EUROPEAN UNION

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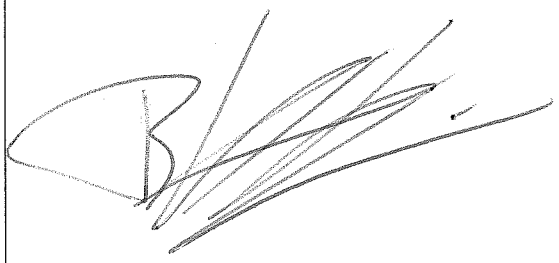
Subject: **EU comments on the OIE Terrestrial Code**

Dear Director General,

Please find enclosed the comments of the European Union on Annexes 23 to 29, 32 and 35 to 38 of the report of the February 2016 meeting of the Terrestrial Animal Health Standards Commission, for consideration at its next meeting in September 2016.

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

Yours sincerely,

Jozef Bíreš CVO and OIE Delegate Slovakia	Bernard Van Goethem Director for Crisis management in food, animals and plants, European Commission, DG Health and Food Safety
	

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 23

GLOSSARY

EU comment

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

CONTAINMENT ZONE

means an *infected* ~~defined~~ *zone* ~~around and~~ in a previously free country or *zone*, in which are included ~~including~~ all *epidemiological units* suspected or confirmed to be infected ~~*establishments*, taking into account the epidemiological factors and results of investigations,~~ and where control, *biosecurity* and *sanitary measures* have been applied to prevent the spread of the *infection* ~~are applied~~.

EU comment

For linguistic reasons, the EU suggests moving the words "are included" after the words "to be infected".

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 the requirements specified in 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, if not otherwise defined in the specific-disease chapter of the *Terrestrial Code*, a *zone* in which a *disease*, *infection* or *infestation* has been diagnosed.

EU comment

For linguistic reasons, the EU suggests replacing the words "specific-disease chapter" by the words "disease-specific chapters".

OIE STANDARD

means a text that has been formally adopted by the OIE World Assembly of Delegates, published by the OIE~~,~~ in the *Codes* and *Manuals*, ~~and that describes requirements, recommendations, criteria, specifications and characteristics that should be used consistently~~ intended to ensure the maintenance or improvement of animal health, veterinary public health and or animal welfare worldwide.

EU comment

For clarity reasons and for consistency with the proposed definition of "OIE Guideline", the EU suggests inserting the words "and that is" before the words "intended to ensure".

Furthermore, the word "and" before the words "or animal welfare" should be deleted for consistency with the draft definition of OIE Guideline (editorial).

Moreover, the EU insists that the same definition of OIE Standard and OIE Guideline must be included in both the Terrestrial and Aquatic Codes, i.e. the wording in both OIE Codes has to be identical.

Finally, the EU would be open to accept certain Resolutions adopted by the World Assembly in application of the OIE Codes to be considered as OIE Standards, e.g. the

ones recognising the official disease status of member countries and zones, or the ones amending the Codes and Manuals.

As the inclusion of certain Resolutions in the definition of OIE Standards however would go beyond the scope of the OIE Codes, it could be debated on whether the definition of OIE Standard and OIE Guideline should be included in the glossary of the Codes, or if such definitions would not be better placed in the basic texts of the OIE.

For the time being however a narrower definition is acceptable for the EU, which could be included in the OIE Codes.

In this context, the EU is of the opinion that a fundamental debate is necessary on the status of Resolutions adopted in application of the Codes and of other Resolutions adopted by the World Assembly (e.g. the ones on Technical Items presented at General Sessions), both within the OIE and at the level of the World Assembly of Delegates.

OIE GUIDELINE

means a text ~~an OIE publication that provides advice to improve animal health, veterinary public health and animal welfare worldwide and~~ that has been endorsed by an OIE Specialist Commission or the OIE Council~~,~~ but ~~has~~ not ~~been formally~~ adopted by the OIE World Assembly of Delegates, and that provides advice intended to maintain or improve animal health, veterinary public health or animal welfare worldwide.

EU comment

With reference to the proposed deletion of the words "an OIE publication" in the above definition, the EU is of the opinion that OIE Guidelines should in any event continue to be published, either as a specific OIE publication or on the OIE website. This should be reflected in the definition.

