Annex 21

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 purpose of *disease* control or *international trade*. *Subpopulations* may be separated by natural or artificial geographical barriers or~~, in certain situations,~~ by the application of appropriate 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 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*. 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. ~~the~~ For the same reasons, the use of compartmentalisation may allow a Member Country to take advantage of epidemiological links among *subpopulations* or common practices relating to *biosecurity*, despite diverse geographical locations~~, to facilitate *disease* control and/or the continuation of trade~~.

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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*.~~

~~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* 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*.~~

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

The procedures used to establish and maintain the distinct *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 ~~the~~ arrangements should be developed through active cooperation of industry and *Veterinary Services*.

The authority, organisation and infrastructure of the *Veterinary Services*, including *laboratories*, should be clearly documented 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.~~

~~*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 the application of *biosecurity*, documenting and recording movements of *animals* and personnel, quality assurance schemes, documenting 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:~~

~~*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.~~

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

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

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

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

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

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

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

3~~5~~) *Animals* and *herds/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 *animal health status* of a *zone* or *compartment* should be appropriate to the particular circumstances, and ~~will~~ depend on the epidemiology of the *disease*, environmental factors, the health status of *animals* in adjacent areas, applicable *biosecurity* ~~measures~~ (including movement controls, use of natural~~,~~ ~~and~~ artificial or legal boundaries, ~~the~~ spatial separation of *animals*, control of fomites, and commercial management and husbandry practices), and *surveillance*.

4~~6~~) Relevant *animals* and animal products 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/~~,~~ flock* ~~lot~~ 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*.

5~~7~~) For a *compartment*, the *biosecurity plan* should describe the partnership between the relevant industry and the *Veterinary Authority*, and their respective responsibilities. It should also describe the ~~routine~~ standard operating procedures to provide clear evidence that the *surveillance* conducted, the ~~live~~ *animal identification* and *traceability* system, and the management practices are adequate to meet the definition of the *compartment*. In addition to information on controls of movements of relevant *animals* and animal products ~~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 ~~by *surveillance*~~ 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 ~~demonstration~~ 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. ~~or~~ 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*~~, the *zone* ~~keeps~~ maintains its free status.

Article 4.3.5.

Infected zone

An *infected zone* is one either in which a *disease*~~, *infection* or *infestation* either~~ has been diagnosed, or that does not meet *disease* freedom provisions of the relevant chapters of the *Terrestrial Code*~~, the absence of which cannot be demonstrated. In the latter case, the *disease*-specific chapter of the *Terrestrial Code* contains an article describing the conditions for free and infected status.~~

An *infected zone* may be:

– a *zone* of a country where the *disease* has been present ~~for a long period~~ and has not yet been eradicated, while other *zones* of the country ~~have been~~ are free;

– a *zone* of a previously free country or *zone* ~~previously free~~, 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 ~~*disease*-specific~~ 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 introduction of a pathogenic agent of a specific *disease*~~, *infection* or *infestation*~~ from adjacent countries or *zones* of different animal health status. 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 ~~country or *zone*~~ 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)~~ ~~specific *animal identification* and *animal traceability* to ensure that *animals* in the *protection zone* are clearly distinguishable from other populations;~~

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

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

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

45) enhanced *biosecurity* including *disinfection* procedures for *vehicles*/*vessels*, vehicles for transportation of feed or fodder, and possible compulsory routes;

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

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

~~The *protection zone* may be a part of an *infected zone* or of a *free zone*.~~

Article 4.3.7.

Containment zone

In the event of ~~limited~~ *outbreaks* in a country or *zone* previously free from a *disease*, a *containment zone*, which includes all *outbreaks* may be established to minimise the impact on the rest of the country or *zone* ~~for the purposes of *disease* control or trade~~.

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, including:

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

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

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

4) clear 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 of *infection*;

6) *biosecurity* and *sanitary measures*, including ongoing *surveillance* and control of the movement of *animals* and *commodities* within and from ~~in~~ the *containment zone*, consistent with the *disease*-specific chapter, when there is one, to prevent spread of the *infection* 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* may continue to occur and a *protection zone*, where no *outbreaks* have occurred, which separates the *infected zone* from the rest of the country or *zone*.

The free status of the areas outside the *containment zone* ~~would be~~ is suspended pending ~~demonstration of the effectiveness~~ effective establishment of the *containment zone*. Once the *containment zone* has been established, the free status of these areas ~~may then be~~ is reinstated~~, irrespective of the provisions of the *disease*-specific chapter~~.

The free status of the *containment zone* should be regained in accordance with Article 1.4.6. or relevant *disease*-specific chapters.

~~The *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*. Well managed, it may allow the rest of the country or *zone* to keep their free status.~~

Article 4.3.8.

Bilateral recognition by trading countries

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 *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*.

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.

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Annex 22

DRAFT CHAPTER 4.X.

VACCINATION

Article 4.X.1.

Introduction and objectives

In general, *vaccination* is intended to control and prevent the occurrence of a *disease* and reduce the transmission of the pathogenic agent. For the purpose of *disease* control, 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 *vaccination* strategy applied depends on 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;

4) the 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 purpose 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.

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

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Article 4.X.3.

