EUROPEAN UNION

Brussels
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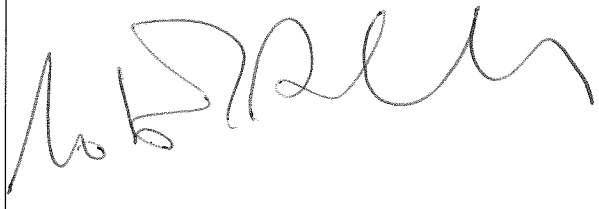
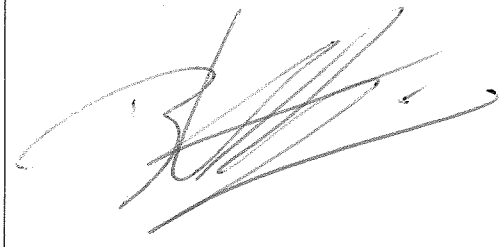
Subject: **EU comments on the OIE Terrestrial Code**

Dear Director General,

Please find enclosed the comments of the European Union on Annexes 21 to 36; Annex 51; and Item 5.7a) of the report of the February 2017 meeting of the Terrestrial Animal Health Standards Commission, for consideration at its next meeting in September 2017.

We trust you will find this useful and I thank you for your continued good cooperation.

Yours sincerely,

Dr Roberto Andrea Balbo CVO and OIE Delegate Malta	Dr Bernard Van Goethem Director for Crisis Management in Food, Animals and Plants European Commission, DG Health and Food Safety
	

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Annex: 1

Copy: All Directors / Chief Veterinary Officers of the EU 28 and Iceland, Liechtenstein, Norway, Switzerland, and Albania, the former Yugoslav Republic of Macedonia, Montenegro, Serbia and Turkey.

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Annex 21

GLOSSARY (PART B)

EU comment
The EU thanks the OIE and in general supports the proposed changes to the glossary. Comments are inserted in the text below.

ANIMAL WELFARE

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

EU comment
The EU thanks the OIE for its work on the definition of animal welfare. The EU welcomes referring to "state of well-being" instead of "coping", as it does not limit the term "welfare" solely to coping with negative situations. However the shortened definition does not include now all the key elements which form part of animal welfare. Furthermore, there is no reference as to what "state of wellbeing" means.
The EU therefore proposes the OIE to develop further the currently proposed definition as to ensure that main key elements are captured, even if in a more concise definition. Furthermore, any key element contributing to animal welfare and removed from the previous definition should be properly highlighted in Article 7.1.1. as representing an important complementary part of the new animal welfare definition currently under revision by OIE.
Justification
The previous OIE's "definition" is extremely helpful in providing a detailed understanding of the factors involved in the concept of animal welfare and provides an international steer of key elements included when referring to animal welfare. Furthermore, the currently adopted definition of animal welfare (that appears in the Glossary and Article 7.1.1) is a core element of the OIE's contribution to animal welfare as it is comprehensive in setting out both the negative factors that must be avoided and the positive factors that should be provided.
Scientific references supporting the justification:
The original definition is in accord with developing scientific thinking as to what is entailed in animal welfare. Mellor (2016) stresses it is necessary not only to minimise negative experiences but also "to provide the animals with opportunities to have positive experiences".
Mellor DJ, 2016. Updating Animal Welfare Thinking: Moving beyond the "Five Freedoms" towards "A Life Worth Living". Animals 2016, 6(3), 21; http://www.mdpi.com/2076-2615/6/3/21

Farm Animal Welfare Committee. Farm animal welfare in Great Britain: past, present and future.
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/319292/Farm_Animal_Welfare_in_Great_Britain_-_Past__Present_and_Future.pdf

COMPARTMENT

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

CONTAINMENT ZONE

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

EU comment

For better readability, the EU suggests the following editorial amendments to the last part of the sentence above:

"[…] where movement controls, biosecurity and sanitary measures are applied to prevent the spread of~~,~~ and to eradicate~~,~~ the infection or infestation.".

~~***DISEASE***~~

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

EU comment

While in general supporting the deletion of the definition of "disease" (and of the proposed one for "pathogenic agent" in Part A), the EU notes that the consequential changes needed throughout the Code will be extensive, and should preferably all be done at the same time. Furthermore, consideration should be given to the same issue in the Aquatic Code, with a view to harmonising both Codes as far as possible.

FREE ZONE

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

INFECTED ZONE

~~means a *zone* in which a *disease* has been diagnosed.~~

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

PROTECTION ZONE

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

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

EU comment

The EU queries whether use of the word "adjacent" (meaning next, adjoining, contiguous according to common dictionaries) is pertinent in the definition above. Indeed, in some geographical areas, the zones in question would not be contiguous and could thus possibly prevent the concept from being applied (e.g. Andorra between France and Spain; parts of Namibia between Botswana and Angola). Therefore, the EU suggests use of the word "neighbouring" instead, which would give more flexibility.

As an alternative, the last part of the sentence could also be deleted completely (as from "from an adjacent […]"), to cater also for situations where a protection zone is established around an international port or airport.

VACCINATION

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

ZONE/~~REGION~~

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

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— Text deleted.

Annex 22bis

CHAPTER 4.3.

ZONING AND COMPARTMENTALISATION

EU comment

The EU thanks the OIE and in general supports the proposed changes to this chapter. Comments are inserted in the text below.

Article 4.3.1.

Introduction

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

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

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

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

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

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

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

~~As well as contributing to the safety of *international trade*, zoning and compartmentalisation may assist *disease* control or eradication within a Member Country's territory.~~ Zoning may encourage the more efficient use of resources within certain parts of a country and compartmentalisation may allow the functional separation of a *subpopulation* from other domestic ~~*animals*~~ or *wild animals* through *biosecurity* ~~measures~~, which a *zone* ~~(through geographical separation)~~ would not achieve through geographical separation. In a country where a *disease* is endemic, establishment of *free zones* may assist in the progressive control and eradication of the *disease*. To facilitate *disease* control and the continuation of trade following a *disease outbreak* in a previously free country or *zone*, ~~to facilitate *disease* control and the continuation of trade, the use of~~ zoning may allow a Member Country to

limit the extension of the *disease* to a defined restricted area, while preserving the status of the remaining territory. ~~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~~.

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

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

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

Article 4.3.2.

General considerations

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

EU comment

The EU suggests adding "movement controls" in the paragraph above, to complement animal identification and traceability, as these three concepts go hand in hand.

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

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

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

EU comment

The EU suggests adding "and where appropriate vaccination, treatment and protection against vectors" at the end of the paragraph above, as there should be resources for these elements as well.

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.

EU comment

The EU suggests adding audits on the use of vaccines in the paragraph above, by inserting the words "use of vaccines" after "reporting". Indeed, this would also be important in cases where vaccines are available but vaccination is prohibited.

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

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

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

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

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

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

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

Article 4.3.3.

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

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

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

EU comment

The EU suggests replacing the term "legal" by "administrative" in point 1) above, which seems more appropriate in this context.

~~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.~~

~~*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~~ operators through official channels.

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

EU comment

For clarity reasons, the EU suggests replacing "disease risk" by "risk of infection or infestation" at the end of the first sentence of the paragraph above.

Furthermore, in the same sentence, it is not clear what is meant by "epidemiological separation". Does it mean a physical separation based on the epidemiology of the disease of concern, i.e. separation measures supported/ justified / founded / based on the science of epidemiology? This should preferably be clarified.

4~~6~~) Relevant ~~*animals* and animal products~~ *commodities* within the *zone* or *compartment* should be identified in such a way that their movements are traceable. Depending on the system of production, identification may be done at the *herd*~~/~~, or *flock* ~~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*.

EU comment

In the first sentence of the paragraph above, the concept of movement controls seems to be missing. Indeed, to be effective, identification and traceability should go hand in hand with movement controls, e.g. movements should restricted or limited to certain times of the day.

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~~ *commodities* ~~animal movement controls~~, the plan should include *herd*~~/~~ or *flock* production records, feed sources, *surveillance* results, birth and *death* records, visitor logbook, morbidity and mortality history, medications, *vaccinations*, documentation of training of relevant personnel and any other criteria necessary for evaluation of *risk management*. The information required may vary in accordance with the species and *diseases* under consideration. The *biosecurity plan* should also describe how the measures will be audited to ensure that the *risks* are regularly ~~re-assessed~~ reassessed and the measures adjusted accordingly.

EU comment

The EU suggests inserting "records of cleansing and disinfection" to the paragraph above, as this should also be included in the biosecurity plan.

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

Article 4.3.4.

Free zone

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

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

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

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

Article 4.3.5.

Infected zone

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

An *infected zone* may be:

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

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

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

Article 4.3.6.

Protection zone

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

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

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

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

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

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

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

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

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

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

Article 4.3.7.

Containment zone

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

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

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

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

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

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

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

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

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

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

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

OR

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

EU comment

In point b) above, it is unclear whether the requirement "for at least two incubation periods" is linked to "from the last detected case" or not (as is the case in point a). The EU is of the opinion that the way the proposal is worded, this is not the case. However, perhaps there is a need to clarify this intended meaning explicitly, to avoid any misinterpretation and international trade problems. Indeed, this is a crucial point that differentiates point b) from point a) so as to offer a true alternative.

The free status of the areas outside the *containment zone* is suspended pending the effective establishment of the *containment zone*. Once the *containment zone* has been established, the areas outside the *containment zone* regain free status ~~of these areas may then be is reinstated,~~.

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

Article 4.3.8.

Bilateral recognition by trading countries

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

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

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

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

EU comment

The EU does not support the final amendment in the paragraph above (changing "certifies" into "demonstrates"), as it seems to invalid self-declarations of disease freedom or regionalisation (as notified to the OIE) in line with OIE recommendations and thus counters the spirit of mutual trust between OIE Members. Indeed, that change seems to imply that the exporting country will have to demonstrate its claims in every case by default. The EU therefore requests that change be withdrawn. As an alternative, the word "certifies" could be replaced by "can demonstrate".

- Text deleted.

Annex 23

DRAFT CHAPTER 4.X.

VACCINATION

EU comment

The EU thanks the OIE and in general supports this proposed new chapter. Comments are inserted in the text below.

Article 4.X.1.

Introduction and objectives

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

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

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

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

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

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

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

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

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

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

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

Article 4.X.2.

Definitions

For the purposes of this chapter:

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

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

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

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

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

Article 4.X.3.

Vaccination programmes

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

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

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

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

EU comment

While in general supporting the changes to point 1) above, the EU refers to its comment on Part B of the glossary as regards use of the word "adjacent" (see Annex 21) and suggests replacing it by the word "neighbouring".

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

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

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

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

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

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

Article 4.X.4.

Launching a vaccination programme

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

1) the epidemiology of the *disease*;

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

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

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

3bis) the zoonotic potential of the *disease*;

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

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

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

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

8) the availability of an appropriate vaccine and human, financial, and material resources;

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

Article 4.X.5.

Vaccination strategies

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

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

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

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

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

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

Choice of vaccine

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

1. Availability and cost

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

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

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

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

2. Vaccine characteristics

   a) Physical characteristics

   – route and ease of administration;

   – volume of dose;

– type of adjuvant and other components.

b) Biological characteristics

– immunity against circulating strains;

– live, inactivated or biotechnology-derived vaccines;

– number of strains and pathogens included in the vaccine;

– potency of the vaccine;

– onset of immunity;

– shelf-life and expiry date;

– thermostability;

– duration of the effective immunity;

– number of doses required to achieve effective immunity;

– ability to be monitored for vaccine-induced antibodies;

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

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

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

c) Side effects

– adverse reactions;

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

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

Other critical elements of a vaccination programme

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

1. Legal basis

The legal basis for a *vaccination* campaign, including a legal obligation for the *vaccination* and compensation for farmers for possible side effects, should be in place.

EU comment

The EU thanks the OIE for having considered its suggestion in relation to legal basis by including the above point. However, the EU notes that in its original proposal, it had suggested reference to possible legal obligation for the vaccination. Indeed, depending on the situation and the disease, not in all cases will a legal obligation to vaccinate be necessary or justified. This may sometime even be counterproductive, as seen in recent years in some countries.

The EU therefore suggests inserting the word "possible" before "legal obligation for the vaccination".

2. Target population

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

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

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

32. Vaccination coverage

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

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

43. Stakeholder involvement

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

EU comment

The EU reiterates its previous comment on the point above, in that it is unclear what is meant by "The vaccination programme should demonstrate good governance by the Veterinary Services". Indeed, it is not the vaccination programme that should demonstrates good governance, but rather the Veterinary Services. Perhaps turning the sentence around would help, e.g. as follows:

"When implementing the vaccination programme, Veterinary Services should demonstrate good governance by […]"

54. Resources

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

65. Actions and timeline

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

76. Timing of vaccination campaigns

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

The objective of the *vaccination* campaign ~~is~~ should be to achieve the ~~necessary~~ *vaccination* coverage necessary to attain or maintain ~~and~~ the minimum population immunity in the target population within a

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

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

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

b) accessibility of the target population;

c) animal handling facilities;

d) animal body condition and physiological state;

e) geographical factors;

f) climate conditions;

fbis) vector activity;

g) awareness, acceptance and engagement of stakeholders;

h) types of production systems and animal movement patterns;

i) timing of agricultural, social or cultural activities;

j) availability of resources.

87. Auditing of the vaccination campaigns

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

Indicators related to auditing of the *vaccination* campaign include:

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

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

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

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

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

e) timing and length of the campaign;

f) overall cost and cost per individual animal vaccinated.

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

Article 4.X.8.

Logistics of vaccination

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

1. Procurement of vaccine

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

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

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

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

2. Implementation of the vaccination programme

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

a) implement the communication plan;

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

c) store, transport and administer the vaccine;

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

e) dispose of waste;

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

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

f) identify vaccinated animals;

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

h) record activities of vaccination teams;

i) document *vaccinations*.

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

3. Human resources

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

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

4. Public awareness and communication

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

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

5. Animal identification

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

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

6. Record keeping and vaccination certificates

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

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

7. Additional animal health related activities

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

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

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

Article 4.X.9.

Evaluation and monitoring of a vaccination programme

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

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

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

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

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

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

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

Article 4.X.10.

Exit strategy of a vaccination programme

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

Criteria to cease *vaccination* may include:

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

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

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

EU comment

To be consistent with the proposed amendment of point 4) of Article 4.X.9., the EU suggests likewise amending point 3) above, as follows:

"reduction of the incidence, ~~or~~ prevalence or impact of the disease […]"

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

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

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

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

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

Article 4.X.11.

Impact on disease status and management of vaccinated animals

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

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

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

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— Text deleted.

Annex 24

CHAPTER 4.8.

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

EU comment

The EU thanks the OIE and in general supports the proposed changes to this chapter. Comments are inserted in the text below.

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.

Article 4.8.3.

Conditions applicable to the processing laboratories

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

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

Additionally:

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

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

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

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

EU comment

Referring to our previous comment regarding the mention of use of laminar flows in the article above and the Code Commissions request for a concrete text proposal, we are pleased to provide the following:

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

Article 4.8.4.

Conditions applicable to donor animals

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

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

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

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

EU comment

The EU shares the concerns expressed in the second part of the paragraph above as regard batch collection. As disease specific chapters of the Code currently do not include recommendations for in vitro produced embryos, this commodity should be addressed and included in the relevant chapters in future.

Additionally:

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

EU comment

In point 1) above, consideration should be given to replacing the term "Veterinary Authority" with "Veterinary Services". This would be consistent with the changes proposed in point 8) below and in point 6 of Article 4.8.2.

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.

EU comment

Referring to our previous comment regarding the insertion of a fourth test ("a pool of at least three washes of the washing medium used for the oocytes/the embryos") and the Code Commissions request for a scientific rationale, we are pleased to provide the following:

The rationale of the fourth test is the suggestion of Marquard-le Guienne *et al.* in Chapter 5 of the IETS Manual (page 62). The authors postulated to sample a pool of the last three washes from the 10 washes performed on the developed embryos as a control that the washing medium prior to transfer/cryoperservation was free of infectious agents.

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

Additionally:

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

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

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

2) Any biological product of animal origin, including co-culture cells and media constituents, used in oocyte recovery, maturation, fertilisation, culture, washing and storage should be free ~~of~~ from ~~living pathogens~~ pathogenic agents. Media should be sterilised prior to use by approved methods in accordance with the IETS Manual[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 or semen for fertilisation of oocytes are collected;

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

2) the second phase covers risk mitigation by the use of internationally accepted procedures for the processing of embryos which are set out in the IETS Manual[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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— Text deleted.

[i] Manual of the International Embryo Transfer Society.

Annex 25bis

[Marked up text]

CHAPTER 6.1.

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

EU comment

The EU thanks the OIE and in general supports the proposed changes to this chapter. Comments are inserted in the text below.

Article 6.1.1.

Introduction

Veterinarians are trained in both animal health (including *zoonoses*) and food safety, which makes them uniquely equipped to play a central role in ensuring food safety, especially the safety of food~~s~~ of animal origin. Close cooperation and effective communication between all actors, including *veterinarians*, other relevant professionals and stakeholders, is critical for the effective operation of the food safety system.

EU comment

The EU suggests amending the first sentence of the paragraph above as follows:

"Veterinarians are trained in both animal health (including animal infections such as foodborne zoonoses) and food hygiene ~~safety~~, which [...]".

Indeed, the Chapter deals with food safety and therefore focus should be set on foodborne zoonoses, which are not always a health issue for the animals. Food safety has two pillars: prevention of infection in live animals and avoidance of contamination of meat/food by microbiological, chemical and physical hazards, which can be summarised as "food hygiene".

~~Food safety systems are now considerably different from those of earlier years and this provides a wider role for the *Veterinary Services*. The characteristics of these systems are global,~~ The global, regional, national and local implications of food safety systems, ~~in reach,~~ especially in relation to the globalisation of the food supply, ~~which requires a greater~~ demands a high level of engagement and collaboration between *Competent Authorities* responsible for animal health, food safety and public health, in line with the One Health approach. This provides a wider role and greater responsibilities for *Veterinary Services*. ~~There is a particular emphasis on risk-based food safety systems where implementation is a responsibility shared with a wide range of actors along with assurance of non-food safety requirements that are of high importance to consumers.~~

Food safety activities performed by *Veterinary Service*s should be integrated to the greatest extent possible with the activities of all other responsible public agencies throughout the food chain.

EU comment

Several sentences in the text above (the second one of the first paragraph; the first one of the second paragraph; and the third paragraph) all express the same idea, i.e. collaboration, which is also repeated and further elaborated on in Article 6.1.3.1. and again repeated in the second sentence of Article 6.1.3.4. It is thus suggested to merge these sentences.

~~The education and training of *veterinarians*, which includes both *animal* health (including *zoonoses*) and food safety components, makes them uniquely equipped to play a central role in ensuring food safety, especially the~~

~~safety of foods of *animal* origin. In addition to *veterinarians*, other professionals are involved in ensuring an integrated food safety system throughout the food chain.~~

Article 6.1.2.

Purpose and scope

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

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

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

Article 6.1.3.

Characteristics of a food safety system

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

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

EU comment

The EU does not support the deletion of the following sentence, which should be reinstated:

"The prevention, detection, and control of foodborne hazards throughout the food chain is generally more effective in reducing or eliminating the risk of unwanted health effects than relying on controls of the final product".

Indeed, a pro-active approach detecting the hazard as early as possible may limit the spread and consequently the potential public health impact. It will also reduce the economic impact by limiting recalls and the potential reputational damage.

Furthermore, the EU suggests deleting the last sentence since this is developed in detail in points 3 and 4 below and because the sentence might be misleading (the primary responsibility for food safety is with the food business operator).

Finally, it is proposed to add the following new sentence after the sentence on the food chain information (i.e. the one ending with "[...] enhance the effectiveness of a food safety system."):

"In particular, providing sound information on the occurrence of infections at the farm prior to arrival of the animals, may allow a more targeted, risk-based inspection in slaughterhouses."

Indeed, meat inspection in the slaughterhouse plays a central role in food safety and must therefore be carried out in a way taking into account the history of the animals on the farm.

2. Risk-based food safety systems

Risk-based food safety systems include measures based on good practices (such as good agricultural practice ~~Good Agricultural Practice~~, good hygienic practice ~~Good Hygienic Practice~~), hazard analysis and critical control points (HACCP) principles and risk assessment. The design and application of a risk-based food safety system depends ~~this risk-based approach depend~~ on the availability of adequate scientific information and effective utilisation of the technical resources of food business operators and *Competent Authorities* ~~and technical resources of the *Competent Authority*. Monitoring and review are essential to evaluate the performance of a risk-based food safety system~~. Monitoring food safety outcomes and reviewing control measures are essential to ensure the effective performance of a risk-based food safety system.

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

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

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

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

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

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

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

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

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

Article 6.1.4.

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

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

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

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

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

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

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

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

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

2. Activities of Veterinary Services throughout the food chain

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

a) Primary production

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

EU comment

The EU regrets the replacement of the last sentence of the paragraph above by merely two words ("good sanitary"). The EU considers that the role of the veterinary services in providing advice to the prevention of infections at primary production should be underlined and therefore further elaborated as it will reduce the entry of foodborne pathogens and limit the use of antimicrobial agents. We therefore propose the following sentences be added at the end of the paragraph above:

"The veterinary services advise on good animal husbandry practices to prevent and limit transmission of infections, including foodborne diseases. They include biosecurity measures before entering a holding or different building, use of compartments, best practices to avoid stress during weaning or gathering of animals, optimal ventilation, etc."

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

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

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

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

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

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

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

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

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

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

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

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

EU comment

In the sentence above, two separate concepts are interlinked, for both of which the Veterinary Services are ascribed an essential role. However, while the role of Veterinary Services is indeed essential as regards certification, it is not necessarily essential in the oversight of assurance schemes. The EU therefore suggests replacing the word "essential" with "<u>important</u>", and inserting the words "<u>an essential role</u>" before "certifying", as this would more adequately qualify the role of Veterinary Services.

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

3. Foodborne disease outbreaks

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

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

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

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

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

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

Annex 26

CHAPTER 6.7.

HARMONISATION OF NATIONAL ANTIMICROBIAL RESISTANCE SURVEILLANCE AND MONITORING PROGRAMMES

EU comment

The EU thanks the OIE and supports the proposed changes to this chapter.

Article 6.7.1.

Objective

This chapter provides criteria for the:

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

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

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

Article 6.7.2.

Purpose of surveillance and monitoring

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

Surveillance and monitoring of antimicrobial resistance is necessary to:

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

2) detect the emergence of new antimicrobial resistance mechanisms;

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

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

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

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

Article 6.7.3.

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

~~1.~~ ~~General aspects~~

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

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

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

1~~a~~) statistically based surveys;

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

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

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

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

6) sampling and testing of feed ingredients or feed.

Article 6.7.4.

Sampling

1~~2~~. Sampling strategies

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

– the sample is representative of the population of interest;

– the robustness of the sampling method.

b) The following criteria are to be considered:

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

– animal species;

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

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

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

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

– sample size.

2~~3~~. Sample size

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

The sample should avoid bias and provide a representative sample whilst taking into account the expected prevalence of the resistance phenotype and the desired level of precision and confidence.

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

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

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

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

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

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

a) Animal feed

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

b) Food producing animals

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

c) Food

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

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

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

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

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

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

Annex 26 (contd)

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

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

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

Article 6.7.5.

Bacteria subjected to surveillance and monitoring

~~6. Bacterial isolates~~

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

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

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

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

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

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

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

~~b~~*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.

~~c~~*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, such as ~~(~~vaccines and Good Agricultural Practices~~)~~.

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

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

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

2~~b~~) Zoonotic bacteria

a~~i~~) *Salmonella*

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

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

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

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

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

Annex 26 (contd)

b~~ii~~) *Campylobacter*

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

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

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

3~~c~~) Commensal bacteria

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

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

Article 6.7.6.