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~~ that may include, but are not limited to, *vaccination*, movement control and ~~an~~ intensified ~~degree of~~ *surveillance*.

EU comment

The EU suggests putting also the word "measures" in italics in the definition above, as the term "sanitary measure" is defined in glossary.

ZONE/~~REGION~~

means a clearly defined part ~~of a territory~~ of a country containing an animal *population* or *subpopulation* with a distinct health status with respect to a 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 24

CHAPTER 1.4.

ANIMAL HEALTH SURVEILLANCE

[Article 1.4.1.]

[Article 1.4.2.]

[Article 1.4.3.]

[Article 1.4.4.]

[Article 1.4.5.]

EU comment

The EU in general supports the proposed changes to this article. Comments are inserted in the text below.

Article 1.4.6.

Surveillance to demonstrate freedom from a disease, ~~or~~ infection or infestation

1. Requirements to declare a country or a zone free from disease or infection ~~without pathogen-specific surveillance~~

This article provides general principles for declaring a country or a *zone* free from a *disease*, ~~or~~ *infection* or *infestation* in relation to the time of last occurrence and in particular for the recognition of historical freedom.

The provisions of this article are based on Article 1.4.3. and the following premises:

– in the absence of *disease* and *vaccination*, the animal population would become susceptible over a period of time;

– the disease agents to which these provisions apply are likely to produce identifiable clinical signs in susceptible *animals*;

– competent and effective *Veterinary Services* will be able to investigate, diagnose and report *disease*, if present;

– *the disease*, ~~or~~ *infection* or *infestation* can affect both domestic *animals* and *wildlife*;

– the absence of the *disease*, ~~or~~ *infection* or *infestation* over a long period of time in a susceptible population can be substantiated by effective disease investigation and reporting by a Member Country.

a) Historical~~ly~~ freedom

Unless otherwise specified in the relevant *disease*-specific chapter, a country or *zone* may be recognised as free ~~from *infection*~~ without formally applying a pathogen-specific *surveillance* programme when:

i) there has never been occurrence of *disease*, or

EU comment

The EU suggests inserting the words "or infestation" after the word "disease" in point i) above, as well as in point ii) below where relevant.

ii) eradication has been achieved or the *disease* ~~or *infection*~~ has ceased to occur for at least 25 years, provided that for at least the past 10 years:

~~iii)~~ the *disease* has been a *notifiable disease*;

~~iv)~~ an early detection system has been in place for all relevant species;

~~v)~~ measures to prevent the introduction of the *disease* ~~or *infection*~~ ~~introduction~~ have been in place; no *vaccination* against the *disease* has been carried out unless otherwise provided for in the *Terrestrial Code*;

~~vi)~~ the *infection* or *infestation* is not known to be established in *wildlife* within the country or *zone*. A country or *zone* cannot apply for historical freedom if there is any evidence of *infection* or *infestation* in *wildlife*.

b) Last occurrence within the previous 25 years

Countries or *zones* that have achieved eradication (or in which the *disease* or *infection* has ceased to occur) within the previous 25 years, should follow the pathogen-specific *surveillance* requirements in the *Terrestrial Code* if they exist. In the absence of specific requirements, countries should follow the general recommendations on *surveillance* outlined in this chapter provided that for at least the past 10 years:

i) the *disease* has been a *notifiable disease*;

ii) an early detection system has been in place;

iii) measures to prevent the introduction of the *disease* ~~or *infection*~~ ~~introduction~~ have been in place;

EU comment

The EU suggests inserting the words "or infestation" after the word "disease" in point iii) above.

iv) no *vaccination* against the *disease* has been carried out unless otherwise provided for in the *Terrestrial Code*;

v) the *infection* or *infestation* is not known to be established in *wildlife* within the country or *zone*. A country or *zone* cannot apply for recognition of freedom if there is any evidence of *infection* or *infestation* in *wildlife*.

EU comment

Taking into account the draft revised ASF chapter and in order to avoid any possible confusion or inconsistency, the EU suggests adding the following at the end of point v) above:

"[...] in wildlife, unless otherwise specified in the relevant disease specific chapter.".