Vaccination programmes

The objectives 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*, 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 of a *disease* with the objective of control and possible eradication. In *disease* free countries or *zones*, the objective of systematic *vaccination* is to limit the impact in the case of an introduction of *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 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 considerother ongoing animal health related activities involving the target population. This can improve the efficiency of the programme and reduce the cost by sharing resources.

Article 4.X.4.

Launching a vaccination programme

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

1) the probability that the *disease* cannot be rapidly contained;

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

3) an increased likelihood of introduction or emergence of a *disease*;

4) the density of susceptible animals;

5) an insufficient level of population immunity;

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

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

8) the availability of resources;

9) cost-benefit considerations of *vaccination*, 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 *establishments* where an *outbreak* has occurred. To prevent outward spread of *disease*, *vaccination* should be applied from the outer 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:** v*accination* of a *subpopulation* of susceptible animals defined by a greater likelihood of exposure or severity of the consequences.

Article 4.X.6.

Critical elements of a vaccination programme

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

1. 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.

2. 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 for the minimum population immunity required to achieve the objectives of the programme. The minimum population immunity required will vary according to the epidemiology of the *disease*, density of susceptible animals and geographical factors.

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

3. Stakeholder involvement

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

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4. Resources

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

5. Actions and timeline

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

6. 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 to achieve the necessary *vaccination* coverage 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;

g) awareness, acceptance and engagement of stakeholders;

h) types of production systems and animal movement patterns;

i) timing of agricultural, social or cultural activities;

j) availability of resources.

7. Auditing of the vaccination campaigns

The *vaccination* programme should include periodic auditing of 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 the *vaccination* campaign include:

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

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

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

d) performance of vaccinator teams in respect of 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.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 depends on different factors including:

1. Availability and cost

   a) availability of the vaccine 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.

   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;

   – 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 environment.

   c) Side effects

   – adverse reactions;

   – transmission of live vaccine strains.

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 be subjected to the registration procedure of the country, which is congruent with the recommendation of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medical 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 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 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;

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 *vaccination* 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-vaccinated 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.

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 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;
4) reduction of *incidence* or *prevalence*.

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;*
3) reduction of the *incidence* or *prevalence* of the *disease* to a level where alternative measures such as *stamping-out* may be sufficient to achieve *disease* control;
4) inability of the programme to meet the desired objectives;
5) adverse public reaction to the *vaccination* programme.

Annex 22 (contd)

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 *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 a change in the *risk* of occurrence of a *disease* should inform trading partners and the OIE, as appropriate. 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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Annex 23

CHAPTER 4.8.

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

Article 4.8.1.

Aims of control

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

Article 4.8.2.

Conditions applicable to the embryo production team

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

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

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

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

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

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

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

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

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

   These facilities need not necessarily be at the same location.

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

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

Annex 23 (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 oocytes which have been recovered from ovaries are then matured and fertilised, and where the resulting embryos are further cultured *in vitro*.

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

Additionally:

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

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

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

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

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)[1].

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. 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*.

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

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

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

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

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

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

Article 4.8.5.

Optional tests and treatments

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

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

Tests may be carried out on the following materials:

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

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

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

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 meet the health requirements ~~and standards set out~~ in Chapter 4.6. as appropriate to the species.

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

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

Annex 23 (contd)

2) Any biological product of animal origin, including co-culture cells and media constituents, used in oocyte recovery, maturation, fertilisation, culture, washing and storage should be free ~~of~~ from ~~living pathogens~~ pathogenic agents. Media should be sterilised prior to use by approved methods in accordance with the IETS Manual[1] and handled in such a manner as to ensure that sterility is maintained. Antibiotics should be added to all fluids and media as recommended in the IETS Manual[1].

3) All equipment used to recover, handle, culture, wash, freeze and store oocytes~~/~~ or embryos should be new or cleaned and sterilised prior to use as recommended in the IETS Manual[1].

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 are collected;

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

2) the second phase covers risk mitigation by the use of internationally accepted procedures for the processing of embryos which are set out in the IETS Manual[1]. These include the following:

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

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

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

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

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

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

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

Article 4.8.7.

Conditions applicable to the storage and transport of oocytes and embryos

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

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

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

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

2) For frozen oocytes and embryos

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

   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~~ disinfected containers under strict hygienic conditions at a storage place.

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

3) For fresh or chilled oocytes and embryos

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

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

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

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

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

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.

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[1] Manual of the International Embryo Transfer Society

Annex 24

CHAPTER 4.11.

SOMATIC CELL NUCLEAR TRANSFER IN PRODUCTION LIVESTOCK AND HORSES

[Article 4.11.1.]

[…]

Article 4.11.4.

Background: risk analysis–general principles

1) *Risk analysis* in general includes *hazard* identification, *risk assessment*, *risk management* and *risk communication*. The *risk assessment* is the component of the analysis that estimates the *risks* associated with a *hazard* (see Chapter 2.1.). These principles are routinely used by regulators in making decisions about experimental or commercial releases. These analyses can then be used to determine whether the outcomes require management or regulation. *Risk management* is the process by which *risk* managers evaluate alternative actions or policies in response to the result~~(s)~~ of the *risk assessment* taking into consideration the various social, economic, and legal considerations that form the environment in which such activities occur.