~~7.~~Storage of bacterial strains

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

Article 6.7.7.

~~8.~~Antimicrobial susceptibility testing

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

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

Article 6.7.8.

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

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

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

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

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

b) ii) or inhibition zone diameters in millimetres.

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

a) i) sampling programme;

b) ii) sampling date;

c) iii) animal species and production type;

d) iv) type of sample;

e) v) purpose of sampling;

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

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

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

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

x) bacterial ~~recovery~~ isolation rate.

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

a) i) identity of *laboratory*,

b) ii) isolation date,

c) iii) reporting date,

d) iv) bacterial species,

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

e) v) serotype or serovar,

f) vi) phage type,

g) vii) antimicrobial susceptibility result or resistance phenotype,

h) viii) genotype.

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

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

Annex 26 (contd)

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

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

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

Article 6.7.9.

10. Reference laboratory and annual reports

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

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

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

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

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

ai) raw data;

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

ciii) inter-laboratory proficiency testing results;

div) information on the structure of the surveillance or monitoring system;

ev) information on the chosen laboratory methods.

— Text deleted.

Annex 27

CHAPTER 7.1.

INTRODUCTION TO THE RECOMMENDATIONS FOR ANIMAL WELFARE

EU comment

The EU thanks the OIE for its work on this new draft article and for taking EU comments into account. The EU does however have a few comments as indicated in the text below.

The EU would also suggest the OIE clarifying and ensuring consistency in the use of the terminology referring to measures, measurables and criteria.

Article 7.1.X.

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

1) For the OIE *animal welfare* standards to be applicable globally, they should put more emphasis~~e~~ on good outcomes for the animals ~~rather~~ than on ~~prescribe~~ specific conditions of the animals' environment and management. Outcomes are generally measured ~~assessed~~ by assessing animals' enjoyment of the "five freedoms" decribed in Article 7.1.2. ~~animal-based measures such as low mortality rate, low prevalence of injuries, ability to move freely, positive human-animal relationship, and a low incidence of aggression and stereotyped behaviour.~~

EU comment

The EU asks the OIE to consider the following amendment of the first sentence of the above paragraph:

"For the OIE animal welfare standards to be applicable globally, they should ~~put more~~ emphasise ~~on~~ good outcomes for the animals ~~than~~ ~~on~~ while also recognising that the specific conditions of the animals' environment and management will influence animal welfare outcomes."

Justification:

It is important to ensure that there is a balance between outcomes and inputs of resources and management. The relationship between outcomes and inputs is well described in the OIE Chapter on the welfare of dairy cattle. This states that "outcome-based ... criteria can be considered as a tool to monitor the impact of design and management, given that both of these can affect animal welfare." Article 7.11.5 of the Chapter on dairy also states "Ensuring good welfare of dairy cattle 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." Article 7.11.6 also includes 'physical environment'.

Similarly nearly all the principles set out in Article 7.1.4 focus both on resources and the outcomes that each resource should produce.

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

EU comment

The EU asks the OIE to consider the following amendment of the first sentence of the above paragraph:

"For each principle listed in Article 7.1.4., the most relevant measures/criteria, ~~ideally~~ including animal-based measures, should be included."

Justification:

It is important to highlight that only animal-based measures might not be sufficient , and that both inputs and outputs are key, particularly in some areas.

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

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

5) In addition to animal-based measures, resource-based measures and management-based measures ~~can~~ should be defined on the basis of science and expert experience ~~in cases where a~~ showing that a welfare outcome is clearly linked to a resource ~~such as adequate space,~~ or to a management procedure ~~such as pain mitigation~~.

EU comment

The EU asks the OIE to consider including the following sentence at the end of the above paragraph:

"If outcomes are unsatisfactory, producers should consider what changes to resources and/or management are needed to improve outcomes."

Justification:

The above proposed addition would helpfully explain the value of considering changes to resources and management in cases where outcomes are unsatisfactory. The concepts surrounding welfare outcomes were developed by the EU's *Welfare Quality* project. The project aims to base the *assessment* of welfare on animal-based measures and outcomes; however, it stresses that when an assessment reveals welfare to be unsatisfactory, an improvement strategy must consider the need for changes to inadequate housing, resources and management. Indeed, the *Welfare Quality* team has developed practical improvement strategies many of which involve making changes to inputs.

Scientific references supporting the justification:
Welfare Quality, 2009. Practical strategies for improving farm animal welfare: an information resource.

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— Text deleted.

Annex 28

DRAFT CHAPTER 7.X.

ANIMAL WELFARE AND PIG PRODUCTION SYSTEMS

EU comment

The EU thanks the OIE for its work on this new draft chapter and for taking many of the EU comments into account. The EU can in general agree with the proposed changes in this modified chapter. Furthermore the EU would also like to reiterate some previous comments, due to their relevance, as indicated in the text below.

Article 7.X.1.

Definitions

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

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

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

EU comment

The EU asks the OIE to consider the following amendment of the final sentence in this paragraph:

"The aim of providing enrichment should be to improve the ~~biological functioning~~ mental and physical well-being of the animal (Newberry, 1995)."

Justification:

The primary reasoning behind environmental enrichment is to provide animals in a less than ideal environment with resources / facilities that support species-specific positive and rewarding behaviours (Mellor 2015, 2016) and reduce abnormal behaviour (stereotypical, misplaced and agonistic/ aggressive). It is supporting both psychological and physiological development, therefore the "mental" element is as important if not more important than the physical / biological functioning of the animal. "Biological functioning" (Newberry) is more usually understood as the physical / physiological / good health element of animal welfare and this old reference is somewhat confusing.

Scientific references

Mellor DJ, Updating Animal Welfare Thinking: Moving beyond the "Five Freedoms" towards "A Life Worth Living".Animals (Basel). 2016 Mar 14;6(3).

Mellor DJ Positive animal welfare states and encouraging environment-focused and animal-to-animal interactive behaviours. N Z Vet J. 2015 Jan;63(1):9-1

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

EU comment

The EU asks the OIE to consider the following amendment of the above paragraph defining Stereotipy.

"For the purposes of this chapter stereotypy is ~~as~~ a sequence of abnormal and repetitive ~~and unvarying~~ behaviours which have no obvious purpose or function. They can be caused by ~~known~~ factors such as frustration and coping attempts with nutritional, physical and social rearing environments. Permanent ~~or~~ dysfunction of the central nervous system in response to early rearing environment or sustained stressful environments may occur, which may mean that developed stereotypies may not resolve despite later changes to the environment or other treatment. Some stereotypies commonly observed in pigs include sham chewing, stone chewing, tongue rolling, teeth grinding, bar biting and floor licking (NFACC, 2014; Tuyttens, 2007; Mason and Latham, 2004)."

Justification:

1. Typo on the first sentence - remove "as"

2. The key part of the definition is the behaviours have no obvious goal, purpose or function. This has been added (Mason et al 2007)

3. Not all stereotypies' causes are known (although many are); many are multifactorial in origin therefore should not refer to them as "known" just remove known & not all stereotypies are "unvarying" (Mason et al 2007, Grandin 2010)

4. Mason et al 2007 Why and how should we use environmental enrichment to tackle stereotypic behaviour? Applied Animal Behaviour Science 102 (2007) 163–188

5. Temple Grandin 2010 Improving Animal Welfare: A Practical Approach (Chapter 8), CABI.

6. In pigs the impact of low food levels on stereotypies is well established. This is also acknowledged in article 7.X.11 of this draft chapter.

7. Spoolder, H.A.M., Burbidge, J.A., Edwards, S.A, Simmins, P.H. and Lawrence, A.B., 1995. Provision of straw as a foraging substrate reduces the development of excessive chain and bar manipulation in food restricted sows. Applied Animal Behaviour Science, 43: 249-262.

8. Terlouw, E.M.C., Lawrence, A.B. and Illius, A.W., 1991. Influences of feeding level and physical restriction on development of stereotypies in sows. Animal Behaviour, 42: 981-991

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

For the purposes of this chapter agonistic behaviour is a continuum of behaviours expressed in conflict situations,

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

EU comment

The EU asks the OIE to consider including at the end of the above paragraph also reference and definition of displacement / harmful redirected behaviours, as follow:

"However, other behaviours, such as tail biting on some occasions, may occur as a result of harmful redirected bahaviours. Harmful redirected behaviours are foraging or exploration behaviours redirected at pen mates and (eventually) resulting in persistent licking, biting, massaging or chewing of part of the body"

Justification:

The only reference to "biting" is in reference to agonistic behavior. Tail-biting is not an agonistic or aggressive behavior and if not clarified under this section could cause confusion. Tail-biting is referenced later in the Chapter a number of times as an "abnormal" behavior with no further explanation of what an "abnormal behavior" is and this is not captured by any of the definitions described in the Article above.

As regards redirected behaviors, "a redirected behavior is an abnormal behaviour with a clear goal (unlike a stereotypy). It is often driven by lack of access to, or competition for, a substrate or particular environment that is important for meeting the animal's behavioural needs. There can be a number of different motivations for the behaviour and a wide range of environmental, dietary and husbandry factors have been identified as risks for tail-biting. These hazards range from lack of adequate enrichment material, high stocking densities, competition for feed/water, inadequate diet (deficiencies of sodium or essential amino-acids) to poor health status, climate and ventilation conditions, animal characteristics (breed, genetics, gender) or social environment (herd size, mixing animals). For example biting other pigs such as the tail and ears, may be considered a redirected foraging activity in the absence of appropriate and/or sufficient forage material. Competition for essential resources, such as food or water, can result in more aggressive goal-directed biting behaviour but the end result is similar – tail-biting. Certain individual pigs have been identified as obsessive tail-biters, these are individuals that persistently seek to bite other pigs' tails beyond even normal foraging activities or any need to access an essential resource."

References:

-Petersen (1994) The development of feeding and investigatory behaviour in free ranging domestic pigs during their first 18 weeks of life. Appl Anim Beh Sci, 42, 87–98.

-Schrøder-Petersen, DL & Simonsen, HB (2001) Tail Biting in Pigs. Vet J., 162: 196–210

-EFSA (2007) The risks associated with tail biting in pigs and possible means to reduce the need for tail docking considering the different housing and husbandry systems.

-Taylor NR, Main DC, Mendl M, Edwards SA. Tail-biting: a new perspective. 2010 Vet J. 2010 Nov;186(2):137-47

Article 7.X.2.

Scope

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

Article 7.X.3.

Commercial pig production systems

Commercial pig production systems include:

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~~ feed and water. The type of housing depends on the environment, climatic conditions and management system. The animals may be kept in groups or individually.

2. Outdoors

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

3. Combination systems

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

Article 7.X.4.

Criteria (or measurables) for the welfare of pigs

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

1. Behaviour

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

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

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

2. Morbidity rates

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

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

3. Mortality and culling rates

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

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

4. Changes in body weight and body condition

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

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

5. Reproductive efficiency

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

Examples may include:

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

6. Physical appearance

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

– body condition,

EU comment

The EU asks the OIE to consider the following inclusion in the point above:

"- body condition outside normal score"

Justification:

This is a list of attributes of physical appearance that may indicate compromized welfare. All pigs have a body condition, not necessarily indicating compromized welfare. Thus, only body condition outside normal score should be included.

– presence of ectoparasites,
– abnormal texture or hair loss,
– excessive soiling with faeces in indoor systems,

EU comment

The EU asks the OIE to consider the following deletion in the point above:

"excessive soiling with faeces ~~in indoor systems~~"

Justification:

Excessive soiling is also a problem in outdoor systems

= reddish skin discolouration,

EU comment

The EU asks the OIE to consider changing the above sentence to "~~reddish~~ abnormal skin discolouration".

Justification:

There are a number of conditions that cause skin discoloration and they are not necessarily always red. For example you could get blue discoloration with cyanosis.

- swellings, injuries or lesions,
- discharges (e.g. from nose or eyes, including tear staining) (Telkänranta *et al.*, 2016).
- feet and leg abnormalities,
- abnormal posture (e.g. rounded back, head low),
- emaciation or dehydration (in piglets).

EU comment

The EU asks the OIE to consider the following amendement of the above point:

"- emaciation or dehydration (especially detectable in piglets)"

Justification:

Suggested for clarity as emaciation or dehydration also occur in adult pigs, but the conditions are very difficult to detect in this group of animals due to the texture of the skin.

7. Handling response

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

- evidence of poor human-animal relationship, such as marked avoidance of handlers and vocalisation ~~disturbed behaviour~~ when being moved or when *animal handlers* interact with pigs ~~enter a pen~~,
- animals slipping or falling during handling,
- injuries sustained during handling, such as bruising, lacerations and fractured legs,
- animals vocalising abnormally or excessively during ~~restraint and~~ handling.

8. Lameness

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

9. Complications from common procedures

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

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

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

– post-procedure *infection* and swelling,

– post-procedure lameness,

– behaviour indicating pain, fear and distress,

– morbidity, mortality and culling rates,

– reduced feed and water intake,

– post procedure body condition and weight loss.

Article 7.X.5.

Recommendations

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

Articles 7.X.6. to 7.X.26. provide recommendations for measures applied to pigs.

EU comment

The EU asks the OIE to consider in the above bullet point replacing "7.X.26 " with "7.X.27 "

Justification:

Article 7.X.27 also provides recommendations for measures applied to pigs.

Each recommendation includes a list of relevant outcome-based criteria (or measurables) derived from Article 7.X.4.

EU comment

The EU asks the OIE to consider rewording the above sentence as follows: "Each recommendation in Article 7.X.6 to 7.X.24 includes …"

Justification:

Out-come based criteria are included only up to Article 7.X.24.

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~~6.

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

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

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

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

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

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.

EU comment

The EU asks the OIE to consider replacing the word "food" by "feed" in the above sentence.

Justification:

Linguistic change.

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

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

Annex 28 (contd)

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

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

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

Well designed and maintained handling facilities assists proper handling.

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

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

Painful procedures

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

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

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

EU comment

The EU asks the OIE to consider the following amendement in the above paragraph.

"(~~e.g. providing analgesia or anaesthesia under the recommendation of a veterinarian~~ e.g. using anaesthesia or analgesia under the recommendation or supervision of a veterinarian)".

Justification:

To ensure consistency with the second paragraph of Article 7.X.8.

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

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

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

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

activity and exercise.

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

– maintain good health;

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

– ~~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).~~

EU comment

The EU asks the OIE to consider retaining the above sentence.

"Pigs especially pregnant sows and gilts should be fed a diet with sufficient fibrous feedstuffs in order to satisfy their hunger"

Justification:

Sufficient quantity of bulky or high-fibre feed is important especially for sows and it is very important to reduce hunger and the occurance of gastric ulcers. The predominant factor for development of gastric ulcers seems to be the structure (particle size) of the diet. Roughage is also beneficial.

References:

- Whittaker, X., Spoolder, H.A.M., Edwards, S.A., Corning, S. & Lawrence, A.B., 1998. The influence of dietary fibre and the provision of straw on the development of stereotypic behaviour in food restricted pregnant sows. *Applied Animal Behaviour Science,* 61: 89-102

- **Mosseler, A; Wintermann, M ; Sander, SJ ; Kamphues, J. 2012. Effect of diet grinding and pelleting fed either dry or liquid feed on dry matter and pH in the stomach of pigs and the development of gastric ulcers. JOURNAL OF ANIMAL SCIENCE; 90, 343-345**

- Di Martino G., Capello K., Scollo A., Gottardo F., Stefani A.L., Rampin F., Schiavon E., Marangon S., Bonfanti L. (2013).*Continuous straw provision reduces prevalence of oesophago-gastric ulcer in pigs slaughtered at 170 kg (heavy pigs)*. Research in Veterinary Science 95, 1271-1273.

- **Amory, J.R., Mackenzie, A.M., Pearce, G.P., 2006. Factors in the housing environment of finisher pigs associated with the development of gastric ulcers. Veterinary Records 158, 260–264.**

- Day, J.E.L., Burfoot, A., Docking, C.M., Whittaker, X., Spoolder, H.A.M., Edwards, S.A., 2002. The effects of prior experience of straw and the level of straw provision on the behaviour of growing pigs. Applied Animal Behaviour Science 76, 189–202.

- Doster, A.R., 2000. Porcine gastric ulcer. The veterinary clinics of North America. Food Animal Practice 16, 163–174.

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

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

EU comment

The EU asks the OIE to consider the following amendement of the above point:

"(dehydration especially detectable in piglets"

Justification:

Suggested for consistency with the comment made to Article 7.X.4, no. 6.

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

Environmental enrichment

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

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

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

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

– positive human contact (such as pats, rubs and talking when the opportunity arises) (Hemsworth and Coleman, 2011; Hemsworth and Coleman, 1994).

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

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

Prevention of abnormal behaviour

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

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

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

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

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

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

EU comment

The EU asks the OIE to consider the following amendement of the above point:

"Vulva biting may be reduced by minimising competition for resources, including feed and water ~~in accessing the feeding area~~."

Justification:

Whilst feeder competition is a factor, other limited resources that lead to competition, including watering points can be a trigger (Rizvi et al 1998).

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

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

Housing (including outdoor production systems)

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

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

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

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

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

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

EU comment

The EU would like to reiterate its previous comment and asks the OIE to consider the following amendment:

"Pigs ~~Sows and gilts~~ are social animals and prefer living in groups, therefore all pigs and in particular pregnant sows and gilts ~~should preferably~~ are recommended to be housed in groups with sufficient space to perform normal social behaviour."

Justification:

The recommendation to keep pigs in groups should apply to all pigs.

Sufficient space is an aspect that needs to be taken into account and should be mentioned here. Indeed, providing insufficient space to group housed animals is counter-productive and may dramatically decrease animal welfare.

Furthermore, this brings the text in line with OIE introductory chapter 7.1.5 "Social grouping of animals should be managed to allow positive social behaviour and minimise injury, distress and chronic fear".

Scientific references

There are several; an overview related to sows in early pregnancy is provided in: Spoolder, H.A.M, Geudeke, M.J., Van der Peet-Schwering, C.M.C and Soede, N.M., 2009. Group housing of sows in early pregnancy: a review of success and risk factors. Livestock Science, 125: 1-14.

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

Article 7.X.13.

Space allowance

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

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

1. Group housing

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

EU comment

The EU asks the OIE to consider including the following sentence at the end of the above paragraph.

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

Justification:

1. Weng, R.C., Edwards, S.A., English, P.R., 1998. Behaviour, social interactions

and lesion scores of group-housed sows in relation to floor space

allowance. Applied Animal Behaviour Science 59, 307–316.

2. Edwards, S.A., Mauchline, S., Stewart, A.H., 1993. Designing pens to minimise aggression when sows are mixed. Farm Building Progress 113, 20–23.

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

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

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

2. Individual pens

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

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

3. Stalls and ~~(~~crates~~)~~

EU comment

The EU would like to reiterate its previous comment and asks the OIE to consider adding the following introductory sentence:

"Systems using crates and stalls should be discouraged due to the ensuing health and welfare problems."

Justification:

Pigs are highly social animals and it is important for their welfare that they kept in groups as much as possible so that they have the possibility to express natural and social behaviour. Crates limit the pig's possibility for free movement and possibility to express natural/normal behaviour. It is therefore important for the welfare of the pigs that the time they are kept in crates is limited. Furthermore, sows kept in crates where they cannot turn around have reduced bone and muscular strength, reduced cardiovascular fitness and a higher incidence of foot and leg pathologies and stereotypies.

Scientific references

EFSA. 2007. Scientific Report on animal health and welfare aspects of different housing and husbandry systems for adult breeding boars, pregnant, farrowing sows and unweaned piglets. European Food Safety Authority. The EFSA Journal 572:1-107. www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/572.pdf.

Mason G and Rushen J. 2006. Stereotypic Animal Behaviour: Fundamentals and Applications to Welfare, 2nd Edition (Wallingford, U.K.: CABI, p. 347).

Scientific Veterinary Committee, 1997. The welfare of intensively kept pigs.

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

– ~~be able to~~ stand up in their natural stance without contact with either side of the stall or crate,

– stand up ~~without~~ in their natural stance without contact with ~~touching~~ the top bars,

– stand ~~in a stall~~ without simultaneously touching both ends of the stall or crate,

– lie comfortably on their sides without disturbing neighbouring pigs.

EU comment

The EU asks the OIE to consider including above the following sentence.

"When sows or gilts are kept in gestation stalls, it is recommended to keep them only up to a maximum of 4 weeks/28 days after service."

Justification:

Sows and gilts can succesfully be mixed into groups directly after service, without any reproduction consequences. The use of stalls can and should be limited to a restricted amount of days at most.

Scientific reference

Spoolder, H.A.M, Geudeke, M.J., Van der Peet-Schwering, C.M.C and Soede, N.M., 2009. Group housing of sows in early pregnancy: a review of success and risk factors. Livestock Science, 125: 1-14.

However, as in the Scientific Report of EFSA (2007) it is mentioned that if grouping takes place 1-2 weeks after mating, higher re-mating percentages and smaller litter have been found in sows kept in large dynamic groups without bedding compared to sows that have been tethered until testing four weeks after mating (Arey and Edwards, 1998, Te Brake and Bressers, 1990), a maximum period of sows and gilts in gestation stalls of 4 weeks after service could be acceptable as a maximum in the international context.

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

Article 7.X.14.

Flooring, bedding, resting surfaces

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

Floor management in indoor production systems can have a significant impact on pig welfare (Temple *et al.*, 2012; Newton *et al.*, 1980). Flooring, bedding, resting surfaces and outdoor yards should be cleaned as conditions warrant, to ensure good hygiene, comfort and minimise risk of diseases and injuries. Areas with excessive faecal accumulation are not suitable for resting.

Floors should be designed to minimise slipping and falling, promote foot health, and reduce the risk of claw injuries.

If a housing system includes areas of slatted floor, the slat and gap widths should be appropriate to the claw size of the pigs to prevent injuries.

Slope~~s~~ of the floor ~~pens~~ should allow water to drain and not pool ~~in the pens~~.

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

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

Outcome-based criteria (or measurables): physical appearance (e.g. injuries, presence of faeces on the skin,

bursitis), lameness and morbidity rates (e.g. respiratory disorders, reproductive tract infections).

Article 7.X.15.

Air quality

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

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

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

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

Article 7.X.16.

Thermal environment

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

1. Heat stress

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

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

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

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

EU comment

The EU asks the OIE to consider including in the above paragraph the following text:

"(presence of faeces on more than 10% of the skin), morbidity".

Justification:

Welfare Quality Assessment Protocol for pigs, 2009

2. Cold stress

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

Outcome-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.

EU comment

The EU asks the OIE to consider including in the above paragraph the following text:

"(piloerection, skin discoloration of more than 10%of the skin), behaviour".

Justification:

Welfare Quality Assessment Protocol for pigs, 2009.

Article 7.X.17.

Noise

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

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

Article 7.X.18.

Lighting

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

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

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

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

Article 7.X.19.

Farrowing and lactation

Sows and gilts need time to adjust to their farrowing accommodation before farrowing. Nesting material should be provided where possible some days before farrowing (Yun *et al.*, 2014). Sows and gilts should be observed frequently around their expected farrowing times. As some sows and gilts need assistance during farrowing, there should be sufficient space and competent staff.

EU comment

The EU would like to reiterate its previous comment.

The EU asks the OIE to consider the following amendment of the second sentence:

"Nesting material should be provided where possible some days before farrowing (Yun *et al.*, 2014) and if necessary be replenished […] so that the sow or gilt has enough material to carry out proper nest building behaviour."

Justification:

It is unfortunately common that nesting material is only provided (and in low quantities) as the sow or gilt is moved to the farrowing unit approximately one week before expected farrowing. As pigs often do not have access to rooting material in many production systems they tend to eat it rapidly. Little, if any, is then left for the actual nest building behaviour. Other reasons why the material needs to be replenished also occur.