2. Recommendations for the discontinuation of pathogen-specific screening after recognition of freedom from infection or infestation

A country~~,~~ or *zone* ~~or *compartment*~~ that has been recognised as free ~~from *infection*~~ following the provisions of the *Terrestrial Code* may discontinue pathogen-specific screening while maintaining the ~~infection-~~free status provided that:

a) the *disease* is a *notifiable disease*;

b) an *early detection system* is in place;

c) the measures to prevent the introduction of the *disease* or *infection* are in place;

d) *vaccination* against the *disease* is not applied;

e) the *infection* or *infestation* is known not to be established in *wildlife*. It can be difficult to collect sufficient epidemiological data to prove absence of *disease*, ~~or~~ *infection or infestation* in *wild animal* populations. In such circumstances, a range of supporting evidence should be used to make this assessment.

3. Self-declaration of freedom ~~from disease or infection~~

A Member Country may make a self-declaration in accordance with Chapter 1.6. that its entire territory, a *zone* or a *compartment* is free from a *listed disease*, *infection* or *infestation*, based on the implementation of the provisions of the *Terrestrial Code* and the *Terrestrial Manual*. When ~~The~~ the *Veterinary Authority* ~~may wish to~~ transmits this information to ~~OIE~~ the *Headquarters* in accordance with Article 1.1.5., ~~which~~ the *Headquarters* may publish the information.

EU comment

To avoid misunderstandings, the EU suggests adding a sentence to the paragraph above, stating that self-declarations for diseases for which there is a procedure for official country status recognition by the OIE will not be published by the OIE, in line with the first paragraph of Article 1.6.1., as follows:

"The OIE does not publish self declaration for diseases for which there is a procedure for official country status recognition by the OIE".

4. International recognition of ~~disease or infection~~ free status

For *diseases* for which procedures exist whereby the OIE can officially recognise the existence of a *disease* or *infection* free country or *zone*, a Member Country wishing to apply for recognition of this status should, via its Permanent Delegate, send to the OIE all the relevant documentation relating to the country or *zone* concerned. Such documentation should be presented in accordance with the recommendations prescribed by the OIE for the appropriate animal *diseases*.

5. Demonstration of freedom ~~from infection~~

A *surveillance* system to demonstrate freedom from *disease*, *infection* or *infestation* should meet the following requirements in addition to the general requirements outlined in Article 1.4.3.

Freedom ~~from *infection*~~ implies the absence of the pathogenic agent in the country, *zone* or *compartment*. Scientific methods cannot provide absolute certainty of ~~the~~ this absence ~~of *infection*~~. Therefore, demonstrating freedom ~~from *infection*~~ involves providing sufficient evidence to demonstrate (to a level of confidence acceptable to Member Countries) that *infection* or *infestation* with a specified pathogen, if present, is present in less than a specified proportion of the population.

However, finding evidence of *infection* or *infestation* at any prevalence in the target population automatically invalidates any freedom ~~from *infection*~~ claim unless otherwise stated in the relevant *disease*-specific chapter. The implications for the status of domestic *animals* of *disease*, ~~or~~ *infection* or *infestation* present in *wildlife* in the same country or *zone* should be assessed in each situation, as indicated in the relevant *disease*-specific chapter ~~on each *disease*~~ in the *Terrestrial Code*.

Evidence from targeted, random or non-random data sources, as stated before, may increase the level of confidence or be able to detect a lower level of prevalence with the same level of confidence compared to structured surveys.

[Article 1.4.7.]

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— Text deleted.

Annex 25

CHAPTER 4.3.

ZONING AND COMPARTMENTALISATION

EU comment

The EU 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.~~

EU comment

The EU does not support the deletion of the sentence above, as the term "regionalisation" is used in many countries as a synonym to "zoning", including in the EU, and also in the WTO SPS agreement. Therefore, such a clarification seems important somewhere in the Code. As an alternative, this sentence could for example be included in Chapter 5.3.

Establishing and maintaining a *disease* free status throughout the country should be the final goal for Member Countries. However, given the difficulty 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 health status within its territory for the purpose of *disease* control or *international trade*. *Subpopulations* may be separated by natural or artificial geographical barriers or~~, in certain situations,~~ by the application of appropriate management practices.