2) For animal *diseases*, particularly those listed in the *Terrestrial Code*, there is broad agreement concerning the likely *risks* and *risk~~s~~* *assessments* can be qualitative or quantitative (see Chapter 2.1.). In *disease* scenarios it is more likely that a *qualitative risk assessment*, in which the outputs on the likelihood of the outcome or the magnitude of the consequences are expressed in qualitative terms such as 'high', 'medium', 'low' or 'negligible', is all that is required. *Qualitative assessments* do not require mathematical modelling to carry out routine decision-making. *Quantitative risk assessments* ~~or semi-quantitative risk assessments~~ assign magnitudes to the *risks* in numerical terms (e.g. 1/1,000,000) ~~or descriptive (high/medium/low) terms~~.

3) In the context of animal cloning, two broad categories of *risk assessments* are considered: absolute *risk assessment* and comparative *risk assessments*. Absolute *risk assessments* characterise *risk* independent of a comparator (e.g. the likelihood of an animal transmitting a specific livestock *disease*). A comparative *risk assessment* (or relative *risk assessment*) puts the *risk* in the context of a comparator. For example the degree to which an animal produced by one reproductive technology can transmit a particular *disease* to another animal of the same species compared with the degree to which a similar animal produced by another reproductive technology transmits the same *disease* to another animal of same species.

4) Regardless of the methodology used, *hazard* identification is an early step in all science-based *risk assessments*. In the context of assessing the *risks* associated with animal cloning (SCNT) and starting with the embryo and moving on through animal clone development and subsequent progeny, it is important to be clear at this juncture that only a comparative ~~semi-quantitative~~ *risk assessment* can be completed. A systematic, absolute, *quantitative risk assessment* of potential *risks* is difficult, due to the relative newness of the technology, and the variability in outcomes among laboratories and species cloned. Furthermore, with the technology of SCNT there is no introduced *hazard* from the insertion of novel genes (which may potentially happen in transgenesis). Thus, to analyse what factors contribute to animal health *risks*, the existing baseline must be analysed.

5) In short, the specific points where the *risk assessment* needs to be focused need to be identified. As illustrated in the accompanying diagram – the focus is to look at the basics of creating an embryo – using current terminology, starting from the selection of donor of oocyte and the cells to the creation of an embryo by the cloning methodology. The second phase will focus on the recipient of the embryo clone and the animal health and care considerations for the animals. The actual embryo clone that is born as an offspring is the third part of the paradigm that needs clear recommendations for assessment, and the next generation, either the progeny of the animal clone (which is a result of normal sexual reproduction) or animals produced by recloning (clones of clones) is the fourth and final stage.

Annex 24 (contd)

[Article 4.11.5.]

[…]

[Article 4.11.7.]

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Annex 25

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.). 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.

The development of antimicrobial resistance surveillance and monitoring programmes

1. General aspects

Surveillance of antimicrobial resistance 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.

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

Annex 25 (contd)

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

a) statistically based surveys;

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

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

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

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

2. Sampling strategies

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

– the sample is representative of the population of interest;

– the robustness of the sampling method.

b) The following criteria are to be considered:

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

– animal species;

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

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

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

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

– sample size.

3. Sample size

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

~~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

4. Sample sources

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.

c) Food

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

5. Type of sample to be collected

Feed samples 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*.

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

Annex 25 (contd)

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

Source	Type	Output	Additional information required or additional stratification
Herd or flock of origin	Faeces or bulk milk	Prevalence of resistant bacteria originating from animal populations (of different production types) Relationship between resistance – and antimicrobial use	Age categories, production types, etc. Antimicrobial use over time
Abattoir	Faeces	Prevalence of resistant bacteria originating from animals at slaughter	
	Caeca or intestines	As above	
	Carcass	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	

6. Bacterial isolates

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

a) Animal bacterial pathogens relevant to the countries' priorities

i) Surveillance and ~~M~~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)~~ — guide *veterinarians* in their ~~prescribing~~ treatment decisions.

ii) 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.

iii) 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 (vaccines).

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

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

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

b) Zoonotic bacteria

i) Salmonella

Salmonella should be sampled from animal feed, food producing animals and animal derived food products. For the purpose of consistency and harmonisation, samples should be preferably 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.

ii) Campylobacter

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

iii) Other emerging bacterial pathogens

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

c) Commensal bacteria

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

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

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.

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 monitoring purposes. However, 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~~.

9. Recording, storage and interpretation of data

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

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

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

i) as distributions of MICs in micrograms per millilitre;

ii) or inhibition zone diameters in millimetres.

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

i) sampling programme;

ii) sampling date;

iii) animal species and production type;

iv) type of sample;

v) purpose of sampling;

vi) type of antimicrobial susceptibility testing method used;

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

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

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

x) bacterial recovery rate.

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

i) identity of *laboratory*,

ii) isolation date,

iii) reporting date,

iv) bacterial species,

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

v) serotype or serovar,

vi) phage type,

vii) antimicrobial susceptibility result or resistance phenotype,

viii) genotype.

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

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

h) The antimicrobial susceptibility testing standards and guidelines used should be recorded.

i) For surveillance 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.

j) Ideally, data should be collected at the individual isolate level, allowing antimicrobial resistance patterns to be recorded.