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

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

Article 7.X.20.

Weaning

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

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

EU comment

The EU asks the OIE to consider replacing "piglest" with "piglets" in the above sentence.

Furthermore, the EU asks the OIE to amend the above sentence as follow:

"Piglets should ~~be weaned at three weeks or older~~ not be weaned before three weeks of age, older age is recommended"

Justification:

The European Food Safety Authority recommended that piglets should not be weaned before four weeks of age. To permit some piglets to be weaned at less than three weeks of age would be detrimental to their welfare and their immune systems . This is more clearly expressed by the above proposed new wording. Furthermore, a grammar mistake has also been corrected.

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

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

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

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

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

Article 7.X.21.

Mixing

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

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

– providing additional space and a non-slippery floor,

– feeding before mixing,

– feeding on the floor in the mixing area,

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

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

– mixing previously familiarised animals whenever possible,

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

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

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

Article 7.X.22.

Genetic selection

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

Selective breeding can improve the welfare of pigs for example by selection to improve maternal behaviour, piglet viability, temperament and resistance to stress and disease and to reduce tail biting and aggressive behaviour (Turner *et al.*, 2006).

EU comment

The EU asks the OIE to consider including the following sentence at the end of the above paragraph.

"Including social effects into breeding programs may also reduce negative social interactions and increase positive ones which may have major positive effects on group-housed animals."

Justification:

Rodenburg, T.B. ; Bijma, P. ; Ellen, E.D. ; Bergsma, R. ; Vries, S. de; Bolhuis, J.E. ; Kemp, B. ; Arendonk, J.A.M. van (2010) Breeding amiable animals? Improving farm

animal welfare by including social effects in breeding programmes. Animal Welfare 19 (Suppl. 1). - p. 77 – 82.

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

Article 7.X.23.

Protection from predators and pests

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

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

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

Article 7.X.24.

Biosecurity and animal 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 pathogenic agents including:

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

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

– other domestic animals, *wildlife*, and pests,

– people, including sanitation practices,

– equipment, including vehicles, tools and facilities,

– ~~*vehicles*,~~

– ~~air,~~

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

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

– ~~semen~~.

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

a) Animal health management

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

EU comment

The EU asks the OIE to consider replacing "pig" with "pigs" in the above sentence.

Justification:

Clarity, as there the aim should be to optimize the health and welfare of all pigs in the herd.

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

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

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

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

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

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

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

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

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

b) Emergency plans for disease outbreaks

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

Article 7.X.25.

Contingency ~~Emergency~~ plans

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

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

checked regularly.

EU comment

The EU asks the OIE to consider including the following sentence at the end of the above paragraph.

"<u>Electricity installations and devices should also be checked and tested regularly, as a preventive measure to avoid outbreak of fire.</u>"

Justification:

In recent years, experience in NL has shown that 'short circuit' of electrical equipment was the most common risk for and cause of barn fires and that preventive checks and tests on these installations and devices could have prevented the barn fires. Barn fires almost always lead to high mortality of animals.

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.

<u>Procedures for</u> ~~H~~<u>h</u>umane *killing* ~~procedures for~~ <u>of</u> 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.

EU comment

The EU asks the OIE to consider replacing the word "emergency" with the word "<u>contingency</u>" in the above paragraph.

Justification:

To ensure consistency with the title of 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.

<u>For a description of acceptable methods for humane *killing* of pigs see Chapter 7.6.</u>

<u>The *establishment* should have documented procedures for on-farm humane *killing*. Staff should be trained in the humane *killing* procedures appropriate for each class of pig.</u>

Reasons for humane *killing* may include:

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

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

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

– ~~severe, debilitating pain,~~

– ~~compound fracture,~~

– ~~spinal injury,~~

– ~~central nervous system disease,~~

– multiple joint *infections* with chronic weight loss,

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

– as part of disaster management response.

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

— Text deleted.

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EU comment

In the above-mentioned scientific reference, the word "biking" should be replaced by "biting".

Justification:

Spelling mistake.

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Annex 29

CHAPTER 8.3.

INFECTION WITH BLUETONGUE VIRUS

EU comment

The EU thanks the OIE and in general supports the proposed changes to this chapter. However, one important comment is inserted in the text below.

Article 8.3.1.

General provisions

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

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

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

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

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

EU comment

While acknowledging that point 3) above has improved, the EU notes that a key part of its previous suggestion has been dismissed by the Code Commission, without explanation. The EU therefore invites the OIE to look back at its previous comments especially with regard to the inclusion of the words "virulent revertant or reassortant" before "BTV live vaccine strain" in the first line (available here: http://ec.europa.eu/food/sites/food/files/safety/docs/ia_standards_oie_eu_position_tahsc-report_201609.pdf).

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.

Article 8.3.3.

Country or zone free from bluetongue

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

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

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

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

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

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

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

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

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

Article 8.3.4.

Country or zone seasonally free from bluetongue

A country or *zone* seasonally free from bluetongue is, respectively, an infected country or a part of an infected country or an *infected zone*, for which *surveillance* demonstrates no evidence either of transmission of BTV or of adult *Culicoides* for part of a year.

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

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

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

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

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

Article 8.3.5.

Country or zone infected with BTV

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

Article 8.3.6.

Recommendations for importation from countries or zones free from bluetongue

For ruminants and camelids

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

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

AND

2) the animals were kept in a country or *zone* free from bluetongue since birth or for at least 60 days prior to shipment; or

3) the animals were kept in a country or *zone* free from bluetongue for at least 28 days, then were subjected, with negative results, to a serological test to detect antibodies to the BTV group and remained in the free country or *zone* until shipment; or

4) the animals were kept in a ~~free~~ country or *zone* free from bluetongue for at least 14 days, then were subjected, with negative results, to an agent identification test, and remained in the free country or *zone* until shipment; or

5) the animals:

   a) were kept in a country or *zone* free from bluetongue for at least seven days;

   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;

AND

2) were kept during the ~~seasonally~~ free ~~period~~ season in a seasonally free *zone* since birth or for at least 60 days prior to shipment; or

3) were kept during the ~~seasonally~~ free ~~period~~ season in a seasonally free *zone* for at least 28 days prior to shipment, and were subjected during the residence period in the *zone* to a serological test to detect antibodies to the BTV group, with negative results, carried out at least 28 days after the commencement of the residence period; or

4) were kept during the ~~seasonally~~ free ~~period~~ season in a seasonally free *zone* for at least 14 days prior to shipment, and were subjected during the residence period in the *zone* to an agent identification test, with negative results, carried out at least 14 days after the commencement of the residence period; or

5) were kept during the ~~seasonally~~ free ~~period~~ season in a seasonally free *zone* and were vaccinated, at least 60 days before ~~the introduction into the free country or *zone*~~ shipment, against all serotypes demonstrated to be present in the source population through a *surveillance* programme in accordance with Articles 8.3.14. to 8.3.17. and were identified as having been vaccinated and remained in the seasonally free ~~country or~~ *zone* until shipment;

AND

6) either:

   a) did not transit through an infected *zone* during transportation to the *place of shipment*; or

   b) were protected from attacks from *Culicoides* at all times when transiting through an infected *zone*; or

   c) were vaccinated in accordance with point 5 above.

Article 8.3.8.

Recommendations for importation from countries or zones infected with BTV

For ruminants and camelids

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

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

AND

2) were protected from attacks from *Culicoides* in a *vector*-protected *establishment* for at least 60 days prior to shipment and during transportation to the *place of shipment*; or

3) were protected from attacks from *Culicoides* in a *vector*-protected *establishment* for at least 28 days prior to shipment and during transportation to the *place of shipment*, and were subjected during that period to a serological test to detect antibodies to the BTV group, with negative results, carried out at least 28 days after introduction into the *vector*-protected *establishment*; or

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;

AND

b) were kept in a *vector*-protected *establishment* for at least 60 days before commencement of, and during, collection of the semen; or

c) were subjected to a serological test to detect antibodies to the BTV group, with negative results~~, at least every 60 days throughout the collection period and~~ between 28 and 60 days after ~~the final~~ each collection for this consignment; or

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

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

Article 8.3.11.

Recommendations for importation from countries or zones free or zones seasonally free from bluetongue

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

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

1) the donor females:

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

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

   b) comply with point 1 of Article 8.3.12.;

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

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

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

Article 8.3.12.

Recommendations for importation from countries or zones infected with BTV

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

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

1) the donor females:

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

   AND

   b) were kept in a *vector*-protected *establishment* 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.

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

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

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

Article 8.3.15.

General conditions and methods for surveillance

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

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

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

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

2) The bluetongue *surveillance* programme should:

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

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

AND

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

Article 8.3.16.

Surveillance strategies

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

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

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

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

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

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

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

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

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

Annex 29 (contd)

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

1. Clinical surveillance

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

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

2. Serological surveillance

An active programme of *surveillance* of host populations to detect evidence of transmission of BTV is essential to establish the bluetongue status of a country or *zone*. Serological testing of ruminants is one of the most effective methods of detecting the presence of BTV. The species tested should reflect the epidemiology of bluetongue. Bovines ~~Cattle~~ are usually the most sensitive indicator species. Management variables that may influence likelihood of *infection*, such as the use of insecticides and animal housing, should be considered.

Samples should be examined for antibodies against BTV. Positive test results can have four possible causes:

a) natural *infection*,

b) *vaccination*,

c) maternal antibodies,

d) the lack of specificity of the test.

It may be possible to use sera collected for other survey purposes for bluetongue *surveillance*. However, the principles of survey design described in these recommendations and the requirements for a statistically valid survey for the presence of *infection* with BTV should not be compromised.

The results of random or targeted serological surveys are important in providing reliable evidence that no *infection* with BTV is present in a country or *zone*. It is, therefore, essential that the survey is thoroughly documented. It is critical to interpret the results in light of the movement history of the animals being sampled.

Serological *surveillance* in a free *zone* should target those areas that are at highest risk of transmission of BTV, based on the results of previous *surveillance* and other information. This will usually be towards the boundaries of the free *zone*. In view of the epidemiology of bluetongue, either random or targeted sampling is suitable to select *herds* or animals for testing.

Serological *surveillance* in infected *zones* will identify changes in the boundary of the *zone*, and can also be used to identify the BTV types circulating. In view of the epidemiology of bluetongue, either random or targeted sampling is suitable.

3. Virological surveillance

Isolation and genetic analysis of BTV from a proportion of infected animals provides information on serotype and genetic characteristics of the viruses concerned.

Virological *surveillance* can be conducted:

a) to identify virus transmission in at risk populations,

b) to confirm clinically suspected *cases*,

c) to follow up positive serological results,

d) to better characterise the genotype of circulating virus in a country or *zone*.

4. Sentinel animals

Sentinel animals are a form of targeted *surveillance* with a prospective study design. They are the preferred strategy for bluetongue *surveillance*. They comprise groups of unexposed animals that have not been vaccinated and are managed at fixed locations and sampled regularly to detect new *infections* with BTV.

The primary purpose of a sentinel animal programme is to detect *infections* with BTV occurring at a particular place, for instance sentinel groups may be located on the usual boundaries of infected *zones* to detect changes in distribution of BTV. In addition, sentinel animal programmes allow the timing and dynamics of *infections* to be observed.

A sentinel animal programme should use animals of known source and history of exposure, control management variables such as use of insecticides and animal housing (depending on the epidemiology of bluetongue in the area under consideration), and be flexible in its design in terms of sampling frequency and choice of tests.

Care is necessary in choosing the sites for the sentinel groups. The aim is to maximise the chance of detecting transmission of BTV at the geographical location for which the sentinel site acts as a sampling point. The effect of secondary factors that may influence events at each location, such as climate, may also be analysed. To avoid bias, sentinel groups should comprise animals selected to be of similar age and susceptibility to *infection* with BTV. Bovines ~~Cattle~~ are the most appropriate sentinels but other domestic ruminant species may be used. The only feature distinguishing groups of sentinels should be their geographical location.

Sera from sentinel animal programmes should be stored methodically in a serum bank to allow retrospective studies to be conducted in the event of new serotypes being isolated.

The frequency of sampling will depend on the reason for choosing the sampling site. In endemic areas, virus isolation will allow monitoring of the serotypes and genotypes of BTV circulating during each time period. The borders between infected and uninfected areas can be defined by serological detection of *infective period*. Monthly sampling intervals are frequently used. Sentinels in declared free *zones* add to confidence that *infection* with BTV is not occurring unobserved. In such cases, sampling prior to and after the possible period of transmission is sufficient.

Definitive information on the presence of BTV in a country or *zone* is provided by isolation and identification of the viruses. If virus isolation is required, sentinels should be sampled at sufficiently frequent intervals to ensure that samples are collected during the period of viraemia.

5. Vector surveillance

BTV is transmitted between ruminant hosts by species of *Culicoides* which vary around the world. It is therefore important to be able to identify potential *vector* species accurately although many such species are closely related and difficult to differentiate with certainty.

Vector surveillance aims to demonstrate the absence of *vectors* or to determine areas of different levels of risk and local details of seasonality by determining the various *vector* species present in an area, their respective seasonal occurrence, and abundance. *Vector surveillance* has particular relevance to potential areas of spread.

Long term *surveillance* can also be used to assess *vector* abatement measures or to confirm continued absence of *vectors*.

The most effective way of gathering this information should take account of the biology and behavioural characteristics of the local *vector* species of *Culicoides* and may include the use of Onderstepoort-type light traps or similar, operated from dusk to dawn in locations adjacent to domestic ruminants, or the use of drop traps over ruminants.

Annex 29 (contd)

Vector surveillance should be based on scientific sampling techniques. The choice of the number and type of traps to be used and the frequency of their use should take into account the size and ecological characteristics of the area to be surveyed.

The operation of *vector surveillance* sites at the same locations as sentinel animals is advisable.

The use of a *vector surveillance* system to detect the presence of circulating virus is not recommended as a routine procedure as the typically low *vector infection* rates mean that such detections can be rare.

Animal-based *surveillance* strategies are preferred to detect virus transmission.

Article 8.3.17.

Documentation of bluetongue free status

1. Additional surveillance requirements for Member Countries declaring freedom from bluetongue

In addition to the general requirements described above, a Member Country declaring freedom from bluetongue for the entire country or a *zone* should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances and should be planned and implemented in accordance with general conditions and methods described in this chapter, to demonstrate absence of *infection* with BTV during the preceding 24 months in susceptible domestic ruminant populations. This requires the support of a *laboratory* able to undertake identification of *infection* with BTV through virus detection and antibody tests. This *surveillance* should be targeted to unvaccinated animals. Clinical *surveillance* may be effective in sheep while serological *surveillance* is more appropriate in bovines ~~cattle~~.

2. Additional requirements for countries or zones that practise vaccination

Vaccination to prevent the transmission of BTV may be part of a disease control programme. The level of *flock* or *herd* immunity required to prevent transmission will depend on the *flock* or *herd* size, composition (e.g. species) and density of the susceptible population. It is therefore impossible to be prescriptive. The vaccine should also comply with the provisions stipulated for BTV vaccines in the *Terrestrial Manual*. Based on the epidemiology of bluetongue in the country or *zone*, it may be decided to vaccinate only certain species or other *subpopulations*.

In countries or *zones* that practise *vaccination*, virological and serological tests should be carried out to ensure the absence of virus transmission. These tests should be performed on unvaccinated *subpopulations* or on sentinels. The tests should be repeated at appropriate intervals in accordance with the purpose of the *surveillance* programme. For example, longer intervals may be adequate to confirm endemicity, while shorter intervals may allow on-going demonstration of absence of transmission.

— Text deleted.

Annex 30

CHAPTER 8.8.

INFECTION WITH FOOT AND MOUTH DISEASE VIRUS

EU comment

The EU thanks the OIE and in general supports the proposed changes to this chapter. Comments are inserted in the text below.

Article 8.8.1.

1) Many different species belonging to diverse taxonomic orders are known to be susceptible to *infection* with foot and mouth disease virus (FMDV). Their epidemiological significance depends upon the degree of susceptibility, the husbandry system, the density and extent of populations and the contacts between them. Amongst *Camelidae*, only Bactrian camels *(Camelus bactrianus)* are sufficiently susceptible to have potential for epidemiological significance. Dromedaries *(Camelus dromedarius)* are not susceptible to *infection* with FMDV while South American camelids are not considered to be of epidemiological significance.

2) For the purposes of the *Terrestrial Code*, foot and mouth disease (FMD) is defined as an *infection* of animals of the suborder *ruminantia* and of the family *suidae* of the order *Artiodactyla*, and *Camelus bactrianus* with FMDV.

3) The following defines the occurrence of *infection* with FMDV:

   a) FMDV has been isolated from a sample from an animal listed in point 2; or

   b) ~~viral~~ antigen or ~~viral~~ ribonucleic acid specific to FMDV has been identified in a sample from an animal listed in point 2, showing clinical signs consistent with FMD, or epidemiologically linked to a suspected or confirmed *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV; or

   c) antibodies to structural or nonstructural proteins of FMDV, that are not a consequence of *vaccination*, have been identified in a sample from an animal listed in point 2, showing clinical signs consistent with FMD, or epidemiologically linked to a suspected or confirmed *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV.

4) Transmission of FMDV in a vaccinated population is demonstrated by change in virological or serological evidence indicative of recent *infection*, even in the absence of clinical signs.

5) For the purposes of the *Terrestrial Code*, the *incubation period* of FMD shall be 14 days.

6) *Infection* with FMDV can give rise to *disease* of variable severity and to ~~FMDV~~ transmission of FMDV. FMDV may persist in the pharynx and associated lymph nodes of ruminants for a variable but limited period of time beyond 28 days. Such animals have been termed carriers. ~~However,~~ The only persistently infected species from which transmission of FMDV has been proven is the African buffalo *(Syncerus caffer)*. However, transmission to domestic livestock is rare.

7) This chapter deals not only with the occurrence of clinical signs caused by FMDV, but also with the presence of *infection* with, ~~FMDV~~ and transmission of FMDV in the absence of clinical signs.

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

Article 8.8.2.

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

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

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

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

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

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

2) send a declaration to the OIE stating that during the past 12 months, within the proposed ~~FMD~~ free country or *zone*:

   a) there has been no *case* of FMD;

   b) no *vaccination* against FMD has been carried out;

3) supply documented evidence that for the past 12 months:

   a) *surveillance* in accordance with Articles 8.8.40. to 8.8.42. has been implemented to detect clinical signs of FMD and demonstrate no evidence of:

      i) *infection* with FMDV in unvaccinated animals;

      ii) ~~FMDV~~ transmission of FMDV in previously vaccinated animals when the ~~FMD~~ free country or *zone* where *vaccination* is practised is seeking to become one where *vaccination* is not practised;

   b) regulatory measures for the prevention and early detection of FMD have been implemented;

4) describe in detail and provide ~~supply~~ documented evidence that for the past 12 months ~~the following have been properly implemented and supervised~~:

   a) ~~in the case of a FMD free *zone*,~~ the boundaries of ~~the~~ any proposed ~~FMD~~ free *zone* have been established and effectively supervised;

   b) the boundaries and *biosecurity* ~~measures~~ of ~~a~~ any *protection zone*~~, if applicable~~ have been established and effectively supervised;

   c) the system for preventing the entry of FMDV into the proposed ~~FMD~~ free country or *zone* has been established and effectively supervised;

   d) the control of the movement of susceptible animals, their *meat* and other products into the proposed ~~FMD~~ free country or *zone*, in particular the measures described in Articles 8.8.8.~~, 8.8.9. and~~ to 8.8.12. has been effectively implemented and supervised;

   e) measures to prevent the introduction of ~~no~~ vaccinated animals ~~has been introduced,~~ except in accordance with Articles 8.8.8. ~~and~~ 8.8.9., 8.8.9bis., 8.8.11. and 8.8.11bis. have been effectively implemented and supervised. Any animals introduced for *slaughter* were subjected to ante- and post-mortem inspections in accordance with Chapter 6.2. with favourable results. For ruminants the head, including the pharynx, tongue and associated lymph nodes, was either destroyed or treated in accordance with Article 8.8.31.

EU comment

The EU suggests inserting the word "direct" before "slaughter" in point e) above, to clarify that slaughter animals cannot remain or reside in the free country or zone for any prolonged time before being slaughtered. This would also be consistent with the wording used in Articles 8.8.8., 8.8.9. and 8.8.9bis. As alternative, reference could be made to Articles 8.8.8., 8.8.9. and 8.8.9bis.

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

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

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

EU comment

The EU is uncomfortable with the sentence above. From the wording, it is unclear who is in charge, the country concerned, or the OIE, having to decide on the official status of the country or zone in question. Furthermore, this seems to be a very specific and exceptional situation, likely to occur only in rare cases and applicable to very few individual countries. Other such rare exceptions could be possible, for any of the diseases for which there is an official recognition of country and zone status, and it does not seem practicable to address them all individually in the disease specific chapters as they arise.

Thus, while not disagreeing in principle to this type of exception if it is well founded, the EU does not think it is appropriate to include the above specific case in the present FMD chapter. Rather, a general principle and procedure could be included in Chapter 1.6., to be used by the OIE as a "legal base" to decide on the official country or zone status in such rare and exceptional instances as and when they occur. Such procedural issues should be addressed when Chapter 1.6. is thoroughly revised in the near future: The EU would support adding this to the Code Commission and Scientific Commission work programmes.

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

– the zoological collection has the primary purpose of exhibiting animals or preserving rare species, has been identified, including the boundaries of the facility, and is included in the country's contingency plan for FMD;

– appropriate *biosecurity* measures are in place, including effective separation from other susceptible domestic populations or *wildlife*;

– the animals are identified as belonging to the collection and any movements can be traced;

– the vaccine used complies with the standards described in the *Terrestrial Manual*;

– *vaccination* is conducted under the supervision of the *Veterinary Authority*;

– the zoological collection is placed under *surveillance* for at least 12 months after *vaccination*.

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

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

EU comment

As vaccination in a newly established protection zone that is part of a free country or zone where vaccination is not practised will have an effect on the status of that protection zone. Thus, it should be stated that information on vaccination is to be provided by the country concerned to the OIE, in order for the status to be adapted accordingly.

Furthermore, as the reference to Article 4.3.6. in the paragraph above (and in other articles of the present chapter) refers to the draft revised Chapter 4.3. that was not yet adopted, and not to the currently existing version of that chapter, it is important that the revised Chapter 8.8. be adopted only after the adoption of the revised Chapter 4.3., or that both be adopted at the same time.

Article 8.8.3.

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

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

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

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

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

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

2) send a declaration to the OIE stating that, based on the *surveillance* described in point 3, within the proposed ~~FMD~~ free country or *zone*:

   a) there has been no *case* of FMD during the past two years;

   b) there has been no evidence of ~~FMDV~~ transmission of FMDV during the past 12 months;

3) supply documented evidence that:

   a) *surveillance* in accordance with Articles 8.8.40. to 8.8.42. has been implemented to detect clinical signs of FMD for the past two years and demonstrate no evidence of:

EU comment

For clarity reasons, the EU suggests rearranging the wording of point a) above as follows:

"a) surveillance to detect clinical signs of FMD has been implemented in accordance with Articles 8.8.40. to 8.8.42. for the past two years and demonstrated no evidence of:".

   i) *infection* with FMDV in unvaccinated animals for the past two years;

   ii) ~~FMDV~~ transmission of FMDV in vaccinated animals for the past 12 months;

   b) regulatory measures for the prevention and early detection of FMD have been implemented for the past 12 months;

c) compulsory systematic *vaccination* in the target population has been carried out to achieve adequate *vaccination* coverage and population immunity for the past two years;

d) *vaccination* has been carried out following appropriate vaccine strain selection for the past two years;

4) describe in detail and ~~supply~~ provide documented evidence that for the past 12 months ~~the following have been properly implemented and supervised~~:

a) ~~in case of FMD free *zone*,~~ the boundaries of the proposed ~~FMD~~ free *zone* have been established and effectively supervised;

b) the boundaries and *biosecurity* ~~measures~~ of any *protection zone*~~, if applicable~~ have been established and effectively supervised;

c) the system for preventing the entry of FMDV into the proposed ~~FMD~~ free country or *zone*, in particular the measures described in Articles 8.8.8., 8.8.9. and 8.8.12. has been established and effectively supervised;

d) the control of the movement of susceptible animals and their products into the proposed ~~FMD~~ free country or *zone* has been effectively implemented and supervised.