EU comment

The EU suggests deleting the words "especially for diseases, the entry of which is difficult to control through measures at national boundaries" from the paragraph above. Indeed, that part of the sentence does not seem to add anything meaningful and makes the already very long sentence more difficult to read.

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

EU comment

It should be clarified more explicitly in the context of the above general description of zoning that enforcement of measures to regulate the movement of animals and animal products between different zones within a country is necessary to effectively separate the subpopulations and to maintain their status, in line with what is described in more detail in Article 4.3.3.

~~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* in endemic, establishment of *free zones* may assist in the progressive control and eradication of the *disease*. Following a *disease outbreak* in a previously free country, 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~~ 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.

EU comment

In the paragraph above, the words "disease in endemic" should be replaced by the words "disease is endemic" (typographical mistake).

Furthermore, the EU suggests inserting the words "<u>or zone</u>" after "Following a disease outbreak in a previously free country", as the principle of zoning for disease control and trade purposes should apply equally to already defined zones within a country. Consequently, the words "<u>of the country or zone</u>" should be added at the end of that sentence.

For reasons of clarity, the EU suggests inserting the words "<u>for a given disease</u>" after the words "zone or compartment" at the end of the paragraph above.

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

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

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

EU comment

The second sentence of the paragraph above can be understood as excluding the use of zoning and compartmentalisation for diseases for which there are no relevant provisions in the disease specific chapter. The EU disagrees with such a principle. Indeed, zoning for example can be applied to the majority of listed diseases, and the fact that the disease specific chapter of the Code does not (yet) include specific provisions on zoning should not preclude member countries from applying that concept. However the EU agrees that

the principles described in this chapter should be applied in accordance with the specific provisions of the disease specific chapter, where they exist, and encourages the Code Commission to gradually introduce such detailed provisions for relevant disease specific chapters where they do not yet exist whenever these are reviewed in the future, including as regards the use of containment zones. The foot-and-mouth disease chapter should be used as example for such detailed provisions, as it is probably the most advanced in this regard.

Furthermore, given several recent trade problems linked to this issue, the EU strongly suggests clarifying in the introduction that the optional disease control zones specifically described in this chapter (i.e. protection and containment zones, Articles 4.3.6. and 4.3.7.) are examples only which may or may not be used, and that OIE member countries may also use different concepts of zoning, in line with the principles of this chapter, in order to accommodate their specific situations (e.g. regionalisation with protection, surveillance and further restricted zones as provided for in EU legislation to eradicate diseases while upholding the functioning of the single market). Indeed, it should be made very clear that in no case the use of containment zones should be a precondition for applying the concept of zoning at all.

Article 4.3.2.

General considerations

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

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

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

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

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

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

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

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

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

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

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

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

Article 4.3.3.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

~~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.~~

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

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

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

~~7~~5) For a *compartment*, the *biosecurity plan* should describe the partnership between the relevant industry and the *Veterinary Authority*, and their respective responsibilities. It should also describe the routine 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 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.

Article 4.3.4.

Free zone

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

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

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

So long as an ongoing *surveillance* demonstrates there is no occurrence of the specific *disease*, *infection* or *infestation*, the *zone* keeps its free status.

EU comment

In the paragraph above, the EU suggests replacing the words "So long as" by the words "As long as" (style).

Furthermore, in order to avoid any possible confusion, the EU suggests clarifying in the above paragraph that specific provisions apply to diseases for which there is an official OIE country or zone status.

Article 4.3.5.

Infected zone

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

EU comment

The paragraph above is not drafted in a very clear way and is thus confusing. Indeed, there could be disease specific chapters in the Code in which an article describing the conditions for free and infected status is not (yet) included. Therefore, the EU suggests rewording the paragraph above to remove any ambiguity, as follows:

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

An *infected zone* may be:

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

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

EU comment

The EU suggests inserting the words "introduced or" before the word "reintroduced" in the indent above, to cover situations where the disease is being introduced for the first time.