10. Reference laboratory and annual reports

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

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

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

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

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

i) raw data;

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

iii) inter-laboratory proficiency testing results;

iv) information on the structure of the monitoring system;

v) information on the chosen laboratory methods.

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Annex 26

CHAPTER 7.1.

INTRODUCTION TO THE RECOMMENDATIONS FOR ANIMAL WELFARE

Article 7.1.X.

Guiding principles for the use of animal-based measures

1) For the OIE *animal welfare* standards to be applicable globally, they should emphasise good outcomes for the animals rather than prescribe specific conditions of the animals' environment and management. Outcomes are generally assessed by 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, 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.

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 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 be defined on the basis of science and expert experience, in cases where 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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Annex 27

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 intended for production of *meat*.

For the purpose 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, and animal management practices, such as best practice in housing and husbandry and implementation of welfare protocol and audits, all 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 purpose of this chapter, 'environmental enrichment' means increasing the complexity (e.g. foraging opportunities, social housing) of the animal's environment to foster the expression of normal behaviour and reduce the expression of abnormal behaviour and provide cognitive stimulation. The endpoint of enrichment should be to improve the biological functioning of the animal (Newberry, 1995).

Article 7.X.2.

Scope

This chapter addresses the welfare aspects of pig production systems. However, *captive wild* pigs are not considered.

Article 7.X.3.

Commercial pig production systems

Commercial pig production systems include:

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 food 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 may be fully dependent on humans to provide for basic animal needs such as food and water. They are typically confined in paddocks according to their production stage.

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.

Annex 27 (contd)

Article 7.X.4.

Criteria (or measurables) for the welfare of pigs

The following outcome-based criteria, 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 feed and water intake, altered locomotory behaviour and posture, altered lying time, altered respiratory rate and panting, coughing, shivering and huddling, increased agonistic behaviours and stereotypic, apathetic or other abnormal behaviours (e.g. tail biting).

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

Infectious and metabolic diseases, lameness, peri-partum 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 *herd*. Understanding the aetiology of the disease or syndrome is important for detecting potential *animal welfare* problems. Mastitis and metritis, leg and hoof, and reproductive diseases are also particularly important animal health problems for pigs. Scoring systems, such as for body condition, lameness and injuries, provide additional information.

Both clinical 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* 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 loss, are indicators of poor *animal welfare* and health.

In mature animals, body condition outside an acceptable range may be an indicator of compromised *animal welfare*, health and reproductive efficiency.

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, compared with the targets expected for a particular breed or hybrid, can indicate *animal welfare* problems.

Examples may include:

– low conception rates,
– high abortion rates,
– metritis and mastitis,
– low litter size,
– 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:

– presence of ectoparasites,
– abnormal texture or hair loss,
– excessive soiling with faeces in indoor systems,
– swellings, injuries or lesions,
– discharges (e.g. from nose or eyes),
– feet and leg abnormalities,
– abnormal posture (e.g. rounded back, head low),
– emaciation or dehydration.

7. Handling response

Improper handling 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 disturbed behaviour when being moved or when *animal handlers* 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 lameness and to gait abnormalities. Pigs that are lame or have gait abnormalities may have difficulty reaching food and water and may experience pain. 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 requirements and improve human safety and *animal welfare*.

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

Annex 27 (contd)

Indicators of such problems 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 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.

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.

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.

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.

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 in extreme circumstances and provided that the animal can move freely. The use of electric prods should be avoided (see also point 3 of Article 7.3.8.), and in any case should not be used in sensitive areas including the udder, face, eyes, nose or ano-genital 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 handled aggressively (e.g. kicked, 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.

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.9.

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 requirements and improve human safety and *animal welfare*.

These procedures have the potential to cause pain and thus should be performed in such a way as to minimise any pain and distress to the animal.

Options for enhancing *animal welfare* in relation to these procedures include the internationally recognised ‘three Rs’ which involves replacement (entire or inmunocastrated males vs. castrated males), reduction (tail docking and teeth clipping only when necessary) and refinement (providing analgesia or anaesthesia).

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.

Annex 27 (contd)

Article 7.X.10.

Feeding and 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, size and physiological state of the pigs (e.g. pregnancy, lactation), and their state of health, growth rate, previous feeding levels and level of activity and exercise.

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

– maintain good health;

– meet its physiological demands; and

– avoid metabolic and nutritional disorders.

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

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

All pigs should have access to an adequate supply of palatable 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, 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.11.

Environmental enrichment

Animals should be provided with an environment that provides complexity and cognitive stimulation (e.g. foraging opportunities, social housing) to foster normal behaviour, reduce abnormal behaviour and improve biological function.

Pigs should be provided with multiple forms of enrichment that aim to improve the 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 look for feed (edible materials), bite (chewable materials), root (investigable materials) and manipulate (manipulable materials) (Bracke *et al.*, 2006);

– social enrichment which 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).

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.12.

Prevention of abnormal behaviour

In pig production there are a number of abnormal behaviours that can be prevented or minimised with 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 recommendations to reduce their occurrence 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), 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).

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 measurable): 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.13.

Space allowance

Space allowance should be managed taking into account different areas for lying, standing and feeding. Crowding 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 rest simultaneously, and each animal lie down, 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 abnormal behaviour is seen, corrective measures should be taken, such as increasing space allowance and providing barriers where possible.