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

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

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

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

EU comment

, for clarity reasons, we suggest inserting "is recognised by the OIE as and" before "meets the requirements", as having the "free without vaccination" status at the time when applying for the new status is equally important as meeting the requirements – otherwise a country or zone meeting the requirements but without official status could also apply.

For clarity, we also suggest inserting the words "an application and" before "a plan".

In addition, the sentence "The status of this country or zone remains unchanged until approved by the OIE" is unclear (until what is approved? Why should the status be changed further to submitting a plan?); it should thus be deleted.

Finally, as official status recognition takes place during the OIE General Session in May, it is unclear how the plan "indicating the intended date of beginning of vaccination" and

the provision of "As soon as recognised free with vaccination the country or zone will begin the vaccination" will match – either there is no need to indicate the date of beginning of vaccination a it will be immediately following the General Session in May, or the provision of "As soon as recognised free with vaccination the country or zone will begin the vaccination" needs to be changed.

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

EU comment

The paragraph above is a bit awkward. First of all, in line 1 it refers only to "a country", whereas this article is about "country or zone"; line 3 also mentions "country or zone". Furthermore, it is not very clear what is meant by "an increased risk"; the similar paragraph in Article 8.8.2. speaks of "a newly identified likelihood of introduction of FMDV". Also mentioning the application of vaccination in the protection zone is confusing, as this article is about countries or zones free with vaccination – so vaccination would not be new in that zone. Finally, saying the freedom status of the rest of the country or zone remains unchanged once the protection zone has been approved by the OIE is unclear – what happens before approval by OIE? And why would the protection zone lose the status free with vaccination, as long as there is no disease incursion?

The EU therefore suggests amending the paragraph as follows:

"If a country or zone needs to define a protection zone in accordance with Article 4.3.6. in response to a newly identified likelihood of introduction of FMDV ~~an increased risk~~, including by the application of vaccination, once the protection zone has been approved by the OIE, the freedom of the rest of the country or zone is reinstated ~~remains unchanged~~."

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

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

Article 8.8.4.

~~FMD free~~ Compartment free from FMD where vaccination is not practised

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

EU comment

The EU does not support replacing "management system" with "plan". Indeed, separation of animals is not achieved by a plan, but by a system. The fact that the term

"biosecurity plan" is defined in the glossary is not substantive in this context; the term is already used in the right context further down in the article.

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

1) have a record of regular and prompt animal *disease* reporting and, if not ~~FMD~~ free, have an *official control programme* and a *surveillance* system for FMD in place in accordance with Articles 8.8.40. to 8.8.42. that allows knowledge of the prevalence, distribution and characteristics of FMD in the country or *zone*;

2) declare for the ~~FMD~~ free *compartment* that:

   a) there has been no *case* of FMD during the past 12 months;

   b) no evidence of *infection* with FMDV has been found during the past 12 months;

   c) *vaccination* against FMD is prohibited;

   d) no animal vaccinated against FMD within the past 12 months is in the *compartment*;

   e) animals, semen, embryos and animal products may only enter the *compartment* in accordance with relevant articles in this chapter;

   f) documented evidence shows that *surveillance* in accordance with Articles 8.8.40. to 8.8.42. is in operation;

   g) an *animal identification* and *traceability* system in accordance with Chapters 4.1. and 4.2. is in place;

3) describe in detail:

   a) the animal *subpopulation* in the *compartment*;

   b) the *biosecurity plan* to mitigate the risks identified by the *surveillance* carried out in accordance with point 1.

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

EU comment

In the paragraph above (as well as the first paragraph of Article 8.8.4bis. and the last paragraph of in Article 8.8.4bis.), the word "plan" should be replaced with "management system" (see comment above).

Article 8.8.4bis.

Compartment free from FMD where vaccination is practised

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

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

1) have a record of regular and prompt animal *disease* reporting and, if not free, have an *official control programme* and a *surveillance* system for FMD in place in accordance with Articles 8.8.40. to 8.8.42. that allows knowledge of the prevalence, distribution and characteristics of FMD in the country or *zone*;

2) declare for the free *compartment* where *vaccination* is practised that:

a) there has been no *case* of FMD during the past 12 months;

b) no evidence of *infection* with FMDV has been found during the past 12 months;

EU comment

The EU notes that the requirements in both points a) and b) above have been changed compared to the previous version of this draft article (from 2 years to 12 months). While this is acceptable for point b), the EU suggests keeping 2 years in point a). This would be in line with what is recommended in Article 8.8.3. (Country or zone free from FMD where vaccination is practised).

c) compulsory systematic *vaccination* is carried out using a vaccine that complies with the standards described in the *Terrestrial Manual*, including appropriate vaccine strain selection. The *vaccination* coverage and population immunity are closely monitored;

d) animals, semen, embryos and animal products may only enter the *compartment* in accordance with relevant articles in this chapter;

e) documented evidence shows that regular clinical, serological and virological *surveillance* in accordance with Articles 8.8.40. to 8.8.42. is in operation, so as to detect *infection* at an early stage with a high level of confidence;

f) an *animal identification* and *traceability* system in accordance with Chapters 4.1. and 4.2. is in place;

3) describe in detail:

a) the animal *subpopulation* in the *compartment*;

b) the *biosecurity plan* to mitigate the risks identified by the *surveillance* carried out according to point 1) and the *vaccination* plan;

c) implementation of points 2*c)*, 2*e)* and 2*f)*.

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

Article 8.8.5.

~~FMD infected~~ Country or zone infected with FMDV

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

Article 8.8.6.

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

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

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

1) on suspicion, a strict standstill has been imposed on the suspected *establishments* and in the country or *zone* animal movement control has been imposed and effective controls on the movement of other *commodities* mentioned in this chapter are in place;

2) on confirmation, an additional standstill of susceptible animals has been imposed in the entire *containment zone* and the movement controls described in point 1 have been reinforced;

3) the definitive boundaries of the *containment zone* have been established after an epidemiological investigation (trace-back, trace-forward) has demonstrated that the *outbreaks* are epidemiologically related and limited in number and geographic distribution;

4) investigations into the likely source of the *outbreaks* have been carried out;

5) a *stamping-out policy*, with or without the use of emergency *vaccination*, has been applied;

6) no new *cases* have been found in the *containment zone* within a minimum of two *incubation periods* as defined in Article 8.8.1. after the application of a *stamping-out policy* to the last detected *case*;

7) the susceptible domestic and *captive wild* animal populations within the *containment zone* are clearly identified as belonging to the *containment zone*;

8) *surveillance* in accordance with Articles 8.8.40. to 8.8.42. is in place in the *containment zone* and in the rest of the country or *zone*;

9) measures that prevent the spread of FMDV to the rest of the country or *zone*, taking into consideration physical and geographical barriers, are in place.

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

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

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

Article 8.8.7.

Recovery of free status (see Figures 1 and 2)

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

   a) three months after the disposal of the last animal killed where a *stamping-out policy*, without emergency *vaccination*, and *surveillance* are applied in accordance with Articles 8.8.40. to 8.8.42.; or

   b) three months after the disposal of the last animal killed or the *slaughter* of all vaccinated animals, whichever occurred last, where a *stamping-out policy*, emergency *vaccination* and *surveillance* in accordance with Articles 8.8.40. to 8.8.42. are applied; or

   c) six months after the disposal of the last animal killed or the last *vaccination*, whichever occurred last, where a *stamping-out policy*, emergency *vaccination* not followed by the slaughtering of all vaccinated animals, and *surveillance* in accordance with Articles 8.8.40. to 8.8.42. are applied. However, this requires a serological survey based on the detection of antibodies to nonstructural proteins of FMDV to demonstrate no evidence of *infection* in the remaining vaccinated population. This period can be reduced to three months if effectiveness of *vaccination* is demonstrated by a serological survey and serological *surveillance* for antibodies to nonstructural proteins is carried out in all vaccinated *herds* by sampling all vaccinated ruminants and their unvaccinated offspring, and a representative number of FMD susceptible animals of other species.

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

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

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

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

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

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

3) When a *case* of *infection* with FMDV occurs in a ~~FMD free~~ country or *zone* previously free from FMD where *vaccination* is practised, one of the following waiting periods is required to regain this free status:

a) six months after the disposal of the last animal killed where a *stamping-out policy*, with emergency *vaccination*, and *surveillance* in accordance with Articles 8.8.40. to 8.8.42. are applied, provided that serological *surveillance* based on the detection of antibodies to nonstructural proteins of FMDV demonstrates no evidence of ~~virus~~ transmission of FMDV; or

b) 12 months after the detection of the last *case* where a *stamping-out policy* is not applied, but where emergency *vaccination* and *surveillance* in accordance with Articles 8.8.40. to 8.8.42. are applied, provided that serological *surveillance* based on the detection of antibodies to nonstructural proteins of FMDV demonstrates no evidence of ~~virus~~ transmission of FMDV.

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

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

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

4) When a ~~FMD~~ *case* of *infection* with FMDV occurs in a ~~FMD free~~ *compartment* free from FMD, Article 8.8.4. or Article 8.8.4bis. applies.

5) Member Countries applying for the recovery of status should do so only when the respective requirements for the recovery of status are met. When a *containment zone* has been established, the restrictions within the *containment zone* should be lifted in accordance with the requirements of this article only when ~~the *disease*~~ FMD has been successfully eradicated within the *containment zone*.

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

Article 8.8.8.

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

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

1) no FMD susceptible animal has been introduced into the *establishment* of origin and no animal in the *establishment* of origin has shown clinical signs of FMD for at least 30 days prior to movement;

2) the animals were kept in the *establishment* of origin for at least three months prior to movement;

3) FMD has not occurred within a 10 kilometre radius of the *establishment* of origin for at least four weeks prior to movement;

4) the animals ~~should be~~ are transported under the supervision of the *Veterinary Authority* in a *vehicle*, which was cleansed and disinfected before *loading*, directly from the *establishment* of origin to the *slaughterhouse/abattoir* without coming into contact with other susceptible animals;

5) such a *slaughterhouse/abattoir* is not approved for the export of *fresh meat* during the time it is handling the *meat* of animals from the infected *zone*;

6) *vehicles* and the *slaughterhouse/abattoir* ~~should be~~ are subjected to thorough cleansing and *disinfection* immediately after use.

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

Article 8.8.9.

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

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

1) the *containment zone* has been officially established in accordance with the requirements in Article 8.8.6.;

2) the animals ~~should be~~ are transported under the supervision of the *Veterinary Authority* in a *vehicle*, which was cleansed and disinfected before *loading*, directly from the *establishment* of origin to the *slaughterhouse/abattoir* without coming into contact with other susceptible animals;

3) such an *slaughterhouse/abattoir* is not approved for the export of *fresh meat* during the time it is handling the *meat* of animals from the *containment zone*;

4) *vehicles* and the *slaughterhouse/abattoir* ~~should be~~ are subjected to thorough cleansing and *disinfection* immediately after use.

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

Article 8.8.9bis.

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

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

1) no animal in the *establishment* of origin has shown clinical signs of FMD for at least 30 days prior to movement;

2) the animals were kept in the country or *zone* of origin for at least three months prior to movement;

3) the animals are transported under the supervision of the *Veterinary Authority* in a *vehicle*, directly from the *establishment* of origin to the *slaughterhouse/abattoir*;

4) if transiting an infected *zone*, were not exposed to any source of FMDV during transportation to the *place of shipment*.

EU comment

The EU suggests not limiting the new article above to transfers from a zone to another zone, but to expand it to countries as well (i.e. the title would read "Direct transfer of FMD vaccinated animals from a free country or zone where vaccination is practised or not for slaughter in a free country or zone where vaccination is not practised", and the words "country or" would be inserted in the text as appropriate). Indeed, there may be situations where such movements are done not just between zones within a country, but across country borders. We also note that compartments are not included in the scope of the present article, whereas they are covered in the proposed new Article 8.8.11bis.

Finally, for clarity reasons, the words "the animals" should be inserted before "were not exposed [...]" in point 4) above.

Article 8.8.10.

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

For FMD susceptible animals

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

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

2) were kept since birth or for at least the past three months in a ~~FMD free~~ country or *zone* free from FMD where *vaccination* is not practised or a ~~FMD free~~ *compartment* free from FMD;

3) if transiting an infected *zone*, were not exposed to any source of FMDV during transportation to the *place of shipment*~~.~~;

4) if previously vaccinated, comply with point 4 of Article 8.8.11.

Article 8.8.11.

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

For domestic ruminants and pigs

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

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

2) were kept since birth or for at least the past three months in a ~~FMD free~~ country or *zone* free from FMD where *vaccination* is practised;

3) if not vaccinated were subjected to ~~a~~ virological and serological tests for FMD with negative results;

4) if vaccinated were subjected to virological and NSP serological tests for FMD with negative results;

5) if transiting an infected *zone*, were not exposed to any source of FMDV during transportation to the *place of shipment*.

Article 8.8.11bis.

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

For vaccinated animals destined for slaughter

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

1) no animal in the *establishment* of origin has shown clinical signs of FMD for at least 30 days prior to shipment;

2) the animals were kept in the country, *zone* or *compartment* of origin since birth or for at least three months prior to shipment;

3) the animals were transported under the supervision of the *Veterinary Authority* directly from the *establishment* of origin in sealed *vehicles/vessels*;

4) if transiting an *infected zone*, were not exposed to any source of FMDV during transportation to the *place of shipment*.

EU comment

For clarity reasons, the words "the animals" should be inserted before "were not exposed [...]" in point 4) above.

It is not clear why Article 8.8.11bis. is necessary at all, as it deals with importation of animals destined for slaughter, from a country or zone or compartment "free with vaccination", while there is already an article covering that (i.e. Article 8.8.9bis.).

Article 8.8.12.

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

For domestic ruminants and pigs

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

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

2) pigs have not been fed swill not complying with Article 8.8.31bis.;

EU comment

The EU is of the opinion that in principle, the practise of swill feeding is problematic in relation to FMD and, if not prohibited, needs to be done properly. Furthermore, we acknowledge that the addition of the point above is an improvement, as no requirements on treatment of swill were included in the chapter up to now. However, strict enforcement of Article 8.8.31bis. will be necessary to ensure safety. Therefore, the addition of point 2 above is acceptable only if Article 8.8.31bis. is expanded to include requirements aimed at avoiding cross contamination of swill after treatment.

3~~2~~) prior to isolation, the animals were kept in the *establishment* of origin:

a) for 30 days, or since birth if younger than 30 days, if a *stamping-out policy* is applied to control FMD in the *exporting country* or *zone*, or

b) for three months, or since birth if younger than three months if a *stamping-out policy* is not applied to control FMD in the *exporting country* or *zone*;

43) the *establishment* of origin is covered by the *official control programme* and FMD has not occurred within it ~~the *establishment* of origin~~ for the relevant period as defined in points 2a) and 2b) above;

54) the animals were isolated in an *establishment* for the 30 days prior to shipment, and all animals in isolation were subjected to diagnostic virological and serological tests for evidence of FMDV with negative results on samples collected at least 28 days after the start of isolation period, and that FMD did not occur within a 10 kilometre radius of the *establishment* during that period, or the *establishment* is a *quarantine station*;

65) the animals were not exposed to any source of FMDV during their transportation from the *establishment* to the *place of shipment*.

Article 8.8.13.

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

For fresh semen of domestic ruminants and pigs

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

1) the donor males:

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

b) were kept for at least three months prior to collection in a ~~FMD free~~ country or *zone* free from FMD where *vaccination* is not practised or ~~FMD free~~ *compartments* free from FMD;

c) were kept in an *artificial insemination centre* where none of the animals had a history of *infection* with FMDV;

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

Article 8.8.14.

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

For frozen semen of domestic ruminants and pigs

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

1) the donor males:

a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;

b) were kept for at least three months prior to collection in a ~~FMD free~~ country or *zone* free from FMD where *vaccination* is not practised or ~~FMD free~~ *compartments* free from FMD;

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

Article 8.8.15.

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

For frozen semen of domestic ruminants and pigs

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

1) the donor males:

   a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;

   b) were kept for at least three months prior to collection in a ~~FMD free~~ country or *zone* free from FMD where *vaccination* is practised;

   c) either

      i) have been vaccinated at least twice~~,~~ with the last *vaccination* not ~~less~~ more than ~~one~~ six months ~~and not more than six months prior to collection~~, unless protective immunity has been demonstrated for more than six months, and not less than one month prior to collection;

      or

      ii) were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMDV, with negative results;

2) the semen:

   a) was collected, processed and stored in accordance with Chapters 4.5. and 4.6.;

   b) was stored in the country of origin for a period of at least one month following collection, and during this period no animal on the *establishment* where the donor ~~animals~~ males were kept showed any sign of FMD.

Article 8.8.16.

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

For frozen semen of domestic ruminants and pigs

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

1) the donor males:

   a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;

   b) were kept in an *artificial insemination centre* ~~where~~ to which no animal had been added in the 30 days before collection, and within a 10 kilometre radius of which, ~~that~~ FMD has not occurred ~~within a 10 kilometre radius of the *artificial insemination centre* for~~ in the 30 days before and after collection;

   c) either

      i) have been vaccinated at least twice~~,~~ with the last *vaccination* not ~~less~~ more than ~~one~~ six months ~~and not more than six months prior to collection~~, unless protective immunity has been demonstrated for more than six months, and not less than one month prior to collection;

      or

      ii) were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMDV, with negative results;

2) the semen:

   a) was collected, processed and stored in accordance with Chapters 4.5. and 4.6.;

   b) was subjected, with negative results, to a test for evidence of FMDV if the donor male has been vaccinated within the 12 months prior to collection;

c) was stored in the country of origin for a period of at least one month following collection, and that during this period no animal on the *establishment* where the donor males were kept showed any sign of FMD.

Article 8.8.17.

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

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

Article 8.8.18.

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

For *in vitro* produced embryos of bovines ~~cattle~~

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

1) the donor females:

   a) showed no clinical sign of FMD at the time of collection of the oocytes;

   b) were kept for at least three months prior to collection in a ~~FMD free~~ country or *zone* free from FMD where *vaccination* is not practised or ~~FMD free~~ *compartments* free from FMD;

2) fertilisation was achieved with semen meeting the conditions referred to in Articles 8.8.13., 8.8.14., 8.8.15. or 8.8.16., as relevant;

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

Article 8.8.19.

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

For *in vitro* produced embryos of bovines ~~cattle~~

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

1) the donor females:

   a) showed no clinical sign of FMD at the time of collection of the oocytes;

   b) were kept for at least three months prior to collection in a ~~FMD free~~ country or *zone* free from FMD where *vaccination* is practised;

   c) either

      i) have been vaccinated at least twice~~,~~ with the last *vaccination* not ~~less~~ more than ~~one~~ six months ~~and not more than six months prior to collection~~, unless protective immunity has been demonstrated for more than six months, and not less than one month prior to collection;

      or

      ii) were subjected, not less than 21 days after collection, to tests for antibodies against FMDV, with negative results;

2) fertilisation was achieved with semen meeting the conditions referred to in Articles 8.8.13., 8.8.14., 8.8.15. or 8.8.16., as relevant;

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

Article 8.8.20.

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

For fresh meat or meat products of FMD susceptible animals

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

1) have been kept in a ~~FMD free~~ country or *zone* free from FMD, where *vaccination* is not practised or ~~FMD free~~ *compartment* free from FMD, or ~~which~~ have been imported in accordance with Article 8.8.10., Article 8.8.11. or Article 8.8.12.;

2) have been slaughtered in an approved *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections with favourable results.

Article 8.8.21.

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

For fresh meat and meat products of ruminants and pigs

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

Annex 30 (contd)

1) have been kept in the ~~FMD free~~ country or *zone* free from FMD where *vaccination* is practised, or which have been imported in accordance with Article 8.8.10., Article 8.8.11. or Article 8.8.12.;

2) have been slaughtered in an approved *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections ~~for FMD~~ with favourable results;

3) for ruminants the head, including the pharynx, tongue and associated lymph nodes, has been excluded from the shipment.

Article 8.8.22.

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

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

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

1) comes from animals which:

   a) have remained, for at least three months prior to *slaughter*, in a *zone* of the *exporting country* where bovines ~~cattle~~ and water buffaloes are regularly vaccinated against FMD and where an *official control programme* is in operation;

b) have been vaccinated at least twice with the last *vaccination* not more than six months, unless protective immunity has been demonstrated for more than six months, and not less than one month prior to *slaughter*;

c) were kept for the past 30 days in:

– a *quarantine station*; or ~~in~~

– an *establishment*, within a ten-kilometre radius of which ~~and that~~ FMD has not occurred ~~within a 10 kilometre radius of the *establishment*~~ during that period~~, or the *establishment* is a *quarantine station*~~;

d) have been transported, in a *vehicle* which was cleansed and disinfected before the bovines ~~cattle~~ and water buffaloes were loaded, directly from the *establishment* of origin or *quarantine station* to the approved *slaughterhouse/abattoir* without coming into contact with other FMD susceptible animals which do not fulfil the required conditions for export;

e) have been slaughtered in an approved *slaughterhouse/abattoir*:

i) which is officially designated for export;

ii) in which no FMD has been detected during the period between the last *disinfection* carried out before *slaughter* and the shipment for export has been dispatched;

f) were subjected to ante- and post-mortem inspections in accordance with Chapter 6.2., with favourable results ~~have been subjected, with favourable results, to ante-mortem inspection within 24 hours of *slaughter* and to post-mortem inspections within 24 hours before and after *slaughter* with no evidence of FMD~~;

2) comes from deboned carcasses:

a) from which the major lymphatic nodes have been removed;

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

Article 8.8.22bis.

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

For fresh meat of domestic pigs

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

1) the *meat* comes from animals complying with points 1 to 6 of Article 8.8.12.;

2) the animals were transported, in a *vehicle* which was cleaned and disinfected before the pigs were loaded, directly from the *establishment* of origin or *quarantine station* to the approved *slaughterhouse/abattoir* without coming into contact with other FMD susceptible animals that do not fulfil the conditions required for export, either during transport or at the *slaughterhouse/abattoir*;

3) the animals were slaughtered in an approved *slaughterhouse/abattoir*:

a) which is officially designated for export;

b) in which no FMD has been detected during the period between the last *disinfection* carried out before *slaughter* and the shipment for export has been dispatched;

4) the animals were subjected to ante- and post-mortem inspections in accordance with Chapter 6.2., with favourable results;

5) the carcasses were not released earlier than 24 hours after *slaughter* and not before *Veterinary Authorities* have confirmed that FMD has not occurred in the *establishment* of origin.

Article 8.8.23.

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

For meat products of FMD susceptible animals

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

1) the entire consignment of *meat products* come from animals which have been slaughtered in an approved *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections ~~for FMD~~ with favourable results;

2) the *meat products* have been processed to ensure the destruction of FMDV in accordance with one of the procedures in Article 8.8.31.;

3) the necessary precautions were taken after processing to avoid contact of the *meat products* with any potential source of FMDV.

Article 8.8.24.

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

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

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

Article 8.8.25.

