and revised definitions sent for comments (SEP 2016 / 2 nd)
Horizontal issues not yet in the Code Section 4 Disease control	1) New CH on vaccination (Member Countries comments and implications for status recognition)	Revised CH sent for comments (SEP 2016 / 2 nd)
	2) New CH on management of outbreaks of the listed diseases (Member Countries comments and part of restructuring of Section 4)	Preliminary discussion
	3) New introductory CH in Section 4 (Part of restructuring of Section 4)	Draft new CH sent for comments (FEB 2017 / 1 st)
	4) New CH on zoning application (Member Countries comments)	Preliminary discussion

Annex 37 (contd)

Subject	Issue (By priority order, reason for new work)	Status and Action (Start date, # of rounds for comments)
Horizontal issues not yet in the Code Section 6 Veterinary Public Health	1) New introductory CH in Section 6 (APFSWG proposal)	Draft new CH sent for comments (FEB 2017)
	2) New CH on <i>Salmonella</i> in bovines (In conjunction with Codex's work on <i>Salmonella</i> spp. in cattle & pigs)	Proposed for adoption in 2017 (FEB 2015 / 4 th)
	2bis) New CH on <i>Salmonella</i> in pigs (In conjunction with Codex's work on <i>Salmonella</i> spp. in cattle & pigs)	Proposed for adoption in 2017 (SEP 2014 / 4 th)
	3) Control of Shiga toxin-producing <i>E. coli</i> (STEC) in food-producing animals (Member Countries comments)	Preliminary discussion pending FAO/WHO expert consultation
Horizontal issues not yet in the Code Section 7 Animal Welfare	1) New CH on AW and pig production systems (Member Countries comments)	Revised CH sent for comments (SEP 2016 / 2 nd)
	2) New CH on slaughter and killing methods of farmed reptiles (Member Countries comments)	Draft new CH reviewed and sent back to HQs for revision (SEP 2016)
	3) New CH on AW and laying hen production systems (Member Countries comments)	Draft new CH reviewed and sent back to HQs for revision (FEB 2017)
The Code texts on horizontal issues in need of revision: Section 1 Notification	1) Revision of CH 1.4. on Animal Health Surveillance (Member Countries comments and implications for status recognition)	1 st and 2 nd revision prepared by TAHSC and pending AHG (FEB 2016 / 1 st)
	2) CH 1.6. on Status: revision and reorganisation (Member Countries comments and implications for status recognition)	Revised questionnaires sent for comments and other articles pending HQs review (FEB 2017 / 1 st)
	3) CH 1.3. on listed diseases: assess CWD & WNF against the criteria (Member Countries comments)	Pending SCAD advice on CWD Pending HQs advice on WNF
The Code texts on horizontal issues in need of revision: Section 2 Risk analysis	1) New CH on criteria for assessing safe commodities (Member Countries comments)	Proposed for adoption in 2017 (SEP 2015 / 4 th)
The Code texts on horizontal issues in need of revision: Section 3 Veterinary Services	1) Revision of CHs of Section 3 in the light of the return of experience of the PVS Pathway	Pending discussion at PVS think tank

Annex 37 (contd)

Subject	Issue (By priority order, reason for new work)	Status and Action (Start date, # of rounds for comments)
The Code texts on horizontal issues in need of revision: Section 4 Disease control	1) Revision of CH 4.3. on zoning (Member Countries comments and implications for status recognition)	Revised CH sent for comments (FEB 2016 / 3 rd)
	2) Revision of CH 4.13. on disinfection (Member Countries comments)	Preliminary discussion
	3) Revision of CH 4.6. on semen collection (Member Countries comments and trade implications)	Pending experts advice
	4) Revision of CHs 4.7. and 4.8. on embryos (Member Countries comments and trade implications)	Pending experts advice
	5) Revision of CH 4.16. on HHP (To reflect the recent publication of "the OIE handbook for management of HHP horses")	Proposed for adoption in 2017 (SEP 2016 / 2 nd)
The Code texts on horizontal issues in need of revision: Section 5 Trade measures	1) Revision of CH 5.3. on SPS agreement (Outdated CH and trade implications)	Proposed for adoption in 2017 (SEP 2015 / 4 th)
	2) Revision of CH 5.12. on Model certificates for competition horses (Member Countries comments)	Preliminary discussion and pending revision of CHs on horse diseases
The Code texts on horizontal issues in need of revision: Section 6 Veterinary Health	1) Revision of CH 6.1. on the role of VS in food safety (Planned work by TAHSC)	Revised CH sent for comments (FEB 2016 / 2 nd)
	2) Revision of CH 6.2. on meat inspection (Planned work by TAHSC)	Pending AHG report
	3) Revision of CH 6.7. on AMR surveillance and monitoring programme (Member Countries comments and to align with Codex work on AMR)	Revised CH sent for comments (Sep 2015 / 3 rd)
	4) Revision of Article 6.8.1. on monitoring of AMR in food producing animals (In conjunction with Codex work on AMR)	Report of AHG on AMR sent for comments (FEB 2017)