   In outdoor systems where pigs have 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. presence of faeces on the skin).

2. Individual pens

   Pigs must be provided with sufficient space so that they can stand up, turn around and lie comfortably in a natural position, and that provides for separation of dunging, lying and eating areas.

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

Annex 27 (contd)

3. Stalls (crates)

Stalls must be sized appropriately to allow pigs to:

– be able to stand up in their natural stance without contact with either side of the stall,
– stand up without touching the top bars,
– stand in a stall without simultaneously touching both ends of the stall,
– 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 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 pens should allow water to drain and not pool in the pens.

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

If bedding 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. Dust, micro-organisms and noxious gases, including ammonia, hydrogen sulphide, and methane, 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 in enclosed housing should not exceed 25 ppm. A useful indicator is that if air quality is unpleasant for humans it is also likely to be a problem for pigs.

Outcome-based criteria (or measurables): morbidity, mortality and culling rates, behaviour (especially respiratory rate or coughing), reductions in weight and body condition.

Annex 27 (contd)

Article 7.X.16.

Thermal environment

Although pigs can adapt to different thermal environments particularly if appropriate breeds 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 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, stocking density, shade and wallow availability in outdoor systems, 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 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 to create a serious risk to the welfare of pigs, particularly in neonates and young pigs and others that are physiologically compromised (e.g. ill animals). This can be provided by 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 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 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.

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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 measurable): 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 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.

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

Article 7.X.20.

Weaning

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

An average weaning age of three weeks or older is recommended (Worobec *et al.*, 1999).

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 is important. The area that piglets are weaned into should be clean and dry.

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

Outcome-based criteria (or measurable): 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 animals should be supervised.

Measures to prevent excessive fighting and injuries can include (Arey and Edwards, 1998):

– providing additional space and a non-slippery floor,

– feeding before mixing,

– feed on the floor in the mixing area,

– provision of straw in the mixing area,

– providing opportunities to escape and to hide from other pigs, such as visual barriers,
– mix previously familiarised animals whenever possible,
– young animals should be mixed as soon after weaning as possible,
– avoid 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 measurable): physical appearance, 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

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

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

Article 7.X.24.

Biosecurity and animal health

1. Biosecurity and disease prevention

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

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

   – pigs, including introductions to the *herd*,
   – young animals coming from different sources,
   – other domestic animals, *wildlife*, and pests,
   – people, including sanitation practices,
   – equipment, tools and facilities,
   – *vehicles*,
   – air,
   – water supply, feed and bedding,
   – manure, waste and disposal of dead animals,
   – semen.

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 *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), 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 pigs should not be transported or moved unless absolutely necessary for treatment or diagnosis. Such movements should be done carefully using methods that avoid dragging the animal or lifting it in a way that might 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 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 measurable): morbidity, mortality and culling rates, reproductive efficiency, behaviour (apathetic behaviour), lameness, physical appearance (injuries) and changes in body weight and body condition.

b) Emergency plans for disease outbreaks

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

Article 7.X.25.

Emergency plans

Where the failure of power, water and 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.

Humane *killing* procedures for 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.

Reasons for humane *killing* may include:

– severe emaciation, weak pigs that are non-ambulatory or at risk of becoming non-ambulatory,
– non-ambulatory pigs that will not stand up, refuse to eat or drink, have not responded to therapy,
– rapid deterioration of a medical condition for which therapies have been unsuccessful,
– severe, debilitating pain,
– compound fracture,
– spinal injury,
– central nervous system disease,
– multiple joint *infections* with chronic weight loss,
– piglets that are premature and unlikely to survive, or have a debilitating congenital defect, and
– as part of disaster management response.

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

Annex 27 (contd)

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Annex 28

CHAPTER 8.3.

INFECTION WITH BLUETONGUE VIRUS

Article 8.3.1.

General provisions

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

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

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

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

3) antigen or ribonucleic acid specific to a BTV 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 vaccine strain, or

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

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

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

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

Article 8.3.2.

Safe commodities

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

1) *milk* and *milk products*;

2) *meat* and *meat products*;

3) hides and skins;

4) wool and fibre;

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

Annex 28 (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.

Zone seasonally free from bluetongue

A *zone* seasonally free from bluetongue is 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 bluetongue

For ruminants and camelids

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

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

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 bluetongue

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;

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

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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;

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

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 bluetongue

For semen of ruminants and camelids

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

1) the donor males:

   a) showed no clinical sign of bluetongue on the day of collection~~;~~ and

   ~~*b)*~~ were kept in a country or *zone* free from bluetongue or in a seasonally free *zone* during the ~~seasonally~~ free season ~~period~~ for at least 60 days before commencement of, and during, collection of the semen; or

   b~~c~~) comply with point 1 of Article 8.3.10.;~~were subjected to a serological test to detect antibodies to the BTV group, with negative results, between 28 and 60 days after the last collection for this consignment, and, in case of a seasonally free *zone*, at least every 60 days throughout the collection period; or~~

   ~~*d)* were subjected to an agent identification test on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;~~

2) the semen was collected, processed and stored in accordance with Chapters 4.5. and 4.6.