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

For milk and milk products

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

1) these products:

   a) originate from *establishments* which were not infected or suspected of being infected with FMD at the time of *milk* collection;

   b) have been processed to ensure the destruction of FMDV in accordance with one of the procedures in Article 8.8.35. and in Article 8.8.36.;

2) the necessary precautions were taken after processing to avoid contact of the products with any potential source of FMDV.

Article 8.8.26.

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

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

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

1) the manufacturing method for these products included heating to a minimum core temperature of 70°C for at least 30 minutes~~.~~;

2) the necessary precautions were taken after processing to avoid contact of the products with any potential source of FMDV.

Article 8.8.27.

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

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

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

1) these products have been processed to ensure the destruction of FMDV in accordance with one of the procedures in Articles 8.8.32., 8.8.33. and 8.8.34.;

2) the necessary precautions were taken after collection or processing to avoid contact of the products with any potential source of FMDV.

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

Article 8.8.28.

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

For straw and forage

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

1) are free of grossly identified contamination with material of animal origin;

2) have been subjected to one of the following treatments, which, in the case of material sent in bales, has been shown to penetrate to the centre of the bale:

   a) either to the action of steam in a closed chamber such that the centre of the bales has reached a minimum temperature of 80°C for at least ~~ten~~ 10 minutes,

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

OR

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

Article 8.8.29.

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

For skins and trophies derived from FMD susceptible wildlife

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

Article 8.8.30.

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

For skins and trophies derived from FMD susceptible wildlife

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

Article 8.8.31.

Procedures for the inactivation of FMDV in meat and meat products

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

Annex 30 (contd)

1. Canning

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

2. Thorough cooking

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

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

3. Drying after salting

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

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

Article 8.8.31bis.

Procedures for the inactivation of FMDV in swill

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

1) the swill is maintained at a temperature of at least 90°C for at least 60 minutes, with continuous stirring; or

2) the swill is maintained at a temperature of at least 121°C for at least ten minutes at an absolute pressure of 3 bar; or

3) the swill is subjected to an equivalent treatment that has been demonstrated to inactivate FMDV.

EU comment

As explained in the EU comment on Article 8.8.12., the EU suggests expanding the article above to include further provisions on handling of swill with a view to preventing recontamination after treatment.

Article 8.8.32.

Procedures for the inactivation of FMDV in wool and hair

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

1) for wool, industrial washing, which consists of the immersion ~~of the wool~~ in a series of baths of water, soap and sodium hydroxide (~~soda~~ NaOH) or potassium hydroxide (~~potash~~ KOH);

2) chemical depilation by means of slaked lime or sodium sulphide;

3) fumigation with formaldehyde in a hermetically sealed chamber for at least 24 hours;

4) for wool, industrial scouring which consists of the immersion ~~of wool~~ in a water-soluble detergent held at 60-70°C;

5) for wool, storage ~~of wool~~ at 4°C for four months, 18°C for four weeks or 37°C for eight days.

Article 8.8.33.

Procedures for the inactivation of FMDV in bristles

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

1) boiling for at least one hour; or

2) immersion for at least 24 hours in a 1% aqueous solution of formaldehyde.

Article 8.8.34.

Procedures for the inactivation of FMDV in raw hides and skins

For the inactivation of FMDV present in raw hides and skins for industrial use, the following procedure should be used: treatment for at least 28 days with salt (NaCl) containing 2% sodium carbonate (Na_2CO_3).

Article 8.8.35.

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

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

1) a process applying a minimum temperature of 132°C for at least one second (ultra-high temperature [UHT]); or

2) if the *milk* has a pH less than 7.0, a process applying a minimum temperature of 72°C for at least 15 seconds (high temperature - short time pasteurisation [HTST]); or

3) if the *milk* has a pH of 7.0 or greater, the HTST process applied twice.

Article 8.8.36.

Procedures for the inactivation of FMDV in milk for animal consumption

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

1) the HTST process applied twice; or

2) HTST combined with another physical treatment, e.g. maintaining a pH 6 for at least one hour or additional heating to at least 72°C combined with desiccation; or

3) UHT combined with another physical treatment referred to in point 2 above.

Article 8.8.37.

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

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

1) boiling in water for an appropriate time so as to ensure that any matter other than bone, horns, hooves, claws, antlers or teeth is removed; or

2) gamma irradiation at a dose of at least 20 kiloGray at room temperature (20°C or higher); or

3) soaking, with agitation, in a 4% (weight/volume) solution of sodium carbonate (Na_2CO_3) maintained at pH 11.5 or greater for at least 48 hours; or

4) soaking, with agitation, in a formic acid solution (100 kg salt [NaCl] and 12 kg formic acid per 1,000 litres water) maintained at pH less than 3.0 for at least 48 hours; wetting and dressing agents may be added; or

5) in the case of raw hides, treating for at least 28 days with salt (NaCl) containing 2% sodium carbonate (Na_2CO_3).

Article 8.8.38.

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

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

Article 8.8.39.

OIE endorsed official control programme for FMD

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

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

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

1) have a record of regular and prompt animal *disease* reporting in accordance with the requirements in Chapter 1.1.;

2) submit documented evidence of the capacity of the *Veterinary Services* to control FMD; one way of providing this evidence is through the OIE PVS Pathway;

3) submit a detailed plan of the programme to control and eventually eradicate FMD in the country or *zone* including:

   a) the timeline;

   b) the performance indicators for assessing the efficacy of the control measures to be implemented;

   c) documentation indicating that the *official control programme* for FMD is applicable to the entire country;

4) submit a dossier on the epidemiology of FMD in the country describing the following:

   a) the general epidemiology in the country highlighting the current knowledge and gaps and the progress that has been made in controlling FMD;

   b) the measures implemented to prevent introduction of *infection*, the rapid detection of, and response to, all FMD *outbreaks* in order to reduce the incidence of FMD *outbreaks* and to eliminate ~~FMDV~~ transmission of FMDV in at least one *zone* in the country;

c) the main livestock production systems and movement patterns of FMD susceptible animals and their products within and into the country;

5) submit evidence that ~~FMD *surveillance* is in place~~:

a) FMD *surveillance* is in place, ~~taking into account~~ ~~provisions~~ in accordance with Chapter 1.4. and the provisions on *surveillance* of this chapter;

b) it has ~~have~~ diagnostic capability and procedures, including regular submission of samples to a *laboratory* that carries out diagnosis and further characterisation of strains;

6) where *vaccination* is practised as a part of the *official control programme* for FMD, provide:

a) evidence (such as copies of legislation) that *vaccination* of selected populations is compulsory;

b) detailed information on *vaccination* campaigns, in particular on:

i) target populations for *vaccination*;

ii) monitoring of *vaccination* coverage, including serological monitoring of population immunity;

iii) technical specification of the vaccines used, including matching with the circulating FMDV strains, and description of the licensing procedures in place;

iv) the proposed timeline for the transition to the use of vaccines fully compliant with the standards and methods described in the *Terrestrial Manual*;

7) provide an emergency preparedness and response plan to be implemented in case of *outbreaks*.

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

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

– non-compliance with the timelines or performance indicators of the programme; or

– significant problems with the performance of the *Veterinary Services*; or

– an increase in the incidence or an extension of the distribution of FMD that cannot be addressed by the programme.

Article 8.8.40.

General principles of surveillance

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

1. Early detection

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

2. Demonstration of freedom

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

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

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

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

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

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

3. OIE endorsed official control programme

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

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

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

4. Surveillance strategies

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

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

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

An effective *surveillance* system will identify suspected *cases* that require immediate follow-up and investigation to confirm or exclude that the cause of the condition is FMDV. Samples should be taken and submitted for diagnostic testing, unless the suspected *case* can be confirmed or ruled out by epidemiological and clinical investigation. Details of the occurrence of suspected *cases* and how they were investigated and dealt with should be documented. This should include the results of diagnostic testing and the control measures to which the animals concerned were subjected during the investigation.

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

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

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

– characterisation of the existing production systems;

– results of clinical *surveillance* of the suspects and their cohorts;

– description of number of, and protocol for, *vaccinations* performed in the area under assessment;

– *biosecurity* and history of the *establishments* with reactors;

– identification and traceability of animals and control of their movements;

– other parameters of regional significance in historic ~~FMDV~~ transmission of FMDV.

6. Demonstration of population immunity

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

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

Annex 30 (contd)

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

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

Article 8.8.41.

Methods of surveillance

1. Clinical surveillance

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

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

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

2. Virological surveillance

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

Virological *surveillance* aims to:

a) confirm clinically suspected *cases*;

b) follow up positive serological results;

c) characterise isolates for epidemiological studies and vaccine matching;

d) monitor populations at risk for the presence and transmission of the virus.

3. Serological surveillance

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

Serological *surveillance* may be used to:

a) estimate the prevalence or substantiate freedom from ~~FMDV~~ *infection* with, or transmission of, FMDV;

b) monitor population immunity.

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

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

Article 8.8.42.

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

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

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

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

Positive FMDV antibody test results can have four possible causes:

– *infection* with FMDV;

– *vaccination* against FMD;

– maternal antibodies (maternal antibodies in bovines ~~cattle~~ are usually found only up to six months of age but in some individuals and in some other species, maternal antibodies can be detected for longer periods);

– non-specific reactivity of the serum in the tests used.

1. Procedure in case of positive test results

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

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

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

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

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

Annex 30 (contd)

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

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

2. Follow-up of field and laboratory findings

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

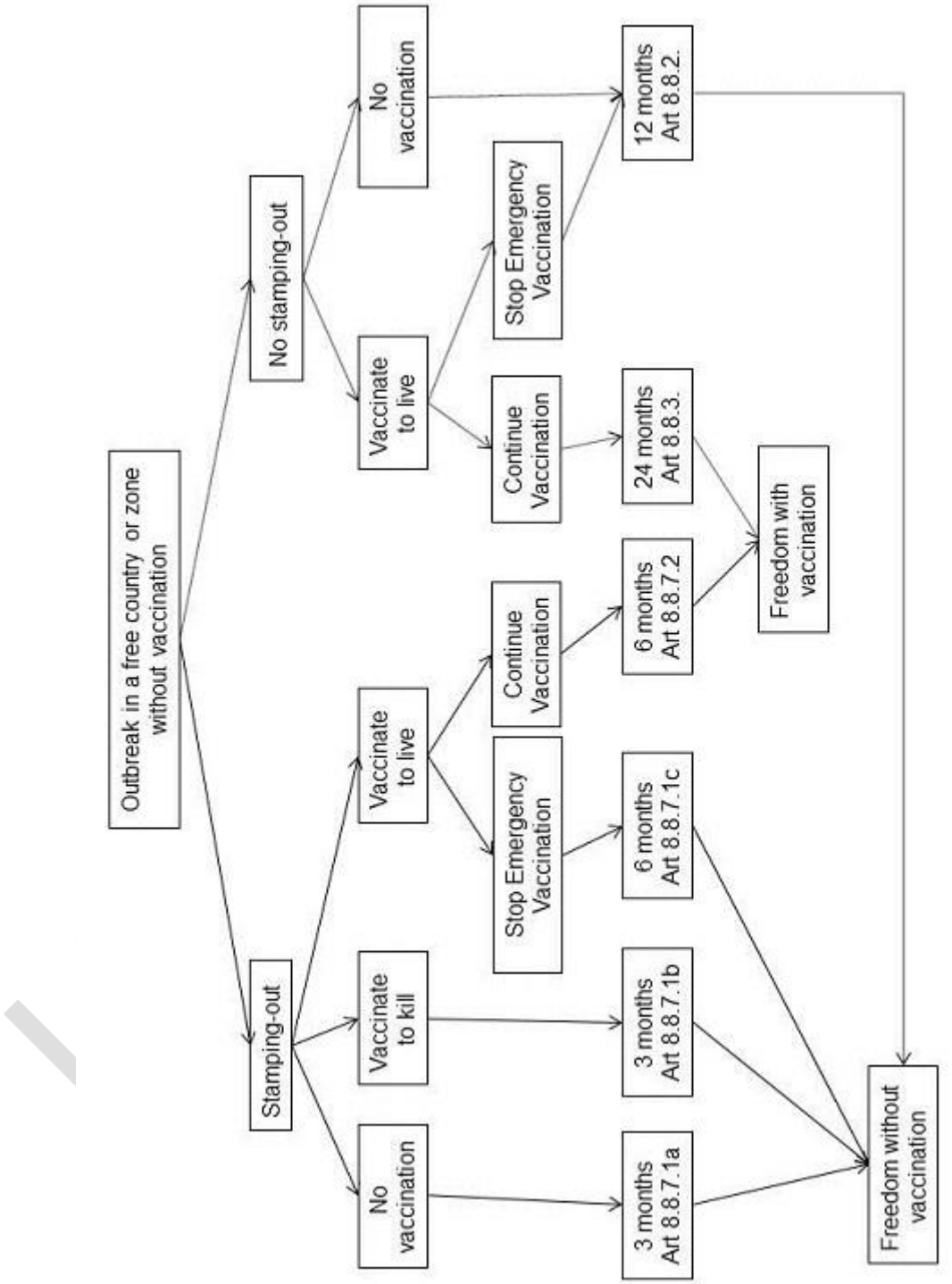
It is difficult to determine ~~T~~he significance of small numbers of seropositive animals in the absence of current FMDV transmission ~~is difficult to determine~~. Such findings may be an indication of past *infection* followed by recovery or by the development of a carrier state, in ruminants, or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

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

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

Annex 30 (contd)

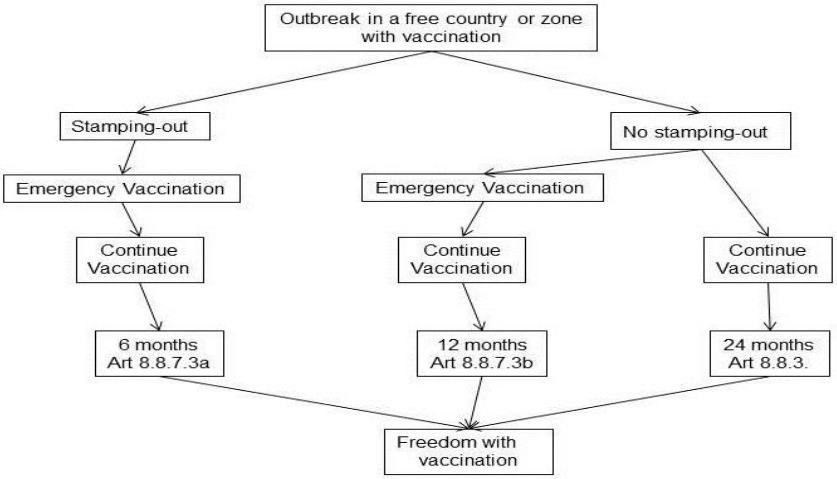
Fig. 1. Schematic representation of the minimum waiting periods and pathways for recovery of ~~FMD~~ free status after an outbreak of FMD in a previously free country or zone where vaccination is not practised



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

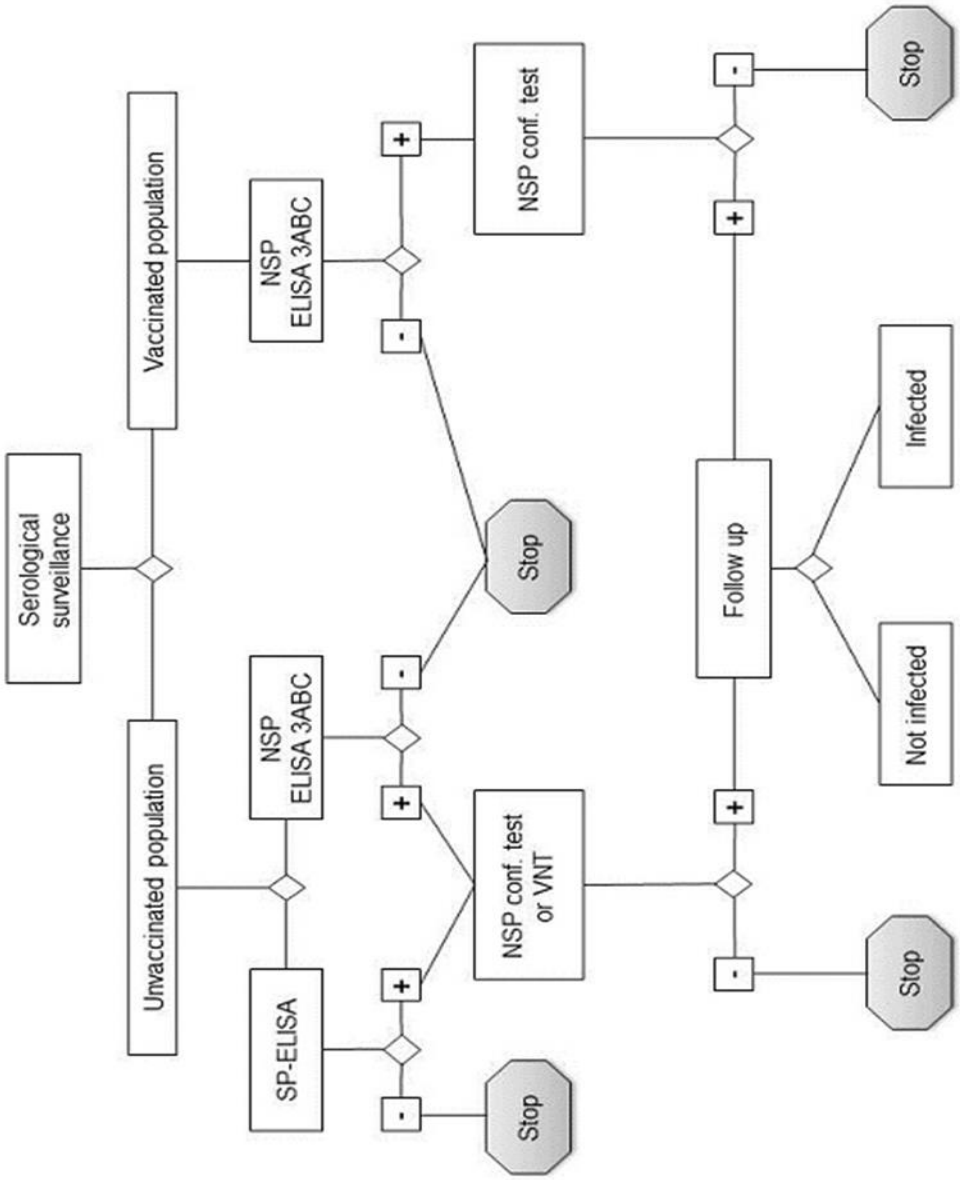
Annex 30 (contd)

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



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

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



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Annex 31

SECTION 6. VETERINARY PUBLIC HEALTH

EU comment

The EU in general supports this proposed new chapter. Some comments are inserted in the text below.

CHAPTER 6.Z.

INTRODUCTION TO RECOMMENDATIONS FOR VETERINARY PUBLIC HEALTH

Article 6.X.1.

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

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

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

EU comment

Food security (supply of sufficient food of adequate quality) should be added to the list of examples above, as it is a very important component of veterinary public health. Indeed, the work of Veterinary Services – *inter alia* by controlling animal diseases and food-borne zoonoses at the animal source – mitigates food production losses due to animal diseases, and contributes to both the safety and availability of food of animal origin, thus meeting the nutritional needs of the population.

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

EU comment

The term "emerging diseases" should be italicised, as the glossary definition includes veterinary public health.

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

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

Annex 32

CHAPTER 4.Y.

MANAGEMENT OF OUTBREAKS OF LISTED DISEASES

EU comment

The EU commends the Code Commission for embarking on this new work of drafting a Code chapter on the management of outbreaks of listed diseases. We acknowledge that this is not an easy task and are therefore willing to support this difficult work with detailed comments over the coming years.

At this stage, the EU cannot support the chapter as currently drafted. Indeed, there is an issue with the overall scope of the chapter, which currently includes all OIE listed diseases. However, the disease control measures described in the text mostly relate to animal health emergencies linked to highly contagious animal diseases and would thus be justified only for a limited number of diseases with major impact on animal (and/or public) health, livestock production and the economy (e.g. former "List A" diseases or transboundary diseases with high regional priority). It therefore does not seem justified to include all OIE listed diseases in the scope of this chapter as presented; the scope thus needs to be clarified.

Furthermore, many sections are drafted in rather prescriptive language, and certain provisions seem overly rigid. However, the decision by OIE member countries to apply or not certain control measures such as stamping-out policy is entirely voluntary and depends on many factors, including the previous status of the country with regard to the disease in question, and the ultimate goal of the measures (eradication of the disease vs. limitation of its spread or economic impact). Ultimately, this is mainly a question of resources and cost-benefit analysis, which are not adequately covered in the current draft chapter. This needs to be better reflected in the text, as eradication cannot realistically be the goal for all 116 OIE listed diseases (nor can there be contingency plans for all listed diseases, or an in-depth epidemiological investigation of each outbreak).

In addition, the title of the chapter does not seem to very well match its content, which mostly describes general principles of outbreak management, contingency planning and emergency preparedness. The title should preferably reflect this and be amended accordingly.

Furthermore, the EU requests that the role of stakeholders be adequately addressed in the chapter. Indeed, there is a need to identify the role and responsibilities of the industry in disease prevention and control, stressing the importance of collaboration between Veterinary Services and the private sector for disease control.

In general, the chapter should be reviewed with a view to avoiding overlaps with provisions of other Code chapters (e.g. as regards the descriptions of notification obligations) and ensure consistency with the glossary (e.g. as regards references to *Stamping-out policy*; previously *free country or zone*).

Finally, in light of the glossary definition of "case", use of the term "suspected *case*" should in general be avoided, as it is not clear what is meant. Instead, it would be preferable to refer to an "animal in which an infection is suspected"(as is the case for example in Article 4.Y.5).

Article 4.Y.1.

Introduction

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

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

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

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

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

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

Article 4.Y.2.

Legal framework and regulatory environment

1) In order to be able to effectively control *listed diseases*, the *Veterinary Authority* should ensure that:

   – the *Veterinary Services* comply with the principles of Chapter 3.1., especially the services dealing with the prevention and control of contagious animal *disease*s, including zoonoses;

   – the *veterinary legislation* complies with the principles of Chapter 3.4.

2) In particular, in order for the *Veterinary Services* to be the most effective when combatting animal *disease outbreaks*, the following should be addressed in the *veterinary legislation*:

   – legal powers and structure of command and responsibilities, including responsible officials with defined powers; especially a right of entry to *establishments* or other related enterprises such as live *animal* markets, *slaughterhouses/abattoirs* and animal products processing plants, for regulated purposes of *surveillance* and *disease* control actions, with the possibility of obliging owners to assist;

   – sources of financing for epidemiological enquiries, laboratory diagnostic, disinfectants, insecticides, vaccines and other critical supplies;

   – sources of financing and compensation policy for livestock and property that may be destroyed as part of *disease* control programmes;

   – coordination with other authorities, especially law enforcement and public health authorities.

3) Furthermore, the specific regulations on *disease* control policies should include the following:

– *risk analysis* to identify and prioritise potential *disease risks*, including a regularly updated list of *notifiable diseases*;

– definitions and procedures for the reporting and management of a suspected *case*, *case*, suspected infected *establishment*, infected *establishment*, contact *establishment*;

– definitions and procedures for the declaration and management of *infected zones* and other *zones*, such as *free zones*, *protection zones*, *containment zones*, or less specific ones such as *zones* of intensified *surveillance*;

– procedures for the collection, transport and testing of animal samples;

– procedures for the identification of *animals*;

– procedures for the restrictions of movements, including possible standstill or compulsory veterinary certification, of relevant *animals* and animal products within, to, or from given *zones* or *establishments* or other related enterprises;

– procedures for the destruction or *slaughter* and safe disposal or processing of infected or potentially infected *animals*, including relevant *wildlife*, and contaminated or potentially contaminated products and materials;

– procedures for compensation for the owners of *animals* or animal products, including defined standards and means of implementing such compensation;

– procedures for cleaning, *disinfection* and disinsection of *establishments* and related premises, *vehicles* or equipment;

– procedures for the compulsory emergency *vaccination* or treatment of *animals*, as relevant, and for any other necessary *disease* control actions.