Furthermore, the wording at the beginning of the sentence is confusing ("a zone of a country or zone previously free"). For clarity reasons, the EU suggests replacing it by the following, even if some of the wording will be repetitive:

"- a zone of a previously free country, or a previously free zone ~~previously free~~, in which […]".

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

Article 4.3.6.

Protection zone

A *protection zone* may be established to preserve the *animal health status* of an *animal population* in a free country or a *free zone* from introduction of a pathogenic agent of a specific *disease*, *infection* or *infestation* from adjacent countries or *zones* of different status. *Biosecurity* and *sanitary measures* should be implemented based on the animal management systems, the epidemiology of the *disease* under consideration and the epidemiological situation prevailing in an adjacent infected country or *zone*.

EU comment

For reasons of consistency and to avoid any possible confusion, the EU suggests also putting "adjacent infected country or zone" at the end of the paragraph above in plural, like in the first sentence.

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

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

EU comment

The EU is of the opinion that point 1 above should not be optional. Indeed, saying that animal identification and traceability may be included in these measures is contrary to the general provisions already described in point 4 of Article 4.3.3., which would apply in aby case. Therefore, the EU suggests moving the content of point 1 above up, as follows:

"These measures should include intensified movement control and surveillance as well as specific animal identification and animal traceability to ensure that animals in the protection zone are clearly distinguishable from other populations, and may include: […]".

Consequently, point 2 below would become the new point 1 etc.

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

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

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

5) enhanced *biosecurity* including *disinfection* procedures for *vehicles*/*vessels*, and possible compulsory routes;

EU comment

In the point above, the EU is of the opinion that it is important to include also other means of transport used for the transportation e.g. of feed which may also carry the pathogen.

Furthermore, for clarity reasons, the EU suggests clarifying for which goods or means of transport possible compulsory routes would be needed.

Finally, the EU notes that the glossary definition of "vehicles/vessels" is too narrow, as it only includes means of transport used to carry live animals. That definition should therefore be reviewed.

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

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

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

EU comment

The EU suggests amending the sentence above as follows:

"The protection zone may be a part of an infected country or zone or of a free country or zone."

Indeed, it should be possible to establish a protection zone within a country not previously divided into zones.

Article 4.3.7.

Containment zone

In the event of limited *outbreaks* in a country or *zone* previously free from a *disease*, a *containment zone* may be established for the purposes of *disease* control or trade.

EU comment

For the sake of consistency, the EU suggests inserting the words ", infection or infestation" after the words "free form a disease" in the sentence above.

Furthermore, in order to avoid confusion and misinterpretation, the EU feels that a more detailed description should be added on when this concept of containment zone can be used, and for what goal. Indeed, a containment zone would typically be used to quickly eradicate a limited disease incursion in order to regain freedom for trade purposes, not only for the non-affected part of the country or zone, but also for the affected part itself. The disease specific chapter should thus contain provisions on the use of containment zones, and on the regaining of disease freedom in the containment zone itself (reference is made to the FMD chapter, which should serve as model).

In addition, it should be clarified that in case of continuing or multiple disease incursions, i.e. when the outbreaks are not limited in number or in time, the concept of containment zone cannot be used, however without precluding the use of other concepts of zoning. These could be used e.g. to prevent the further spread of the disease to other parts of the previously free country or zone, which in turn could regain free status in accordance with the provisions in the disease specific chapter.

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

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

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

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

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

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

6) *sanitary measures*, including on-going *surveillance* in the *containment zone*, consistent with the *disease*-specific chapter, to prevent spread of the *infection* from the *containment zone* to the rest of the country or *zone*.

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

EU comment

The EU suggests adding some flexibility to the above provision, by adding the following at the end of the sentence:

"[…] last detected case, unless otherwise provided for in the disease specific chapter.".

Indeed, as the purpose of containment zones is to serve as a shortcut to re-establish trade from non-affected parts of a country or zone, for some diseases two incubation periods might be excessive in comparison to the time prescribed in the disease specific chapter for regaining freedom (e.g. glanders, with an incubation period of 6 months and 6 months for regaining free status according to the latest draft chapter circulated by the Code Commission; or HPAI, with an incubation period of 21 days and 3 months for regaining free status).