Annex 37 (contd)

Subject	Issue (By priority order, reason for new work)	Status and Action (Start date, # of rounds for comments)
The Code texts on horizontal issues in need of revision: Section 7 Animal welfare	1) Revision of CH 7.5. on slaughter and CH 7.6. on killing of animals for disease control purposes (Member Countries comments)	Revised CHs to be referred to experts for further advice (FEB 2015 / 3 rd)
	2) Revision of CH 7.12. on AW of working equids (Member Countries comments)	Proposed for adoption in 2017 (SEP 2016 / 2 nd)
	3) Revision of Article 7.11.6. on AW and cattle production systems (Member Countries comments)	Proposed for adoption in 2017 (SEP 2016 / 2 nd)
	4) Revision of CH 7.1. on introduction to recommendations on AW (AWWG proposals)	Draft new Article 7.1.X. on guiding principle on the use of animal-based measures and revision of Article 7.1.1. (definition of AW) sent for comments (FEB 2017 / 1 st)
Diseases issues not yet in the Code	1) New CH 15.X. on PRRS (Member Countries comments, listed disease without chapter)	Proposed for adoption in 2017 (FEB 2014 / 4 th)
	2) New CH on Surra and revision of CH on Dourine (Non-tsetse transmitted Trypanosomosis) (Member Countries comments)	Review at SEP 2017 meeting
	3) New CH on Crimean Congo hemorrhagic fever (Member Countries comments, listed disease without chapter)	Preliminary discussion
The Code texts on diseases in need of revision: Sections 8 to 15	1) Revision of CH 15.1. on ASF (Member Countries comments)	Proposed for adoption in 2017 (FEB 2015 / 5 th)
	2) New CH 8.X. on tuberculosis to merge CHs 11.5. & CH 11.6. (taking the example of new CH on <i>Brucella</i>)	Proposed for adoption in 2017 (SEP 2015 / 4 th)
	3) Revision of CH 11.11. on lumpy skin disease (Member Countries comments and animal health concern)	Proposed for adoption in 2017 (FEB 2016 / 3 rd)
	4) Revision of CH 10.4. on AI (Member Countries comments and trade implications)	Pending revision by experts
	5) Revision of CH 12.10. on glanders (outdated CH and trade implications)	Pending review of new scientific evidence (SEP 2014 / 3 rd)
	6) Revision of CH 11.4. on BSE (Member Countries comments and trade implications)	HQs evaluation and possible AHG (FEB 2015 / 1 st)

Annex 37 (contd)

Subject	Issue (By priority order, reason for new work)	Status and Action (Start date, # of rounds for comments)
	7) Revision of CH 8.8. on FMD (Member Countries comments and implications for status recognition)	Revised CH sent for comments (SEP 2015 / 2 nd)
	8) Revision of CH 8.13. on Rabies (Member Countries comments)	Pending AHG
	9) Revision of CH 11.12. on Theileriosis (outdated CH)	Discussion of AHG report in September 2017
	10) Revision of CH 8.3. on Bluetongue (Member Countries comments)	Revised CH sent for comments (SEP 2016 / 2 nd)
	11) Revision of CH 15.2. on CSF (Member Countries comments and implications for status recognition)	Revised CH sent for comments (FEB 2017 / 1 st)
	12) Revision of CH 14.8. on scrapie (Member Countries comments)	Pending experts opinion on Member Countries comments
	13) Revision of CH 10.5. on avian mycoplasmosis (Member Countries comments and trade implications)	Pending experts' opinion
	14) Revision of CH 11.7. on CBPP (Implications for status recognition)	Pending review of AHG report at SEP 2017 TAHSC meeting
	15) Revision of Article 8.15.2. on rinderpest (Member Countries comments and proposal by JAC)	Revised article sent for comments (FEB 2017 / 1 st)

List of abbreviations	
AAHSC	Aquatic Animal Health Standards Commission
AHG	<i>ad hoc</i> Group
AI	Avian influenza
APFSWG	Animal Production Food Safety Working Group
ASF	African Swine Fever
AW	Animal Welfare
AWWG	Animal Welfare Working Group
BSC	Biological Standards Commission
BSE	Bovine Spongiform Encephalopathy
CBPP	Contagious bovine pleuropneumonia
CH	Chapters
CSF	Classical swine fever
CWD	Chronic Wasting Disease
FMD	Foot and mouth disease
HQs	Headquarters
JAC	FAO-OIE Rinderpest Joint Advisory Committee
PRRS	Porcine reproductive and respiratory syndrome
PVS	Performance of Veterinary Service
TAHSC	Terrestrial Animal Health Standards Commission
WNF	West Nile fever