Article 4.Y.3.

Preparedness

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

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

1. Risk analysis

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

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

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

2. Planning

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

a) a preparedness plan, which outlines what should be done before an *outbreak* of a *notifiable disease* occurs;

b) a response or contingency plan, which details what should be done in the event of an occurrence of a

notifiable disease, beginning from the point when a suspected *case* is reported;

c) a comprehensive set of instructions for field staff and other stakeholders on how to undertake specific tasks required by the response or contingency plan;

d) a recovery plan for the safe restoration of normal activities, possibly including procedures and practices modified in light of the experience gained during the management of the *outbreak*.

3. Simulation exercises

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

Article 4.Y.4.

Early detection system

1) Depending on the priorities identified by the *Veterinary Authority*, *Veterinary Services* should implement adequate *surveillance* for *listed diseases* in accordance with Chapter 1.4. or *disease*-specific chapters, in order to detect suspected *cases* and either rule them out or confirm them. The *surveillance* should be adapted to the epidemiological and environmental situation. *Vector surveillance* should be conducted in accordance with Chapter 1.5.

2) In order to implement adequate *surveillance*, the *Veterinary Authority* should have access to good diagnostic capacity. This means that the *veterinarians* and other relevant personnel of the *Veterinary Services* have adequate knowledge of the *disease*, its clinical and pathological manifestation and its epidemiology, and that laboratories approved for the testing of animal samples for the relevant *diseases* are available.

3) Suspected *cases* of *notifiable diseases* should be reported without delay to the *Veterinary Authority*, ideally with the following information:

– the *disease* or pathogenic agent suspected, with brief descriptions of clinical signs or lesions observed, or laboratory test results as relevant;

– the date when the signs were first noticed at the initial site and any subsequent sites;

– the names and addresses or geographical locations of suspected infected *establishments* or premises;

– the animal species affected, including possible human cases, and the approximate numbers of sick and dead *animals*;

– initial actions taken, including *biosecurity* and precautionary movement restrictions of *animals*, products, staff, vehicles and equipment;

4) Immediately following the report of a suspected *case*, investigation should be conducted by the *Veterinary Services*, taking into account the following:

– *biosecurity* to be observed when entering and leaving the *establishment*, premises or locality;

– clinical examinations to be undertaken (number and types of *animals*);

– samples to be taken from *animals* showing signs or not (number and types of *animals*), with specified sampling and sample handling equipment and sample handling procedures, including for the safety of the investigator and animal owners;

– procedure for submitting samples for testing;

– size of the affected *establishment*, premises or locality and possible entry pathways;

– investigation of the approximate numbers of similar or possibly susceptible *animals* in the *establishment* and its surroundings;

– details of any recent movements of possibly susceptible *animals* or *vehicles* or people to or from the affected *establishments*, premises or locality;

– any other relevant epidemiological information, such as presence of the suspected *disease* in *wildlife* or abnormal *vector* activity;

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

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

6) When a *case* of a *listed disease* is detected, *notification* shall be made to the OIE in accordance with Chapter 1.1.

Article 4.Y.5.

General considerations when managing an outbreak

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

1) eliminating the source of pathogenic agent, through:

– the *killing* or *slaughter* of *animals* infected or suspected of being infected, and safe disposal of dead *animals* and potentially contaminated products;

– the cleaning, *disinfection* and, if relevant, disinsection of premises and equipment;

2) stopping the spread of *infection*, through:

– movement restrictions on *animals*, *vehicles* and equipment;

– *biosecurity*;

– *vaccination*, treatment or culling of *animals* at risk;

– communication and public awareness.

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

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

Article 4.Y.6.

Culling and disposal

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

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

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

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

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

1. Stamping-out

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

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

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

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

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

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

2. Test and cull

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

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

Article 4.Y.7.

Movement control

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

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

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

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

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

Article 4.Y.8.

Biosecurity

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

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

Article 4.Y.9.

Vaccination and treatment

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

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

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

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

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

Article 4.Y.10.

Zoning

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

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

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

Article 4.Y.11.

Communication in outbreak management

For the best implementation of *disease* control measures, *Veterinary Services* should ensure good

communication with all concerned stakeholders, including the general public. This should be carried out, among others, through awareness campaigns targeted at breeders, *veterinarians*, local authorities, consumers and general public.

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

Article 4.Y.12.

Specific post-control surveillance

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

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

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

Article 4.Y.13.

Further outbreak investigation, monitoring, evaluation and review

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

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

Annex 33

CHAPTER 8.4.

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

EU comment

The EU in general supports the proposed changes to this article. A comment is inserted in the text below.

[…]

Article 8.4.10.

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

1) To qualify as free from *infection* with *Brucella* without *vaccination*, a *herd* or *flock* of bovids, sheep and goats, camelids or cervids should satisfy the following requirements:

a) the *herd* or *flock* is in a country or *zone* free from *infection* with *Brucella* without *vaccination* in the relevant animal category and is certified free without *vaccination* by the *Veterinary Authority*;

OR

b) the *herd* or *flock* is in a country or *zone* free from *infection* with *Brucella* with *vaccination* in the relevant animal category and is certified free without *vaccination* by the *Veterinary Authority*; and no animal of the *herd* or *flock* has been vaccinated in the past three years;

OR

c) the *herd* or *flock* met the following conditions:

i) *infection* with *Brucella* in animals is a *notifiable disease* in the entire country;

ii) no animal of the relevant category of the *herd* or *flock* has been vaccinated in the past three years;

iii) no case has been detected in the *herd* or *flock* for at least the past year;

iv) animals showing clinical signs consistent with *infection* with *Brucella* such as abortions have been subjected to the necessary diagnostic tests with negative results;

v) for at least the past year, there has been no evidence of *infection* with *Brucella* in other *herds* or *flocks* of the same *establishment*, or measures have been implemented to prevent any transmission of the *infection* with *Brucella* from these other *herds* or *flocks*;

vi) two tests have been performed with negative results on all sexually mature animals, except castrated males, present in the *herd* at the time of testing, the first test being performed not before ~~3~~ three months after the *slaughter* of the last case and the second test at an interval of more than ~~6~~ six and less than 12 months.

EU comment

While agreeing that castrated males should be excluded from testing, the EU suggests an alternative wording to avoid any confusion, as follows:

"vi) two tests have been performed with negative results on all sexually mature animals <u>(excluding castrated males)</u> ~~(, except castrated males,~~ present in the herd at the time of testing, [...]".

Indeed, using the word "except" would insinuate that castrated males are sexually mature, which according to the ad hoc group report they are not.

2) To maintain the free status, the following conditions should be met:

a) the requirements in points 1*a)* or 1*b)* or 1*c) i)* to *v)* above are met;

b) regular tests, at a frequency depending on the prevalence of *herd* or *flock infection* in the country or *zone*, demonstrate the continuing absence of *infection* with *Brucella*;

c) animals of the relevant category introduced into the *herd* or *flock* are accompanied by a certificate from an *Official Veterinarian* attesting that they come from:

i) a country or *zone* free from *infection* with *Brucella* in the relevant category without *vaccination*;

OR

ii) a country or *zone* free from *infection* with *Brucella* with *vaccination* and the animals of the relevant category have not been vaccinated in the past three years;

OR

iii) a *herd* or *flock* free from *infection* with *Brucella* with or without *vaccination* and that the animals have not been vaccinated in the past three years and were tested for *infection* with *Brucella* within 30 days prior to shipment with negative results; in the case of post-parturient females, the test is carried out at least 30 days after giving birth. This test is not required for sexually immature animals.

[...]

— Text deleted.

Annex 34

CHAPTER 8.15.

INFECTION WITH RINDERPEST VIRUS

EU comment

The EU in general supports the proposed changes to article 8.15.2. Comments are inserted in the text below.

Article 8.15.1.

[…]

Article 8.15.2.

Definitions and general provisions

For the purpose of the *Terrestrial Code*:

1) RPV-containing material means field and laboratory strains of RPV; vaccine strains of RPV including valid and expired vaccine stocks; tissues, sera and other ~~clinical~~ *pathological material* ~~from animals known or suspected to be infected~~; diagnostic material containing or encoding live virus, recombinant morbilliviruses (segmented or nonsegmented) containing unique RPV nucleic acid or amino acid sequences, and full length genomic material including virus ~~ribonucleic acid (~~RNA~~)~~ and cDNA copies of virus RNA;

EU comment

Referring to the glossary definition of "pathological material", the EU suggests deleting the words "tissues, sera and other" in point 1) above. Indeed, as "pathological material" is defined as "samples obtained from live or dead animals, containing or suspected of containing infectious or parasitic agents, [...]", tissues and sera would already be covered by the italicised "pathological material".

Furthermore, it is very much unclear what is meant by "diagnostic material [...] encoding live virus". Indeed, should this mean RNA specific to RPV, the wording may lead to confusion, as both RNA from infectious and inactivated RPV (in inactivated serum for example) could be detected in diagnostic material; whereas both would be "encoding" the same thing, the risk associated with such material would not be the same. Only material containing live virus should be included in the case definition.

Finally, the EU suggests deleting the words ", and full length genomic material including virus RNA and cDNA copies of virus RNA". Indeed, unlike FMDV, for example, the RNA of negative strand viruses such as RPV is not infectious, nor is a full-length cDNA copy of the genome. There is thus no risk posed by such material. However, this restriction for example prevents a laboratory keeping a sample of RPV RNA as a control for a diagnostic PCR, which restricts the ability of member countries to maintain basic diagnostic capabilities. It is important to weigh the risk posed by delays in detecting a reappearance of RPV against the (in this case non-existent) risk posed by purified nucleic acids.

2) subgenomic fragments of RPV genome (either as plasmid or incorporated into other recombinant viruses) ~~morbillivirus nucleic acid~~ that ~~are not capable of being~~ cannot be incorporated in a replicating morbillivirus or morbillivirus-like virus are not considered ~~as~~ to be RPV-containing material~~;~~, neither are sera that have been

either heat-treated at 56˚C for at least 2 hours, or shown to be free from RPV genome sequences by a validated RT-PCR assay;

EU comment

While in general agreeing with the proposed changes in point 2) above, the EU suggests clarifying what is meant by "(either as plasmid or incorporated into other recombinant viruses)". We assume that what is meant by "plasmid" are vector virus cDNA cassettes containing subgenomic fragments of RPV genome used to produce recombinant viruses expressing RPV genes. However, the wording as proposed ("other recombinant viruses") is confusing as plasmids are not recombinant viruses. Furthermore, "other recombinant viruses" are not incorporated into replicating (morbilli- or morbilli-like) viruses. Thus, the word "other" before "recombinant viruses" should be deleted, and the parenthesis reworded to clarify the intended.

In addition, the EU suggests replacing the word "in" with "<u>into</u>" before "a replicating morbillivirus".

3) ban on *vaccination* against rinderpest means a ban on administering any vaccine containing RPV or RPV components to any *animal*;

4) the *incubation period* for rinderpest shall be 21 days;

5) a *case* is defined as an *animal* infected with RPV whether or not showing clinical signs; and

6) for the purpose of this chapter, 'susceptible *animals*' means domestic, *feral* and *wild* artiodactyls.

[…]

– Text deleted.

Annex 35

CHAPTER 15.2.

INFECTION WITH CLASSICAL SWINE FEVER VIRUS

EU comment

The EU thanks the OIE and in general supports the proposed changes to this chapter. Comments are inserted in the text below.

Article 15.2.1.

General provisions

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

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

– *wild* and *feral* pigs.

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

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

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

OR

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

OR

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

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

~~– domestic and captive wild pigs, permanently captive or farmed free range, used for the production of *meat*, or other commercial products or use, or for breeding these categories of pigs;~~

~~– wild and feral pigs.~~

For the purposes of the *Terrestrial Code*, the *incubation period* shall be 14 days. Pigs exposed to CSFV prenatally may not show clinical signs at birth and be persistently infected throughout life ~~and may have an *incubation period* of several months before showing signs of disease~~. ~~Pigs exposed postnatally have an *incubation period* of 2-14 days, and are usually infective between post-infection days 5 and 14, but up to 3 months in cases of chronic *infections*.~~

~~A Member Country should not impose bans on the trade in *commodities* of domestic and captive wild pigs in response to a *notification* of *infection* with CSFV in wild and feral pigs provided that Article 15.2.2. is implemented.~~

Commodities of domestic or *captive wild* pigs can be traded safely in accordance with the relevant articles of this chapter from countries complying with the provisions of Article 15.2.2, even if they notify *infection* with CSFV in *wild* or *feral* pigs.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Annex 35 (contd)

Article 15.2.2.

General criteria for the determination of the ~~classical swine fever~~ CSF status of a country, zone or compartment

1) CSF ~~should be~~ is notifiable in the whole territory, and all pigs showing clinical signs or pathological lesions suggestive of CSF ~~should be~~ are subjected to appropriate field or *laboratory* investigations;

2) an on-going awareness programme ~~should be~~ is in place to encourage reporting of all cases suggestive of CSF;

EU comment

The EU suggests replacing the word "encourage" with "enhance" in point 2 above. Indeed, as the disease is notifiable, its notification is already compulsory, so "enhance reporting" seems more appropriate.

Furthermore, to avoid confusion, the EU suggests replacing the word "cases" with "suids showing signs". Indeed, the glossary definition of the term "case" does not allow for "cases suggestive" of a disease.

3) the *Veterinary Authority* ~~should have~~ has current knowledge of, and authority over, all domestic and *captive wild* pig *herds* in the country, *zone* or *compartment*;

4) the *Veterinary Authority* ~~should have~~ has current knowledge ~~about~~ of the ~~population~~ distribution and habitat of *wild* and *feral* pigs in the country or *zone*;

5) for domestic and *captive wild* pigs, appropriate *surveillance* in accordance with Articles 15.2.26. to 15.2.32. is in place;

6) for *wild* and *feral* pigs, if present in the country or *zone*, a *surveillance* programme is in place according to Article 15.2.31., taking into account the presence of natural and artificial boundaries, the ecology of the *wild* and *feral* pig population, and an assessment of the *risks* of *disease* spread;

7) based on the assessed *risk* of spread within the *wild* and *feral* pig population, and according to Article 15.2.29., the domestic and *captive wild* pig population ~~should be~~ is separated from the *wild* and *feral* pig population by appropriate measures.

Article 15.2.3.

Country or zone free from CSF ~~Classical swine fever free country or zone~~

A country or *zone* may be considered free from CSF when Article 15.2.2. is complied with, and when:

1) *surveillance* in accordance with Articles 15.2.26. to 15.2.32. has been in place for at least 12 months;

2) there has been no *outbreak* of CSF in domestic and *captive wild* pigs during the past 12 months;

3) no evidence of *infection* with CSFV has been found in domestic and *captive wild* pigs during the past 12 months;

4) no *vaccination* against CSF has been carried out in domestic and *captive wild* pigs during the past 12 months unless there are means, validated according to Chapter 2.8.3. of the *Terrestrial Manual*, of distinguishing between vaccinated and infected pigs;

5) imported pigs and pig *commodities* comply with the requirements in Articles 15.2.7. to 15.2.14bis.

The proposed free country or ~~the proposed free~~ *zone* will be included in the list of CSF free countries or *zones* only after the submitted evidence, based on the provisions of Article 1.6.9., has been accepted by the OIE.

Retention on the list requires that the information in points 1 to 5 above be re-submitted annually and changes in the epidemiological situation or other significant events should be reported to the OIE according to the requirements in Chapter 1.1.

Article 15.2.4.

Compartment free from CSF ~~Classical swine fever free compartment~~

The bilateral recognition of a *compartment* free from CSF ~~free *compartment*~~ should follow the relevant requirements of this chapter and the principles laid down in Chapters 4.3. and 4.4. Pigs in the *compartment* free from CSF should be separated from any other pigs by the application of effective *biosecurity*.

EU comment

The EU suggests replacing "Pigs in the compartment" with "Pigs in a ~~the~~ compartment", for consistency with the rest of the text and similar articles of other chapters.

Furthermore, the second sentence of the paragraph above should be deleted as it is superfluous. It seems to state the obvious which is already covered in the previous sentence with cross-references to the principles in Chapters 4.3. and 4.4. Indeed, those chapters and the requirements for compartments already include and go beyond merely effective separation by effective biosecurity

Article 15.2.5.

Establishment of a containment zone within a ~~classical swine fever free~~ country or zone free from CSF

In the event of limited *outbreaks* or *cases* of CSF within a ~~CSF free~~ country or *zone* free from CSF, including within a *protection zone*, a *containment zone*, which includes all *outbreaks*, can be established for the purpose of minimising the impact on the entire country or *zone*.

EU comment

The EU suggests inserting the word "previously" before "free from CSF". Indeed, once outbreaks occur, the country or zone no longer is free. Furthermore, this would be consistent with Article 15.2.6. (and Article 8.8.6. of the proposed revised chapter on FMD).

For this to be achieved and for the Member Country to take full advantage of this process, the *Veterinary Authority* should submit documented evidence as soon as possible to the OIE.

In addition to the requirements for the establishment of a *containment zone* outlined in point 3 of Article 4.3.3., the *surveillance* programme should take into consideration the involvement of *wild* and *feral* pigs and measures to avoid their dispersion.

The free status of the areas outside the *containment zone* is suspended while the *containment zone* is being established. The free status of these areas may be reinstated irrespective of the provisions of Article 15.2.6., once the *containment zone* is clearly established. It should be demonstrated that *commodities* for *international trade* have originated outside the *containment zone*.

In the event of the recurrence of CSF in the *containment zone*, the approval of the *containment zone* is withdrawn. and the free status of the country or *zone* is suspended until the relevant requirements of Article 15.2.3. have been fulfilled.

EU comment

The reference in the paragraph above should be to Article 15.2.6. and not to Article 15.2.3., i.e. same as for recovery of free status after reoccurrence in a containment zone (see paragraph below, and relevant provisions of Chapter 8.8. on FMD).

The recovery of the CSF free status of the *containment zone* should follow the provisions of Article 15.2.6 and be achieved within 12 months of its approval.

Article 15.2.6.

Recovery of free status

Should an *outbreak* of CSF occur in a previously ~~a CSF *outbreak* occur in a~~ free country or *zone*, ~~the free~~ its status may be restored where *surveillance* in accordance with Article~~s~~ 15.2.~~26~~30~~. to 15.2.32.~~ has been carried out with negative results either:

1) three months after the last *case* where a *stamping-out policy* without *vaccination* is practised;

OR

2) where a *stamping-out policy* with emergency *vaccination* is practised:

   a) three months after the last *case* and the *slaughter* of all vaccinated *animals*, or

   b) three months after the last *case* without the *slaughter* of vaccinated *animals* where there are means, validated according to Chapter 2.8.3. of the *Terrestrial Manual*, of distinguishing between vaccinated and infected pigs;

OR

3) where a *stamping-out policy* is not practised, the provisions of Article 15.2.3. should be followed.

The country or *zone* will regain CSF free status only after the submitted evidence, based on the provisions of Article 1.6.9., has been accepted by the OIE.

The country or *zone* will regain CSF free status only after the submitted evidence, based on the provisions of Article 1.6.10., has been accepted by the OIE.

EU comment

The EU would like to reiterate its previous general comments in relation to inconsistencies in different Code chapters as regards the timing for recovery of free status after a stamping-out policy has been applied (see also EU comment on Chapter 8.8., Annex 24 of the Code Commission September 2015 meeting report).

First of all, the EU notes that in general there seems to be a lack of clarity in the Code provisions regarding stamping-out policy. Indeed, as explained in previous EU comments, the EU is of the opinion that the stamping out policy as defined in the glossary encompasses the 3 elements of killing of animals, destruction of carcasses, and cleansing and disinfection of establishments, and that the stamping-out policy can be considered completed only when all these 3 elements have been implemented.

Indeed, the article above suggests that the waiting period for recovery of free status starts counting "after the last case" or "after the last case and the slaughter of vaccinated animals" etc. It is far from clear what is meant by "after the last case" – this could be interpreted as being the day the last case was confirmed, killed, disposed of, or cleaned / disinfected. The difference in time between the day of confirmation and the day of final disinfection would be significant, thus the interpretation of "after the last case" is rather important for determining the day of recovery of the free status.

In addition, the EU notes that the wording in the article above differs significantly from corresponding articles in other disease specific chapters (e.g. the FMD Chapter refers to "disposal of the last animal killed", or "slaughter of all vaccinated animals", or "last vaccination", depending on the chosen disease control strategy). This leads to even more

uncertainty as it is unclear whether "disposal of the last animal killed" is equivalent to "destruction of carcasses" in the glossary definition of stamping-out policy, and whether the stamping out policy needs to be completed (i.e. including cleansing and disinfection) before the waiting period starts.

Furthermore, the Avian Influenza and Newcastle disease chapters for example refer explicitly to "including disinfection of all affected establishments" in relation to the waiting period.

The EU therefore strongly suggests addressing this also in a horizontal way. A good opportunity would be to do that in the framework of the new chapter on outbreak management.

Article 15.2.6bis.

Direct transfer of pigs within a country from an infected zone to a free zone for slaughter

In order not to jeopardise the status of a free *zone*, pigs should only leave the *infected zone* if transported by mechanised *vehicle* directly for *slaughter* in the nearest designated *slaughterhouse/abattoir* under the following conditions:

1) no pig has been introduced into the *establishment* of origin and no pig in the *establishment* of origin has shown clinical signs of CSF for at least 30 days prior to *slaughter*;

2) the pigs were kept in the *establishment* of origin for at least three months prior to movement for *slaughter*;

3) CSF has not occurred within a 10-kilometre radius of the *establishment* of origin for at least three months prior to movement;

4) the pigs should be transported under the supervision of the *Veterinary Services* in a *vehicle*, which was cleaned and disinfected before *loading*, directly from the *establishment* of origin to the *slaughterhouse/abattoir* without coming into contact with other pigs;

5) such a *slaughterhouse/abattoir* is not approved for the export of *fresh meat* during the time it is handling the *meat* of pigs from the *infected zone*;

6) *vehicles* and the *slaughterhouse/abattoir* should be subjected to *disinfection* immediately after use.

The pigs should be subjected to ante- and post-mortem inspections in accordance with Chapter 6.2. with favourable results and the *meat* should be treated according to Article 15.2.23.

Any other products obtained from the pigs, and any products coming into contact with them, should be considered contaminated and treated in accordance with Article 15.2.22. or Articles 15.2.24. to 15.2.25.ter to destroy any residual virus.

EU comment

In the last paragraph of the Article above, the EU suggests replacing the words "residual virus" with "potentially present CSFV". Indeed, following the logic of the article in question, there should not be any (residual) virus present. Therefore "potentially present" better captures the intended. This would also be consistent with the wording of Articles 8.8.8. and 8.8.9. of the proposed revised chapter on FMD.

Furthermore, to avoid any confusion, the EU suggests clarifying in the title or chapeau of the article that the slaughter pigs and their fresh meat are solely intended for the national market, whereas processed meat may be exported in accordance with the relevant article of the present chapter.

Article 15.2.6ter.

Direct transfer of pigs within a country from a containment zone to a free zone for slaughter

In order not to jeopardise the status of a free *zone*, pigs should only leave the *containment zone* if transported by mechanised *vehicle* directly to *slaughter* in the nearest designated *slaughterhouse/abattoir* under the following conditions:

EU comment

In the paragraph above, the EU suggests replacing the word "to" with "for" before "slaughter", for linguistic and consistency reasons (see Article 15.2.6bis. as well as Articles 8.8.8. and 8.8.9. of the proposed revised chapter on FMD).