The free status of the areas outside the *containment zone* would be suspended pending demonstration of the effectiveness of the *containment zone*. The free status of these areas may then be reinstated, irrespective of the provisions of the *disease*-specific chapter.

The *containment zone* is an infected zone that should be managed in such a way that *commodities* for *international trade* can be shown to have originated from inside or outside the *containment zone*. Well managed, it may allow the rest of the country or *zone* to keep their free status.

EU comment

The wording of the last sentence of the paragraph above is confusing, and should either be amended or deleted altogether. Indeed, as explained in the preceding paragraph and elsewhere, the rest of the country would not keep but first loose and then regain its free status under certain conditions.

Article 4.3.8.

Bilateral recognition by trading countries

Trading partners should exchange information allowing the recognition of different *subpopulations* within their respective territories. This recognition process is best implemented through establishing parameters and gaining agreement on the necessary measures prior to *outbreaks* of *disease*.

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

EU comment

The EU suggests adding the following at the end of the paragraph above:

"Other types of zones than the optional protection and containment zones described in Articles 4.3.6. and 4.3.7. are possible for the purpose of disease control and trade.".

Indeed, as explained above, disease control zones should not be limited to those specifically described in this chapter, i.e. types of zones other than protection and containment zones should be possible and recognised by trading partners.

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

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

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— Text deleted.

Annex 26

CHAPTER 5.3.

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

EU comment

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

In general, the EU suggests adding a statement in this chapter clarifying that for the purposes of the Terrestrial Code, the terms "zoning" and "regionalisation" have the same meaning. Indeed, this is particularly important as the WTO SPS Agreement uses the term "regionalisation", whereas the OIE Code uses the term "zone", and the OIE suggests deleting such a clarifying statement from Chapter 4.3. (see also EU comment to Annex 25).

Article 5.3.1.

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

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

EU comment

In the third line of the paragraph above, the EU suggests moving the words "more stringent" before the words "sanitary measures" (style). The sentence would thus read as follows:

"Members may choose to implement more stringent sanitary standards than those […]".

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

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

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

Article 5.3.2.

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

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

~~These~~ The recommendations in this chapter are intended to assist Member Countries to determine whether *sanitary measures* arising from different ~~animal health and production~~ systems ~~may provide~~ achieve the same level of animal and

human health protection. They discuss principles ~~which might~~ that may be utilised in a ~~judgement~~ determination of equivalence, and outline a step-wise process for trading partners to follow ~~in determining~~ ~~facilitating a judgement of equivalence~~. These provisions are applicable whether equivalence applies ~~at the level of~~ to specific measures or on a systems-wide basis, and whether equivalence applies to specific areas of trade or *commodities*, or in ~~generally~~ general.

Article 5.3.3.

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

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

EU comment

In the first sentence of the paragraph above, the EU suggests deleting the word "its" before the words "animal and human health" (language and clarity).

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

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

1) minimising costs associated with international trade by ~~tailoring~~ allowing *sanitary measures* to be tailored ~~animal health measures~~ to local circumstances;

2) maximising animal health outcomes for a given level of resource input;

3) facilitating trade by achieving the required health protection through less trade restrictive *sanitary measures*; and

4) decreased reliance on relatively costly commodity testing and isolation procedures ~~in bilateral or multilateral agreements~~.

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

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

Article 5.3.4.

Prerequisite considerations ~~in a judgement~~ for the determination of equivalence

1) Application of risk assessment

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

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

2) Categorisation of sanitary measures

Proposals for equivalence may ~~be in terms of a measure comprising~~ consider a single component ~~of a measure~~ (e.g. an isolation or sampling procedure, a test or treatment requirement, a certification procedure) or multiple components (e.g.

a production system for a *commodity*) of a measure, or a combination of measures. ~~Multiple components or combinations of measures~~ Measures may be applied consecutively or concurrently.

EU comment

In the first line of the paragraph above, the EU suggests replacing the word "consider" by the word "include" (linguistic and clarity).