Article 8.3.10.

Recommendations for importation from countries or zones infected with BTV

For semen of ruminants and camelids

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

1) the donor males:

   a) showed no clinical sign of bluetongue on the day of collection;

   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

   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:

Annex 28 (contd)

1) the donor females:

a) showed no clinical sign of bluetongue on the day of collection;

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

c) were subjected to a serological test to detect antibodies to the BTV group, between 28 and 60 days after collection, with negative results; or

d) were subjected to an agent identification test on a blood sample taken on the day of collection, with negative results;

2) the embryos were collected, processed and stored in accordance with Chapters 4.7., 4.8. and 4.9., as relevant.

Article 8.3.12.

Recommendations for importation from countries or zones infected with BTV

For *in vivo* derived embryos of ruminants (other than bovine embryos) and other BTV susceptible animals and for *in vitro* produced bovine embryos

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

1) the donor females:

a) showed no clinical sign of bluetongue on the day of collection;

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;

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.

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.

Annex 28 (contd)

An important component of the epidemiology of bluetongue is the capacity of its *vector*, which provides a measure of *disease risk* that incorporates *vector* competence, abundance, biting rates, survival rates and extrinsic *incubation period*. However, methods and tools for measuring some of these *vector* factors remain to be developed, particularly in a field context. Therefore, *surveillance* for bluetongue should focus on transmission of BTV in domestic ruminants and camelids.

The impact and epidemiology of bluetongue widely differ in different regions of the world and therefore it is not appropriate to provide specific recommendations for all situations. Member Countries should provide scientific data that explain the epidemiology of bluetongue in the country or *zone* concerned and adapt the *surveillance* strategies for defining their status to the local conditions. There is considerable latitude available to Member Countries to justify their status at an acceptable level of confidence.

Surveillance for bluetongue should be in the form of a continuing programme.

Article 8.3.15.

General conditions and methods for surveillance

1) A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. In particular:

   a) a formal and ongoing system for detecting and investigating *outbreaks* of *disease* should be in place;

   b) a procedure should be in place for the rapid collection and transport of samples from suspected *cases* of *infection* with BTV to a *laboratory* for diagnosis;

   c) a system for recording, managing and analysing diagnostic and *surveillance* data should be in place.

2) The bluetongue *surveillance* programme should:

   a) in a free country or *zone* or seasonally free *zone*, have an early warning system which obliges farmers and workers, who have regular contact with domestic ruminants, as well as diagnosticians, to report promptly any suspicion of bluetongue to the *Veterinary Authority*.

      An effective *surveillance* system will periodically identify suspected *cases* that require follow-up and investigation to confirm or exclude whether the cause of the condition is bluetongue. The rate at which such suspected *cases* are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. All suspected *cases* of bluetongue should be investigated immediately and samples should be taken and submitted to a *laboratory*. This requires that sampling kits and other equipment be available for those responsible for *surveillance*;

   AND

   b) conduct random or targeted serological and virological *surveillance* appropriate to the status of the country or *zone*.

Article 8.3.16.

Surveillance strategies

The target population for *surveillance* aimed at identification of *disease* or *infection* should cover susceptible domestic ruminants and camelids, and other susceptible herbivores of epidemiological significance within the country or *zone*. Active and passive *surveillance* for bluetongue should be ongoing as epidemiologically appropriate. *Surveillance* should be composed of random or targeted approaches using virological, serological and clinical methods appropriate for the status of the country or *zone*.

It may be appropriate to focus *surveillance* in an area adjacent to a border of an infected country or infected *zone* for up to 100 kilometres, taking into account relevant ecological or geographical features likely to interrupt the transmission of BTV or the presence in the bordering infected country or infected *zone* of a bluetongue *surveillance* programme (in accordance with Articles 8.3.14. to 8.3.17.) that supports a lesser distance.

A Member Country should justify the *surveillance* strategy chosen as being adequate to detect the presence of *infection* with BTV in accordance with Chapter 1.4. and the prevailing epidemiological situation. It may, for example, be appropriate to target clinical *surveillance* at particular species likely to exhibit clinical signs (e.g. sheep).

Similarly, virological and serological testing may be targeted to species that rarely show clinical signs (e.g. cattle).

In vaccinated populations, serological and virological *surveillance* is necessary to detect the BTV types circulating to ensure that all circulating types are included in the *vaccination* programme.

If a Member Country wishes to declare freedom from bluetongue in a specific *zone*, the design of the *surveillance* strategy should be aimed at the population within the *zone*.

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

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

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

The principles involved in *surveillance* for *disease* or *infection* are technically well defined. The design of *surveillance* programmes to prove the absence of *infection* with and transmission of, BTV should be carefully followed to avoid producing results that are either insufficiently reliable to be accepted by international trading partners, or excessively costly and logistically complicated.

1. Clinical surveillance

   Clinical *surveillance* aims to detect clinical signs of bluetongue at the *flock* or *herd* level, particularly during a newly introduced *infection*. In sheep and occasionally goats, clinical signs may include oedema, hyperaemia of mucosal membranes, coronitis and cyanotic tongue.

   Suspected *cases* of bluetongue detected by clinical *surveillance* should always be confirmed by *laboratory* testing.