1) the *containment zone* has been officially established according to the requirements in Article 15.2.5.;

2) the pigs should be transported under the supervision of the *Veterinary Services* in a *vehicle*, which was cleaned and disinfected before *loading*, directly from the *establishment* of origin to the *slaughterhouse/abattoir* without coming into contact with other pigs;

3) such a *slaughterhouse/abattoir* is not approved for the export of *fresh meat* during the time it is handling the *meat* of pigs from the *containment zone*;

4) *vehicles* and the *slaughterhouse/abattoir* should be subjected to *disinfection* immediately after use.

The pigs should be subjected to ante- and post-mortem inspections in accordance with Chapter 6.2. with favourable results and the *meat* should be treated according to Article 15.2.23.

Any other products obtained from the pigs, and any products coming into contact with them, should be considered contaminated and treated in accordance with Article 15.2.22. or Articles 15.2.24. to 15.2.25ter. to destroy any residual virus.

EU comment

In the last paragraph of the Article above, the EU suggests replacing the words "residual virus" with "potentially present CSFV". Indeed, following the logic of the article in question, there should not be any (residual) virus present. Therefore "potentially present" better captures the intended. Furthermore, this would be consistent with the wording of Articles 8.8.8. and 8.8.9. of the proposed revised chapter on FMD.

Article 15.2.7.

Recommendations for importation from countries, zones or compartments free from ~~classical swine fever~~ CSF

For domestic and *captive wild pigs*

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the ~~*animals*~~ pigs:

1) showed no clinical sign of CSF on the day of shipment;

2) were kept ~~in a country, *zone* or *compartment* free from CSF~~ since birth or for at least the past three months in a country, *zone* or *compartment* free from CSF;

3) ~~have~~ were not ~~been~~ vaccinated against CSF, nor are they the progeny of vaccinated sows, unless there are means, validated according to Chapter 2.8.3. of the *Terrestrial Manual*, of distinguishing between vaccinated and infected pigs.

EU comment

In point 3) above, the EU suggests replacing the reference to "Chapter 2.8.3. of the Terrestrial Manual" by a more generic reference to "the CSF chapter of the Terrestrial Manual". Indeed, the numbering of chapters in the Terrestrial Manual changes frequently, therefore use of the chapter name in the reference seems more appropriate.

Article 15.2.8.

Recommendations for importation from countries or zones ~~considered infected with classical swine fever virus~~ not free from CSF

For domestic and *captive wild pigs*

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the ~~*animals*~~ pigs:

1) showed no clinical sign of CSF on the day of shipment;

2) and either:

   a) were kept since birth or for the past three months in a CSF free *compartment*; or

   b) were isolated for 28 days prior to shipment in a *quarantine station*, and were subjected to a virological test and a serological test performed on a sample collected at least 21 days after entry into the *quarantine station*, with negative results;

3) ~~have~~ were not ~~been~~ vaccinated against CSF, nor are they the progeny of vaccinated sows, unless there are means, validated according to Chapter 2.8.3. of the *Terrestrial Manual*, of distinguishing between vaccinated and infected pigs.

EU comment

In point 3) above, the EU suggests replacing the reference to "Chapter 2.8.3. of the Terrestrial Manual" by a more generic reference to "the CSF chapter of the Terrestrial Manual". Indeed, the numbering of chapters in the Terrestrial Manual changes frequently, therefore use of the chapter name in the reference seems more appropriate.

This comment is valid also for point 3 of Article 15.2.9. below.

Article 15.2.9.

Recommendations for the importation of wild and feral pigs

Regardless of the CSF status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the ~~*animals*~~ pigs:

1) showed no clinical sign of CSF on the day of shipment;

2) were ~~kept~~ isolated in a *quarantine station* for ~~40~~ 28 days prior to shipment, and were subjected to a virological test and a serological test performed on a sample collected at least 21 days after entry into the *quarantine station*, with negative results;

3) ~~have~~ were not ~~been~~ vaccinated against CSF, unless there are means, validated according to Chapter 2.8.3. of the *Terrestrial Manual*, of distinguishing between vaccinated and infected pigs.

Article 15.2.10.

Recommendations for importation from countries, zones or compartments free from ~~classical swine fever~~ CSF

For semen of domestic and *captive wild pigs*

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor ~~*animals*~~ males:

   a) were kept ~~in a country, *zone* or *compartment* free from CSF~~ since birth or for at least three months prior to collection in a country, *zone* or *compartment* free from CSF;

   b) showed no clinical sign of CSF on the day of collection of the semen;

2) the semen was collected, processed and stored in ~~conformity~~ accordance with the provisions of Chapters 4.5. and 4.6.

Article 15.2.11.

Recommendations for importation from countries or zones ~~considered infected with classical swine fever virus~~ not free from CSF

For semen of domestic and *captive wild pigs*

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor ~~*animals*~~ males:

   a) were kept ~~in a *compartment* free from CSF since birth or~~ for at least three months prior to collection in an *establishment* in which *surveillance,* in accordance with Articles 15.2.26. to 15.2.32., demonstrated that no *case* of CSF occurred in the past 12 months;

   b) showed no clinical sign of CSF on the day of collection of the semen ~~and for the following 40 days~~;

   c) met one of the following conditions:

      i) were subjected to a virological test performed on a blood sample taken on the day of collection, with negative results; or

      ii) were not ~~been~~ vaccinated against CSF and were subjected to a serological test performed on a sample taken at least 21 days after collection, with negative results; or

      ~~iii~~iii) have been vaccinated against CSF and were subjected to a serological test performed on a sample taken at least 21 days after collection, which ~~and it has been conclusively~~ demonstrated that any antibody ~~is due to~~ was caused by the vaccine; ~~or~~

EU comment

The EU notes that point ii) and iii) above are not implementable and should thus be deleted. Indeed, shelf-life of fresh pig semen is less than 21 days, thus a requirement for testing 21 days after semen collection is not possible to implement in practice.

      ~~*iii)* have been vaccinated against CSF and were subjected to a virological test performed on a sample taken on the day of collection and it has been conclusively demonstrated that the boar is negative for virus genome;~~

2) the semen was collected, processed and stored in ~~conformity~~ accordance with the provisions of Chapters 4.5. and 4.6.

Article 15.2.12.

Recommendations for importation from countries, zones or compartments free from ~~classical swine fever~~ CSF

For *in vivo* derived embryos of domestic pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor females: ~~showed no clinical sign of CSF on the day of collection of the embryos;~~

   a) were kept since birth or for at least three months prior to collection in a country, *zone* or *compartment* free from CSF;

   b) showed no clinical sign of CSF on the day of collection of the embryos;

2) the semen used to fertilise the oocytes complied with the conditions in Articles 15.2.10. or Article 15.2.11., as relevant;

3) the embryos were collected, processed and stored in accordance with Chapters 4.7. and 4.9., as relevant.

Article 15.2.13.

Recommendations for importation from countries or zones ~~considered infected with classical swine fever virus~~ not free from CSF

For *in vivo* derived embryos of domestic pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor females:

   a) were kept ~~in a *compartment* free from CSF since birth or~~ for at least three months prior to collection in an *establishment* in which *surveillance,* in accordance with Articles 15.2.26. to 15.2.32., demonstrated that no *case* of CSF occurred in the past three months;

   b) showed no clinical sign of CSF on the day of collection of the embryos ~~and for the following 40 days~~;

   c) ~~and either~~ met one of the following conditions:

      i) were subjected to a virological test performed on a blood sample taken on the day of collection, with negative results; or

      ii) ~~have~~ were not ~~been~~ vaccinated against CSF and were subjected, with negative results, to a serological test performed at least 21 days after collection; ~~or~~

      ~~iii~~iii) ~~have been~~ were vaccinated against CSF and were subjected to a serological test performed on a sample taken at least 21 days after collection, which ~~and it has been conclusively~~ demonstrated ~~by means, validated according to Chapter 2.8.3. of the *Terrestrial Manual*,~~ that any antibody ~~is due to~~ was caused by the vaccine;

EU comment

In point iii) above, the EU suggests replacing the word "caused" with "elicited" before "by the vaccine", as this is the correct term used to describe antibody responses to vaccines.

2) the embryos were collected, processed and stored in accordance with Chapters 4.7. and 4.9., as relevant.

Article 15.2.14.

Recommendations for importation from countries, zones or compartments free from ~~classical swine fever~~ CSF

For *fresh meat* of domestic and *captive wild pigs*

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *fresh meat* comes from ~~animals~~ pigs which:

1) have been kept in a country, *zone* or *compartment* free from CSF, or which have been imported in accordance with Article 15.2.7. or Article 15.2.8.;

2) have been slaughtered in an approved *slaughterhouse/abattoir*, where they have been subjected to ante- and post-mortem inspections in accordance with Chapter 6.2. with favourable results ~~and have been found free from any sign suggestive of CSF~~.

Article 15. 2.14 bis.

Recommendations for importation from countries or zones not free from CSF, where an official control programme exists

For *fresh meat* of domestic pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the *meat* comes from pigs complying with Article 15.2.8.;

EU comment

Point 1) above refers to Article 15.2.8. (on importation of domestic and captive wild pigs), which requires inter alia that pigs "showed no clinical sign of CSF on the day of shipment". We wonder if this is clear enough in the context of the present article (on importantion of fresh meat); i.e. does "day of shipment" correspond to "day of sending for slaughter", and is this clear enough?

2) the pigs were transported under the supervision of the *Veterinary Services*, in a *vehicle* which was cleaned and disinfected before the pigs were loaded;

3) the pigs were transported directly to the approved *slaughterhouse/abattoir* without coming into contact either during transport or at the *slaughterhouse/abattoir* with other pigs which do not fulfil the conditions required for export;

EU comment

It is not clear what the "conditions required for export" mentioned in point 3) above are. To avoid confusion, the EU suggests adding a clear reference to the relevant article(s) of this present chapter.

4) the pigs were slaughtered in an approved *slaughterhouse/abattoir*:

EU comment

For reasons of clarity and consistency with other articles (e.g. Article 15.2.16. point 1 b I and Article 8.2.19. point 2), the EU suggest amending point 4) above as follows:

" 4) the pigs were slaughtered in a~~n approved~~ slaughterhouse/abattoir approved by the Veterinary Authority for export purposes".

a) which is officially designated for export;

b) in which no *case* of CSF was detected during the period between the last *disinfection* carried out before *slaughter* and the shipment for export has been dispatched;

EU comment

It is not clear from where the shipment mentioned in point 4 b) above is to take place, i.e. is it the slaughterhouse/abattoir, cutting plant, cold store etc. This should preferably be clarified.

5) the pigs were subjected to ante- and post-mortem inspections in accordance with Chapter 6.2. with favourable results;

6) appropriate precautions have been taken after *slaughter* to avoid contact of the *fresh meat* with any source of CSFV.

EU comment

The word "contact" should be replaced by "cross-contamination", as this would be the better term in this context.

Article 15.2.15.

Recommendations for the importation of fresh meat of wild and feral pigs

Regardless of the CSF status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *fresh meat* comes from ~~*animals*~~ pigs:

1) which ~~have been~~ were subjected to a post-mortem inspection in accordance with Chapter 6.2. in an approved examination centre, with favourable results ~~and have been found free from any sign suggestive of CSF~~;

2) from each of which a sample ~~has been~~ was collected and ~~has been~~ subjected to a virological test and a serological test for CSF, with negative results.

EU comment

The EU requests for the article above to be deleted, as fresh meat of wild and feral pigs – even if not an important commodity in terms of international trade volume – represent the highest risk commodity in terms of CSF transmission. Even with 100 % virological and serological testing of carcasses – which is not very practical nor economically sensible – a degree of risk remains, as no test method is 100 % reliable. Note that for the same reasons, the corresponding article in the revised ASF chapter was recently deleted from the draft chapter.

Article 15.2.16.

Recommendations for the importation of ~~meat and~~ meat products of pigs ~~intended for use in animal feeding, for agricultural or industrial use, or for pharmaceutical or surgical use~~

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the *meat products*:

1) ~~have been~~ were prepared:

a) exclusively from *fresh meat* meeting the conditions laid down in Articles 15.2.14., 15.2.14bis. or 15.2.15.;

b) in a processing ~~establishment~~ facility:

i) approved by the *Veterinary Authority* for export purposes;

ii) processing only *meat* ~~meeting~~ satisfying the conditions ~~laid down~~ in Articles 15.2.14., 15.2.14bis. or 15.2.15.;

OR

2) ~~have been~~ were processed in accordance with one of the processes in Article 15.2.23. in ~~an establishment~~ a facility approved by the *Veterinary Authority* for export purposes ~~so as to ensure the destruction of the CSFV in conformity with one of the procedures referred to in Article 15.2.23.~~, and that ~~the necessary~~ appropriate precautions were taken after processing to avoid contact of the product with any source of CSFV.

EU comment

Also in point 2 above, the word "contact" should be replaced by "cross-contamination" (see comment above).

~~Article 15.2.17.~~

~~**Recommendations for the importation of pig products not derived from fresh meat intended for use in animal feeding**~~

~~*Veterinary Authorities* of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:~~

~~1) originated from domestic and *captive wild* pigs in a CSF free country, *zone* or *compartment* and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; or~~

~~2) have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSFV in accordance with Article 15.2.22., and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSFV.~~

~~Article 15.2.18.~~

~~**Recommendations for the importation of pig products not derived from fresh meat intended for agricultural or industrial use**~~

~~*Veterinary Authorities* of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:~~

~~1) originated from domestic and captive wild pigs in a CSF free country, *zone* or *compartment* and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; or~~

~~2) have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSFV, and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSFV.~~

Article 15.2.19.

Recommendations for the importation of bristles

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the bristles ~~products~~:

1) originated from domestic ~~and~~ or *captive wild* pigs in a ~~CSF free~~ country, *zone* or *compartment* free from CSF and ~~have been~~ were ~~prepared~~ processed in a ~~processing establishment~~ facility approved by the *Veterinary Authority* for export purposes; or

2) ~~have been~~ were processed in accordance with one of the processes in Article 15.2.25bis. in ~~an establishment~~ a facility approved by the *Veterinary Authority* for export purposes ~~so as to ensure the destruction of the CSFV~~, and that ~~the necessary~~ appropriate precautions were taken after processing to avoid contact of the product with any source of CSFV.

EU comment

Again, the word "contact" should be replaced by "cross-contamination" in point 2 above (see comment above).

Article 15.2.20.

Recommendations for the importation of litter and manure from pigs

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the litter or manure ~~products~~:

1) originated from domestic ~~and~~ or *captive wild* pigs in a ~~CSF free~~ country, *zone* or *compartment* free from CSF and ~~have been prepared~~ were processed in a ~~processing establishment~~ facility approved by the *Veterinary Authority* for export purposes; or

2) ~~have been~~ were processed in accordance with one of the procedures in Article 15.2.25ter. in ~~an establishment~~ a facility approved by the *Veterinary Authority* for export purposes ~~so as to ensure the destruction of the CSFV~~, and that ~~the necessary~~ appropriate precautions were taken after processing to avoid contact of the product with any source of CSFV.

EU comment

Also in point 2 above, the word "contact" should be replaced by "cross-contamination" (see comment above).

Article 15.2.21.

Recommendations for the importation of skins and trophies from pigs

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the skins or trophies ~~products~~:

1) originated from domestic ~~and~~ or *captive wild* pigs in a ~~CSF free~~ country, *zone* or *compartment* free from CSF and ~~have been prepared~~ were processed in a ~~processing establishment~~ facility approved by the *Veterinary Authority* for export purposes; or

2) ~~have been~~ were processed in accordance with one of the procedures in Article 15.2.25. in ~~an establishment~~ a facility approved by the *Veterinary Authority* for export purposes ~~so as to ensure the destruction of the CSFV in conformity with one of the procedures referred to in Article 15.2.25.,~~ and that ~~the necessary~~ appropriate precautions were taken after processing to avoid contact of the product with any source of CSFV.

EU comment

Again, the word "contact" should be replaced by "cross-contamination" in point 2 above (see comment above).

Article 15.2.21bis.

Recommendations for the importation of other pig products

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:

1) originated from domestic or *captive wild* pigs in a country, *zone* or *compartment* free from CSF and were processed in a facility approved by the *Veterinary Authority* for export purposes; or

2) were processed in a manner to ensure the destruction of CSFV in a facility approved by the *Veterinary Authority* for export purposes, and that appropriate precautions were taken after processing to avoid contact of the product with any source of CSFV.

EU comment

Also in point 2 above, the word "contact" should be replaced by "cross-contamination" (see comment above).

Article 15.2.22.

Procedures for the inactivation of ~~the classical swine fever virus~~ CSFV in swill

For the inactivation of CSFV in swill, one of the following procedures should be used:

1) the swill ~~should be~~ is maintained at a temperature of at least 90°C for at least 60 minutes, with continuous stirring; or

2) the swill ~~should be~~ is maintained at a temperature of at least 121°C for at least 10 minutes at an absolute pressure of 3 bar~~.~~, or

3) the swill is subjected to an equivalent treatment that has been demonstrated to inactivate CSFV.

Article 15.2.23.

Procedures for the inactivation of ~~the classical swine fever virus~~ CSFV in meat

For the inactivation of CSFV in *meat*, one of the following procedures should be used:

1. Heat treatment

Meat should be subjected to one of the following treatments:

a) heat treatment in a hermetically sealed container with a Fo value of 3.00 or more;

b) heat treatment for at least 30 minutes at a minimum temperature of 70°C, which should be reached throughout the *meat*.

2. Natural fermentation and maturation

The *meat* should be subjected to a treatment consisting of natural fermentation and maturation having the following characteristics:

EU comment

The EU suggests replacing the word "having" by the words "resulting in", wich seems to be the better term in the sentence above.

a) an ~~Aw~~ a_w value of not more than 0.93, or

b) a pH value of not more than 6.0.

~~Hams should be subjected to a natural fermentation and maturation process for at least 190 days and loins for 140 days.~~

3. Dry cured ~~pork~~ pig meat

~~a) Italian style hams with bone in should be cured with salt and dried for a minimum of 313 days.~~

~~b) Spanish style pork *meat* with bone in should be cured with salt and dried for a minimum of 252 days for Iberian hams, 140 days for Iberian shoulders, 126 days for Iberian loin, and 140 days for Serrano hams.~~

Meat should be cured with salt and dried for a minimum of six months.

EU comment

The EU requests the scientific rationale for the changes proposed in points 2 and 3 above, which for some of the products lead to a quite significant reduction or prolongation of the curing time.

Article 15.2.24.

Procedures for the inactivation of ~~the classical swine fever virus~~ CSFV in casings of pigs

For the inactivation of CSFV in casings of pigs, the following procedures should be used: ~~salting~~ treating for at least 30 days either with phosphate supplemented dry salt or saturated brine (~~Aw~~ a_w< 0.80) containing 86.5% NaCl, 10.7% $Na2_2HPO4_4$ and 2.8% $Na3_3PO4_4$ (weight/weight/weight)~~, and kept~~ at a temperature of ~~greater than~~ 20°C or above during this entire period.

Article 15.2.25.

Procedures for the inactivation of ~~the classical swine fever virus~~ CSFV in skins and trophies

For the inactivation of CSFV in skins and trophies, one of the following procedures should be used:

1) boiling in water for an appropriate time so as to ensure that any matter other than bone, tusks or teeth is removed;

2) gamma irradiation at a dose of at least 20 kiloGray at room temperature (20°C or higher);

3) soaking, with agitation, in a 4 ~~percent~~ % (w/v) solution of washing soda (sodium carbonate [Na_2CO_3]) maintained at pH 11.5 or above for at least 48 hours;

4) soaking, with agitation, in a formic acid solution (100 kg salt [NaCl] and 12 kg formic acid per 1,000 litres water) maintained ~~at~~ below pH 3.0 for at least 48 hours; wetting and dressing agents may be added;

5) in the case of raw hides, salting for at least 28 days with sea salt containing 2 ~~percent~~ % washing soda (sodium carbonate [Na_2CO_3]).

Article 15.2.25bis.

Procedures for the inactivation of CSFV in bristles

For the inactivation of CSFV in bristles for industrial use, they should be boiled for at least 30 minutes.

Article 15.2.25ter.

Procedures for the inactivation of CSFV in litter and manure from pigs

For the inactivation of CSFV in litter and manure from pigs, one of the following procedures should be used:

1) moist heat treatment for at least one hour at a minimum temperature of 55°C; or

2) moist heat treatment for at least 30 minutes at a minimum temperature of 70°C.

EU comment

The EU notes an inconsistency in the order of commodities in corresponding articles, i.e. Article 15.2.19. deals with bristles, 15.2.20. with litter and manure, and 15.2.21 with skins and trophies, while Article 15.2.25. deals with skins and trophies, 15.2.25bis. with bristles, and 15.2.25ter. with litter and manure. It would be more logic to keep the same order of commodities throughout the chapter, with a preference for skins and trophies – bristles – litter and manure.

Article 15.2.26.

Introduction to surveillance~~: introduction~~

Articles 15.2.26. to 15.2.32. define the principles and provide a guide on the *surveillance* for CSF, complementary to Chapter 1.4., applicable to Member Countries seeking the OIE recognition of CSF status. This may be for the entire country or a *zone*. Guidance is also provided for Member Countries seeking recovery of CSF status for the entire country or for a *zone* following an *outbreak* and for the maintenance of CSF status.

The impact and epidemiology of CSF may vary in different regions of the world. The *surveillance* strategies employed for demonstrating freedom from CSF at an acceptable level of confidence should be adapted to the local situation. For example, the approach should be tailored in order to prove freedom from CSF for a country or *zone* where *wild* and *feral* pigs provide a potential reservoir of *infection*, or where CSF is present in adjacent countries. The method should examine the epidemiology of CSF in the region concerned and adapt to the specific risk factors encountered. This should include provision of scientifically based supporting data. There is, therefore, latitude available to Member Countries to provide a well-reasoned argument to prove that absence of *infection* with CSFV is assured at an acceptable level of confidence.

Surveillance for CSF should be in the form of a continuing programme designed to establish that susceptible populations in a country, *zone* or *compartment* are free from *infection* with CSFV or to detect the introduction of CSFV into a population already defined as free. Consideration should be given to the specific characteristics of CSF epidemiology which include:

– the role of swill feeding, the impact of different production systems and the role of *wild* and feral pigs on *disease* spread;

– the role of semen in transmission of the virus;

– the lack of pathognomonic gross lesions and clinical signs;

– the frequency of clinically inapparent *infections*;

– the occurrence of persistent and chronic *infections*;

– the genotypic, antigenic, and virulence variability exhibited by different strains of CSFV.

Article 15.2.27.

General conditions and methods for surveillance~~: general conditions and methods~~

1) A *surveillance* system in accordance with Chapter 1.4. and under the responsibility of the *Veterinary Authority* should address the following aspects:

   a) formal and ongoing system for detecting and investigating *outbreaks* of *disease* or CSFV *infection* should be in place;

   b) a procedure should be in place for the rapid collection and transport of samples from suspected cases to a laboratory ~~for CSF diagnosis~~;

   c) appropriate laboratory testing capability for CSF diagnosis;

   d~~c~~) a system for recording, managing and analysing diagnostic and *surveillance* data should be in place.

2) The CSF *surveillance* programme should:

   a) include an *early* ~~warning~~ *detection system* throughout the production, marketing and processing chain for reporting suspected cases. Diagnosticians and those with regular contact with pigs should report promptly any suspicion of CSF to the *Veterinary Authority*. The ~~*notification*~~ reporting system under the *Veterinary Authority* should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary paraprofessionals*) by government information programmes. Since many strains of CSFV do not induce pathognomonic gross lesions or clinical signs, cases in which CSF cannot be ruled out should be immediately investigated. Other important *diseases* such as African swine fever should also be considered in any differential diagnosis. As part of the contingency plan, personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in CSF diagnosis, epidemiological evaluation~~,~~ and control;

   b) implement, when relevant, regular and frequent clinical inspections and laboratory testing of high-risk groups (for example, where swill feeding is practised), or those adjacent to a CSF infected country or *zone* (for example, bordering areas where infected *wild* and *feral* pigs are present).

   An effective *surveillance* system will periodically identify suspected cases that require follow-up and investigation to confirm or exclude *infection* with CSFV. The rate at which such suspected cases are likely to occur will differ between epidemiological situations and cannot, therefore, be reliably predicted. Applications for recognition of CSF status should, as a consequence, provide details in accordance with Article 1.6.10. of the occurrence of suspected cases and how they were investigated and dealt with.

   Member Countries should review their *surveillance* strategies whenever an increase in the likelihood of incursion of CSFV is perceived. Such changes include but are not limited to:

EU comment

In the paragraph above, the term "perceived" should be replaced by "identified by risk assessment". Indeed, a risk assessment should be performed, as merely "perceiving a likelihood of incursion" would not be solid enough.

a) an emergence or an increase in the prevalence of CSF in countries or *zones* from which live pigs or products are imported;

b) an increase in the prevalence of CSF in *wild* or *feral* pigs in the country or *zone*;

c) an increase in the prevalence of CSF in adjacent countries or *zones*;

d) an increased entry from, or exposure to, infected *wild* or *feral* pig populations of adjacent countries or *zones*.

Article 15.2.28.

Surveillance strategies

1. Introduction

The population covered by *surveillance* aimed at detecting *disease* and *infection* should include domestic and *wild* pig populations within the country or *zone* to be recognised as free from *infection* with CSFV.

The strategy employed to ~~establish~~ estimate the prevalence or demonstrate the absence of *infection* with CSFV ~~*infection*~~ may be based on clinical investigation or on randomised or targeted ~~clinical investigation or~~ sampling at an acceptable level of statistical confidence. If an increased likelihood of *infection* in particular localities or subpopulations can be identified, targeted sampling may be an appropriate strategy. This may include:

a) swill fed farms;

b) pigs reared outdoors;

c) specific high-risk *wild* and *feral* pig subpopulations and their proximity.

Risk factors may include, among others, temporal and spatial distribution of past *outbreaks*, pig movements and demographics, ~~etc~~ and types of production systems.

Serology in unvaccinated populations is often the most effective and efficient *surveillance* methodology, for reasons of cost, ~~persistence~~ extended duration of antibody levels and the existence of clinically inapparent *infections*. ~~serology in unvaccinated populations is often the most effective and efficient *surveillance* methodology.~~ In some circumstances, such as differential diagnosis of other *diseases*, clinical and virological *surveillance* may also have value.

The *surveillance* strategy chosen should be justified as adequate to detect the presence of *infection* with CSFV in accordance with Chapter 1.4. and the epidemiological situation. Cumulative survey results in combination with the results of routine *surveillance*, over time, will increase the level of confidence in the *surveillance* strategy.

When applying randomised sampling, either at the level of the entire population or withing targeted sub-populations, the design of the sampling strategy should incorporate epidemiologically appropriate design prevalences for the selected populations. The sample size selected for testing should be large enough to detect *infection* if it were to occur at a predefined minimum rate. The choice of design prevalence and confidence level should be justified based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence in particular, needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the approach selected, the sensitivity and specificity of the diagnostic tests should be considered in the survey design, the sample size determination and the interpretation of the results obtained.

The *surveillance* system design should anticipate the occurrence of false positive reactions. This is especially true of the serological diagnosis of CSF because of the recognised cross-reactivity with ruminant pestiviruses, among other factors mentioned in point 4. There needs to be an effective procedure for

following up positives to ultimately determine with a high level of confidence, whether or not they are indicative of *infection* with CSFV. This should involve confirmatory and differential tests for pestiviruses, as well as further investigations concerning the original sampling unit as well as *animals* which may be epidemiologically linked.

2. Clinical surveillance

Clinical *surveillance* continues to be the cornerstone of CSF detection. However, due to the low virulence of some CSFV strains and the spread of *diseases* such as African swine fever, and those associated with porcine circovirus 2 *infection*, clinical *surveillance* should be supplemented, as appropriate, by serological and virological *surveillance*.

Clinical signs and pathological findings are useful for early detection; in particular, any *cases* where clinical signs or lesions suggestive of CSF are accompanied by high morbidity or mortality, these should be investigated without delay. In CSFV *infections* involving low virulence strains, high mortality may only be seen in young *animals* and adults may not present clinical signs.

Wild and *feral* pigs rarely present the opportunity for clinical observation, but should form part of any *surveillance* scheme and should, ideally, be monitored for virus as well as ~~antibody~~ antibodies.

3. Virological surveillance

Virological *surveillance* should be conducted:

a) to monitor at risk populations;

b) to investigate clinically suspected cases;

c) to follow up positive serological results;

d) to investigate increased mortality.

Molecular detection methods can be applied to large-scale screening for the presence of virus. If targeted at high-risk groups, they provide an opportunity for early detection that can considerably reduce the subsequent spread of *disease*. Epidemiological understanding of the pathways of spread of CSFV can be greatly enhanced by molecular analyses of viruses in endemic areas and those involved in *outbreaks* in ~~*disease* free~~ areas previously free from CSF. Therefore, CSFV isolates should be sent to an OIE Reference Laboratory for further characterisation.

4. Serological surveillance

Serological *surveillance* aims at detecting antibodies against CSFV. Positive CSFV antibody test results can have five possible causes:

a) natural *infection* with CSFV;

b) *vaccination* against CSF;

c) maternal antibodies;

d) cross-reactions with other pestiviruses;

e) non-specific reactors.

The *infection* of pigs with other pestiviruses may complicate a *surveillance* strategy based on serology. Antibodies to bovine viral diarrhoea viruses (BVDV) and Border disease virus (BDV) can give positive results in serological tests for CSF, due to common antigens. Such samples will require differential tests to confirm their identity. One route by which ruminant pestiviruses can infect pigs is the use of vaccines contaminated with BVDV.

CSFV may lead to persistently infected, seronegative young animals, which continuously shed virus. CSFV *infection* may also lead to chronically infected pigs which may have undetectable or fluctuating antibody levels. Even though serological methods will not detect these animals, such animals are likely to be ~~in~~ a minority in a *herd* and would not confound a diagnosis based on serology as part of a *herd* investigation.

It may be possible to use for CSF *surveillance* sera collected for other survey purposes ~~for CSF *surveillance*~~. However, the principles of survey design and ~~the requirement for~~ statistical validity should not be compromised.

In countries or *zones* where *vaccination* has been recently discontinued, targeted serosurveillance of young unvaccinated animals can indicate the presence of *infection*. Maternal antibodies are usually found up to 8-10 weeks of age but may be occasionally last up to four and a half months and can interfere with the interpretation of serological results.

Marker vaccines and accompanying DIVA tests which fulfil the requirements of the *Terrestrial Manual* may allow discrimination between vaccinal antibody and that induced by natural *infection*. The serosurveillance results using DIVA techniques may be interpreted either at animal or *herd* level.

~~Member Countries should review their *surveillance* strategies whenever an increase in the *risk* of incursion of CSFV is perceived. Such changes include but are not limited to:~~

~~*a)* an emergence or an increase in the prevalence of CSF in countries or *zones* from which live pigs or products are imported;~~

~~*b)* an increase in the prevalence of CSF in wild or feral pigs in the country or *zone*;~~

~~*c)* an increase in the prevalence of CSF in adjacent countries or *zones*;~~

~~*d)* an increased entry from, or exposure to, infected wild or feral pig populations of adjacent countries or *zones*.~~

Article 15.2.29.

Additional surveillance ~~procedures~~ for Member Countries applying for OIE recognition of ~~classical swine fever~~ CSF free status

The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances in and around the country or *zone* and should be planned and implemented according to the conditions for status recognition described in Article 15.2.2. and 15.2.3. and methods described elsewhere in this chapter. The objective is to demonstrate the absence of *infection* with CSFV in domestic and *captive wild* pigs during the last 12 months and to assess the *infection* status in *wild* and *feral* pig populations as described in Article 15.2.31.

Article 15.2.30.

Additional surveillance ~~procedures~~ for recovery of free status

In addition to the general conditions described in this chapter, a Member Country seeking recovery of country or *zone* CSF free status, including a *containment zone*, should show evidence of an active *surveillance* programme to demonstrate absence of *infection* with CSFV.

Populations under this *surveillance* programme should include:

1) *establishments* in the proximity of the *outbreaks*;

2) *establishments* epidemiologically linked to the *outbreaks*;

3) animals moved from or used to repopulate affected *establishments*;

4) any *establishments* where contiguous culling has been carried out;

5) *wild* and *feral* pig populations in the area of the *outbreaks*.

The domestic and *captive wild* pig populations should undergo regular clinical, pathological, virological and serological examinations, planned and implemented according to the general conditions and methods described in these recommendations. Epidemiological evidence of the *infection* status in *wild* and *feral* pigs should be compiled. To regain CSF free status, the *surveillance* approach should provide at least the same level of confidence as within the original application for recognition of freedom.

Article 15.2.31.

Surveillance for ~~classical swine fever virus~~ CSFV in wild and feral pigs

1) The objective of a *surveillance* programme is either to demonstrate that CSFV *infection* is not present in *wild* and *feral* pigs or, if known to be present, to estimate the distribution and prevalence of the *infection*. While the same principles apply, *surveillance* in *wild* and *feral* pigs presents additional challenges including:

   a) determination of the distribution, size and movement patterns associated with the *wild* and *feral* pig population;

   b) relevance and practicality of assessing the possible presence of CSFV *infection* within the population;

   c) determination of the practicability of establishing a *zone* taking into account the degree of interaction with domestic and *captive wild* pigs within the proposed *zone*.

   The geographic distribution and estimated size of *wild* and *feral* pig populations need to be assessed as a prerequisite for designing a monitoring system. Sources of information to aid in the design of a monitoring system may include governmental and non-governmental *wildlife* organisations such as hunter associations.

2) For implementation of the ~~monitoring~~ *surveillance* programme, ~~it will be necessary to define~~ the limits of the area over which *wild* and *feral* pigs range should be defined~~, in order to delineate the *epidemiological units* within the monitoring programme~~. ~~It is often difficult to define *epidemiological units* for~~ *Subpopulations* of *wild* and *feral* pigs may be separated from each other by natural or ~~. The most practical approach is based on natural and~~ artificial barriers.

3) The ~~monitoring~~ *surveillance* programme should involve serological and virological testing, including ~~animals~~ pigs found dead, road kills, ~~*animals*~~ pigs showing abnormal behaviour or exhibiting gross lesions during dressing.

EU comment

While hunting is mentioned in point 4) below, the EU neverless suggests including it also in point 3 above.

4) There may be situations where a more targeted *surveillance* programme can provide additional assurance. The criteria to define high risk areas for targeted *surveillance* include:

   a) areas with past history of CSF;

   b) subregions with large populations of *wild* and *feral* pigs;

   c) border regions with CSF affected countries or *zones*;

   d) interface between *wild* and *feral* pig populations, and domestic and *captive wild* pig populations;

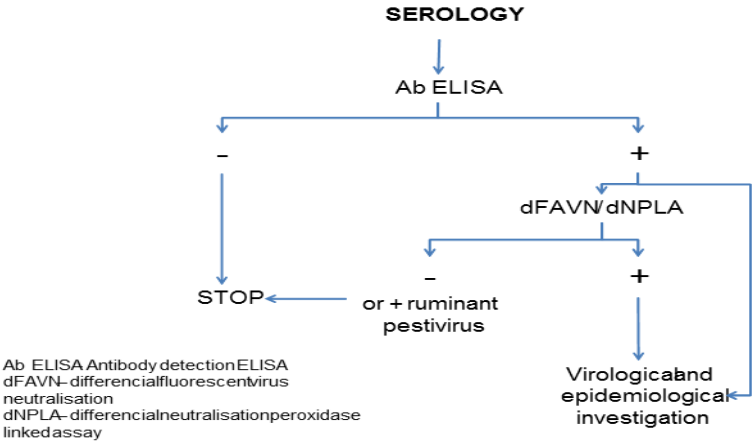
   e) areas with farms with free-ranging and outdoor pigs;

   f) areas with a high level of hunting activity, where animal dispersion and feeding as well as inappropriate disposal of waste can occur;

   g~~f~~) other risk areas determined by the *Veterinary Authority* such as ports, airports, garbage dumps and picnic and camping areas.

Article 15.2.32.

The use and interpretation of diagnostic tests in surveillance



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Annex 36

CHAPTER 7.1.

INTRODUCTION TO THE RECOMMENDATIONS FOR ANIMAL WELFARE

EU comment

The EU thanks the OIE for its work on the definition of animal welfare and Article 7.1.1.

The EU welcomes referring to "state of well-being" instead of "coping", as it does not limit the term "welfare" solely to coping with negative situations. However, the EU proposes the OIE to develop further the currently proposed definition, as explained in the EU comment in the Glossary. Furthermore the EU does have additional comments, as indicated in the text below, which are very relevant to the EU.

Article 7.1.1.

~~Definition~~ General considerations

EU comment

In the above title, the EU would like to retain the term "Definition" and proposing the following amended title which highlights the importance of the elements provided in the proposed called "General considerations".

"Definition and general considerations".

Justification:

The EU understands that the OIE proposes a shorter definition of animal welfare to be included in the Glossary. However, the EU considers that the shortened definition does not include now all the key elements which form part of animal welfare. Furthermore, there is no reference as to what "state of wellbeing" means.

The currently adopted definition of animal welfare (that appears in the Glossary and Article 7.1.1) is a core element of the OIE's contribution to animal welfare as it is comprehensive in setting out both the negative factors that must be avoided and the positive factors that should be provided.

The EU would therefore like to ensure that any key element contributing to animal welfare and removed from the previous definition, are properly highlighted in Article 7.1.1. as "General considerations" representing an important complementary part of the new animal welfare definition currently under revision by OIE.

Furthermore, as to ensure clarity of key elements of the definition, it would be beneficial to include a clarification of what "state of wellbeing" means, as to ensure a full understanding of the animal welfare's definition.

Scientific references supporting the justification:

The original definition is in accord with developing scientific thinking as to what is entailed in animal welfare. Mellor (2016) stresses it is necessary not only to minimise negative experiences but also "to provide the animals with opportunities to have positive experiences".

Mellor DJ, 2016. Updating Animal Welfare Thinking: Moving beyond the "Five Freedoms" towards "A Life Worth Living". Animals 2016, 6(3), 21; http://www.mdpi.com/2076-2615/6/3/21

Farm Animal Welfare Committee. Farm animal welfare in Great Britain: past, present and future.
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/319292/Farm_Animal_Welfare_in_Great_Britain_-_Past__Present_and_Future.pdf

Animal welfare means the state of well-being of ~~how~~ an animal ~~is coping with~~ in relation to the conditions in which it lives.

An animal is in a good state of welfare if (as indicated by scientific evidence) it is healthy, comfortable, well nourished, safe, it is not suffering from unpleasant states such as pain, fear and distress and it is able to express ~~innate~~ behaviours that are important for its well-being~~, and if it is not suffering from unpleasant states such as pain, fear, and distress~~.

Good animal welfare requires disease prevention and appropriate veterinary treatment, shelter, management and nutrition, humane handling and humane slaughter or killing. Animal welfare refers to the state of the animal; the treatment that an animal receives is covered by other terms such as animal care, animal husbandry, and humane treatment.

[…]

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— Text deleted.

EU COMMENTS ON PART E - ANNEX 51 – OF THE OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION FEBRUARY 2017 MEETING REPORT ("*EDITORIAL MODIFICATIONS THAT WILL BE INTRODUCED INTO THE 2017 EDITION OF THE TERRESTRIAL CODE*")

EU comment

The EU agrees in principle with the procedure for modification of the Code proposed under Items 4.1. and 7.4. of the TAHSC February 2017 meeting report.

We also appreciate the circulation of an Annex 51 as Part E of the said report, prepared by the OIE Headquarters, bringing to the attention of member countries the editorial modifications which the OIE intends to introduce in the 2017 edition of the Code.

While commending the OIE Headquarters for this important and extensive work, and acknowledging that those modifications indeed are, for the most part, purely editorial, we would nevertheless like to provide some comments to the OIE, as some of the changes proposed would lead to occasional odd wording and to some inconsistencies.

Furthermore, we note that some of the changes proposed in the document are not listed on the first page (i.e. on p. 521); go beyond the conventions described therein (see below for further details); or change the substance of the provisions and are thus not purely editorial.

Therefore, the EU requests that such changes in future be circulated for member country comments before being applied to a new edition of the Code.

Detailed comments are provided below.

p. 522 - User's guide, Section C *Specific Issues*, point 4:
The suggested change, while being in line with the convention described on p. 521 for replacing "pathogen" with "pathogenic agent", overall leads to a very odd wording ("[...] for the non-listed food-borne pathogenic agent ~~pathogen~~ *Salmonella* in poultry."). Indeed, "foodborne pathogen" is a commonly used term. We would therefore suggest not making this specific change.
Furthermore, we suggest replacing "food-borne" with "foodborne" (reference is made to Item 5.5. of the TAHSC report).

p. 523 - Glossary, definition of "Stamping-out policy":
The word "pathogen" after "pathogenic agent" should be stroked through (editorial).

p. 532 – Article 4.8.6., Point 1. c):
The proposed changes are not purely editorial; the EU therefore does not agree to those changes ("the ~~pathogenic~~ characteristics of the specified ~~disease~~ pathogenic agents listed in point 2 of Article 4.8.4.;)".

EU COMMENTS
On Part E - Annex 51 – of the OIE TAHSC February 2017 meeting report

p. 533 – Article 4.9.1., Introduction:
We note that in line 2, the order has not been amended as per the convention described on p. 521, i.e. oocytes should come before embryos.

p. 534 – Article 4.9.3., Point 2:
Again, in line 2 (text between brackets), the order has not been amended as per the convention described on p. 521, i.e. oocytes should come before embryos.

p. 535 – Article 4.10.1.:
For correct grammar, the term "pathogenic agent" should be in plural, for the sentence to read as follows:
"[...] where known ('specific') pathogenic agent**s** ~~pathogen~~ as well as non-pathogenic micro-organisms may exist.".

p. 537 – Article 4.12.4., Point 11:
The EU does not agree with replacing the term "disease" with "pathogenic agent". Indeed, this goes beyond the convention described on p. 521, i.e. to replace "pathogen" and the like with "pathogenic agent". Furthermore, this is not a purely editorial change.

p. 540 – Article 5.8.2., Point 1:
Again, applying the convention here leads to a odd wording ("The consequences of the introduction into a country of an infectious disease or an animal ~~pathogen~~ pathogenic agent or new strain of animal ~~pathogen~~ pathogenic agent from which it is currently free, are potentially very serious."). Instead of "(new strain of) animal pathogenic agent", the EU suggests "(new strain of) a pathogenic agent of an animal".

p. 540 – Article 5.8.2., Point 2:
We note that in line one, "animal pathogens" has been replaced with "pathogenic agents". Again, this is beyond just an editorial change, as the meaning is changed, i.e. the notion of "animal" is lost. This is an important adjective, as it narrows the scope (animal pathogens only, as opposed to any pathogenic agent which may include human pathogens). Note that by contrast, the word "animal" is not deleted from the title of Article 5.8.4. further down on the same page (see also comment below).

p. 540 – Article 5.8.4., Title and Point 1:
As already noted above, the EU would suggest replacing "animal pathogenic agents" with "pathogenic agents of animals", as this would read better (both in the title and in point 1 of this article).

p. 541 – Article 5.8.5., Title:
For better readability, the EU suggests amending the title ("Laboratory containment of pathogenic agents animal pathogens") to read as follows:
"Laboratory containment of pathogenic agents **of** animal**s** ~~pathogens~~ ".

EU COMMENTS
On Part E - Annex 51 – of the OIE TAHSC February 2017 meeting report

p. 541 – Article 5.8.5., Point 1 and Point 2:
As noted above, the EU does not agree with the proposed replacing of "animal pathogens" with "pathogenic agents" (both in points 1 and 2 of this article), as the scope and thus the meaning of the provision is changed. It is therefore not to be considered a purely editorial change.

p. 542 – Article 5.9.1.:
While in principle not opposed to this proposed change ("~~The present~~ This chapter defines" [...]), the EU notes that this change is not mentioned on the list of editorial changes on p. 521.

p. 544 – Article 6.7.3., Point 6. a):
Again, the proposed change alters the meaning, as the scope is broadened by the deletion of the term "bacterial". Furthermore, the new wording "Animal (bacterial) pathogenic agents" (in lines 1, 2 and 3) is odd. We would prefer the following: "(Bacterial) pathogenic agents of animals". Note that the term "bacterial" is not deleted e.g. from Point 5 of Article 6.10.2.

p. 544 – Article 6.7.3., Point 6. b) iii):
As explained in the comment above, deletion of the word "bacterial" changes the meaning and scope of the provision, is thus not purely editorial, and therefore not acceptable for the EU.

p. 546 – Article 6.10.2., Point 3:
Similar as explained above, the EU suggests replacing "human pathogenic agents" with "pathogenic agents of humans".

p. 551 – Article 8.4.12., Point 1. e):
The EU does not agree with the deletion of the words "or flocks" (in both lines 1 and 3). Indeed, this is not in line with the convention described on p. 521, that says that "herd/flock" is to be replaced with "herd or flock", and is thus inconsistent with changes proposed e.g. for Article 8.3.16. Furthermore, this would change the substance of the provision and is thus not acceptable as part of a "purely editorial" exercise.
Furthermore, we note that both "flock" and "herd" are separately defined terms in the glossary, however the definition is essentially the same. Perhaps this should be addressed as part of the ongoing revision of the glossary.

p. 555 – Article 14.4.3.:
The EU does not agree with any of the changes proposed to this article, as they do not conform to the convention described on p. 521 and are not of a purely editorial nature. We request that these changes be discussed more thoroughly as part of a possible future revision of the whole chapter.

p. 555 – Article 14.7.19., Point 1. a):
For the same reasons as explained in the comment above, the EU does not agree with the deletion of the words "herds or".

EU COMMENTS ON PART B - ITEM 5.7A) – OF THE OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION FEBRUARY 2017 MEETING REPORT ("*DEFINITIONS ('THERAPEUTIC USE', 'PREVENTIVE USE', 'GROWTH PROMOTION') AS PROPOSED BY THE AD HOC GROUP ON AMR*")

EU comment

The EU agrees that monitoring of use of antimicrobial agents in food-producing animals should cover all types of use, and that preventive use should be defined in the global context. However, taking into account also that the OIE Terrestrial Code Chapter 6.8. *Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals* is primarily intended for data collection purposes, the EU is of the opinion that:

- the need to collect data on all types of use of antimicrobial agents - including on preventive use - could be reflected in the text of Chapter 6.8. without amending the definition of therapeutic use. Indeed, explicit reference to preventive use could be added in the last sentence of Article 6.8.1. ("*In order to evaluate antimicrobial exposure in food-producing animals, quantitative information should be collected to monitor usage patterns by animal species, antimicrobial agents or class, type of use (therapeutic, preventive or non-therapeutic) and route of administration.*").

- as the Codex *Code of Practice to Minimise and Contain Antimicrobial Resistance* (CAC/RCP 61-2005) including the definitions of therapeutic / preventive / growth promotion use is foreseen to undergo a revision very soon, defining the preventive use and growth promotion in Chapter 6.8. as proposed by the OIE *ad hoc* group would not be appropriate at this stage.