2. Serological surveillance

   An active programme of *surveillance* of host populations to detect evidence of transmission of BTV is essential to establish the bluetongue status of a country or *zone*. Serological testing of ruminants is one of the most effective methods of detecting the presence of BTV. The species tested should reflect the epidemiology of bluetongue. 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. 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.

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 cattle.

Annex 28 (contd)

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.

Annex 29

FUTURE WORK PROGRAMME FOR THE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

General Topic		
Detailed issue or action (By priority order)	**By whom to be managed**	**Status and further steps**
Restructuring of the *Terrestrial Code*, including harmonisation of the *Terrestrial* and *Aquatic Codes*		
1) Work with AAHSC towards harmonisation, as appropriate, of the horizontal parts of the *Codes,* notably Glossary, User's Guide and section 4 on disease control and section 6 on Veterinary Public Health	TAHSC & AAHSC & HQs	Ongoing
2) Work with BSC for accurate disease description and diagnostic in the *Manual* and case definitions in the *Code* and names of diseases and country and zone disease status	TAHSC & BSC & HQs	Ongoing
3) Revision and formatting of chapters (articles numbering, tables and figures), especially of Section 7	TAHSC & AWWG &HQs	Ongoing
4) Revision of the Users' guide to address the precedence of chapters	TAHSC & AAHSC &HQs	Preliminary discussion
Glossary		
1) OIE standard, OIE guideline	TAHSC & AAHSC & BSC & SCAD & HQs	To be considered by OIE Council
2) Global revision of glossary for consistency throughout the Code	TAHSC & HQs	Ongoing and proposed some editorial & deletion for MC
3) Vaccination	TAHSC & BSC & SCAD & AHG & HQs	Revised definition for MC
4) Zone, free zone, infected zone, containment zone, protection zone	TAHSC & SCAD & HQs	Revised definitions for MC
Horizontal issue not yet in the *Terrestrial Code*		
1) CH on vaccination	TAHSC & BSC & SCAD & AHG & HQs	Draft new CH proposed for MC
2) CH on management of outbreaks of the listed diseases	TAHSC & AAHSC & SCAD & HQs	Draft new CH to be discussed in Feb 2017
3) CH on *Salmonella* in pigs and in cattle	TAHSC & APFSWG	Reviewed and sent for further MC
4) CH on AW and pig production systems	TAHSC & AWWG	Draft CH (section 7): proposed for MC
5) CH on killing methods for farmed reptiles	TAHSC & AWWG	Preliminary discussion

Annex 29 (contd)

***Terrestrial Code* texts on horizontal issues in need of revision: Section 1 Notification**		
1) CH 1.4. on Animal Health Surveillance	TAHSC & SCAD & HQs	Further revision of draft modifications to be discussed in Feb 2017
2) CH 1.3. on listed diseases: assess CWD & WNF against the criteria	TAHSC & HQs	Preliminary discussion
3) CH 1.6. on Status: reorganisation	TAHSC & SCAD & HQs	Ongoing
***Terrestrial Code* texts on horizontal issues in need of revision: Section 2 Risk analysis**		
Draft new CH on criteria for assessing safe commodities	TAHSC	Sent for MC and adoption
***Terrestrial Code* texts on horizontal issues in need of revision: Section 3 Veterinary Services**		
Revision of CHs of Section 3 in the light of the return of experience of the PVS Pathway	TAHSC &HQs	Preliminary discussions
***Terrestrial Code* texts on horizontal issues in need of revision: Section 4 Disease control**		
1) CH 4.3. on zoning	TAHSC & SCAD & HQs	New revised version sent for MC
2) CH 4.6. on semen collection	TAHSC &BSC	Pending experts' advice
3) CH 4.7. and 4.8. on embryos	TAHSC & BSC	Pending experts' advice
4) Global restructuring of Section 4	TAHSC & HQs	Ongoing
***Terrestrial Code* texts on horizontal issues in need of revision: Section 5 Trade measures**		
1) CH 5.3. on SPS agreement	TAHSC &HQs	Sent for further MC and adoption
2) CH 5.12. on Model certificates for competition horses	TAHSC & SCAD & HQs	Preliminary discussion
***Terrestrial Code* texts on horizontal issues in need of revision: Section 6 Veterinary Public Health**		
1) New Introductory CH on Section 6	TAHSC & APFSWG	Preliminary discussion
2) Revision of CH 6.1.	TAHSC & APFSWG	Sent to APFSWG
3) Revision of CH 6.2.	TAHSC & APFSWG	Pending WG report
***Terrestrial Code* texts on horizontal issues in need of revision: Section 7 Animal welfare**		
1) CH 7.5. on slaughter and CH 7.6. on killing	TAHSC & AWWG	Sent to experts for further advice
2) CH 7.12. on AW of working equids		Proposed for adoption
Diseases issues not yet in the *Terrestrial Code*		
1) New CH 15.X. on PRRS	TAHSC & SCAD	Sent for MC and adoption
2) Non-tsetse transmitted Trypanosomosis (new CH on Surra and revision of CH on Dourine)	TAHSC & SCAD & AHG	Pending AHG
3) Crimean Congo hemorrhagic fever	TAHSC & HQs	Preliminary discussion

Annex 29 (contd)

***Terrestrial Code* texts on diseases in need of revision: Sections 8 to 15, by priority order**		
1) Revised CH 15.1. on ASF	TAHSC	Sent for further MC and adoption
2) New CH 8.X. on tuberculosis to merge CHs 11.5. & CH 11.6.	TAHSC	Sent for MC and adoption
3) Update CH 11.11. on lumpy skin disease	TAHSC	Sent for MC and adoption
4) Revised CH 12.10. on glanders	TAHSC	Sent for MC and adoption
5) Revised CH 11.4. on BSE	TAHSC & SCAD & BSC & AHG	Pending revision of AHG report
6) Revision CH 8.8. on FMD	TAHSC & SCAD & AHG & HQs	For discussion in Feb 2017
7) Update CH 10.4. on avian influenza viruses	TAHSC & HQs	Pending work on zoning and outbreak management
8) Update CH 10.5. on avian mycoplasmosis	TAHSC & HQs	Pending experts' opinion
9) Update/Revise CH 11.12. on theileriosis	TAHSC & SCAD	Pending AHG
10) Update CH 14.8. on scrapie	TAHSC	Review MC, seek expert opinion

List of abbreviations	
AAHSC	Aquatic Animal Health Standards Commission
AHG	*ad hoc* Group
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
CH	Chapters
CWD	Chronic Wasting Disease
FMD	Foot and mouth disease
HQs	Headquarters
MC	Member Countries' comments
PRRS	Porcine reproductive and respiratory syndrome
PVS	Performance of Veterinary Service
SCAD	Scientific Commission for Animal Diseases
TAHSC	Terrestrial Animal Health Standards Commission
WNF	West Nile fever

Annex 29 (contd)

ITEM, ANNEX, CHAPTER NUMBERS AND CURRENT STATUS

Item	Annex	Chapter	Title	Action	To be proposed for Adoption at 85 GS
1	-	-	General comments	-	-
2	4	-	Glossary A and A′	C	O
2	4	-	Glossary A"	I	X
2	5	-	Glossary B and B′	C	X
3	-	1.1.	Notification of diseases, infections and infestations	N	X
4	6	1.2.	Criteria for listing diseases	C	O
5	7	1.3.	Diseases listed by the OIE	C	O
6	-	1.4.	Animal health surveillance	D, E	X
7	8	2.X.	Draft new chapter on criteria for assessing the safety of commodities	C	O
8a	21	4.3.	Zoning and compartmentalisation	C	X
8b	22	4.X.	Draft new chapter on vaccination	C	X
8c	-	4.Y.	Draft new chapter on management of outbreaks of listed diseases	D, E	X
9a	-	4.6.	Collection and processing of bovine, small ruminant and porcine semen	E	X
9b	23	4.8.	Collection and processing of *in vitro* derived embryos from livestock and equids	C	X
9c	24	4.11.	Somatic cell nuclear transfer in production livestock and horses	C	X
10	9	5.3.	OIE procedures relevant to the WTO/SPS Agreement	C	O
11a	-	6.1.	The role of the veterinary services in food safety	D, E	X
11b	25	6.7.	Harmonisation of national antimicrobial resistance surveillance and monitoring programmes	C	X
12a	10	6.X.	Draft new chapter on prevention and control of *Salmonella* in commercial cattle production system	C	O
12b	11	6.Y.	Draft new chapter on prevention and control of *Salmonella* in pig production systems	C	O
13b	26	Art 7.1.X.	Draft article on guiding principles on the use of animal-based measures	C	X
13c	-	7.Y.	Draft new chapter on methods of killing farmed reptiles for their skins and meat	D, E	X
13d	-	7.5. & 7.6.	Slaughter of animals/killing of animals for disease control purposes	E	X
13f	12	Art 7.11.6.	Animal welfare and dairy cattle production systems	C	O
13g	13	7.12.	Welfare of working equids	C	O
13h	27	7.X.	Draft new chapter on AW and pig production systems	C	X
14	28	8.3.	Infection with Bluetongue virus	C	X
15	-	8.8.	Infection with Foot and mouth disease virus	D, E	X
16	14	8.X.	Infection with *Mycobacterium tuberculosis* complex	C	O
17	15	Art 10.4.25	Infection with Avian influenza viruses	C	O
18	16	11.11.	Infection with Lumpy skin disease	C	O
19	18	15.1.	Infection with African swine fever virus	C	O
20	19	15.X.	Draft new chapter on Infection with PRRS	C	O
21a	20	Art 4.16.3.	High health status horse subpopulation	C	O

Annex 29 (contd)

Item	Annex	Chapter	Title	Action	To be proposed for Adoption at 85 GS
21b	17	12.10.	Infection with *Burkholders mallei* (Glanders)	C	O
22	29	-	Work programme	C	-
23b	-	8.18.	West Nile fever	I	X
13a	30	-	Report of AWWG	I	-
13h	31	-	Report of AHG on AW and pig production systems	I	-

C: For Member comments; **E**: under expert consultation (*ad hoc* groups, Specialist Commissions, etc.); **D**: deferred to FEB 2017 meeting; **I**: For Member Country information, **N**: No action; **O**: will be proposed for adoption at 85th General Session; **X**: will not be propose for adoption at 85th General Session.