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

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

a) infrastructure~~:~~ including the legislative base (e.g. animal health law) and administrative systems (e.g. organisation of *Veterinary Services* ~~national and regional animal health authorities, emergency response organisations~~);

b) programme design and~~/~~implementation~~:~~ including documentation of systems, performance and decision criteria, *laboratory* capability, and provisions for certification, audit and enforcement;

c) specific technical requirement~~:~~ including requirements applicable to the use of secure facilities, treatment (e.g. retorting of cans), specific test (e.g. ELISA) and procedures (e.g. pre-export inspection).

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

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

Article 5.3.5.

Principles for ~~judgement~~ determination of equivalence

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

1) an *importing country* has the right to set the level of protection it deems appropriate ~~(its ALOP)~~ in relation to human and animal life and health in its territory; this ~~ALOP~~ may be expressed in qualitative or quantitative terms;

2) the *importing country* should be able to describe the reason for each *sanitary measure* i.e. the level of protection intended to be achieved by application of the identified measure against a ~~*hazard*~~ *risk*;

3) an *importing country* should recognise that *sanitary measures* different from the ones it has proposed may be capable of ~~providing~~ achieving the same level of protection, in particular, it should consider the existence of specified disease-free *zones*~~/*regions*~~ or *compartments*;

4) the *importing country* should, upon request, enter into consultations with the *exporting country* with the aim of facilitating a ~~judgement~~ determination of equivalence;

EU comment

In point 4 above, the EU suggests replacing the words "enter into consultations with" by the words "consult with" (style and clarity).

5) any *sanitary measure* or combination of *sanitary measures* can be proposed for ~~judgement~~ determination of equivalence;

6) an interactive process should be followed that applies a defined sequence of steps, and utilises an agreed process for exchange of information, so as to limit data collection to that which is necessary, to minimise administrative burden, and to facilitate resolution of claims;

7) the *exporting country* should be able to demonstrate objectively how the alternative *sanitary measure*~~(*s*)~~ proposed as equivalent will provide the same level of protection;

8) the *exporting country* should present a submission for equivalence in a form that facilitates ~~judgement~~ determination by the *importing country*;

9) the *importing country* should evaluate submissions for equivalence in a timely, consistent, transparent and objective manner, and in accordance with appropriate *risk assessment* principles;

10) the *importing country* should take into account any knowledge of and prior experience with the *Veterinary Authority* or other *Competent Authority* of the *exporting country*;

10bis) the *importing country* should take into account any arrangements it has with other *exporting countries* on similar issues;

10ter) the *importing country* may also take into account any knowledge of the *exporting country's* arrangements with other *importing countries*;

11) the *exporting country* should provide access to enable the procedures or systems ~~which~~ that are the subject of the equivalence ~~judgement~~ determination to be examined and evaluated upon request of the *importing country*;

12) the *importing country* should be the sole ~~determinant~~ judge of equivalence, but should provide to the *exporting country* a full explanation for its judgement;

13) to facilitate a ~~judgement~~ determination of equivalence, Member Countries should base their *sanitary measures* on relevant OIE standards and guidelines, where these exist. However, they may choose to implement more stringent *sanitary measures* if these are scientifically justified by a *risk analysis*;

14) to allow the ~~judgement~~ determination of equivalence to be reassessed if necessary, the *importing country* and the *exporting country* should keep each other informed of significant changes to infrastructure, health status or programmes ~~which~~ that may bear on the ~~judgement~~ determination of equivalence; and

15) appropriate technical assistance from an *importing country*, following a ~~should give positive consideration to a~~ request by an *exporting* ~~developing~~ *country*, ~~for appropriate technical assistance that would~~ may facilitate the successful completion of a ~~judgement~~ determination of equivalence.

Article 5.3.6.

Sequence of steps to be taken in ~~judgement~~ determination of equivalence

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

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

Recommended steps are:

1) the *exporting country* identifies the measure~~(s)~~ for which it wishes to propose an alternative ~~measure(s),~~ and requests from the *importing country* a reason for its *sanitary measure* in terms of the level of protection intended to be achieved against a ~~*hazard*(s)~~ *risk*;

2) the *importing country* explains the reason for the measure~~(s),~~ in terms that ~~which~~ would facilitate comparison with an alternative *sanitary measure*~~(s)~~ and consistent with the principles set out in these provisions;

3) the *exporting country* demonstrates the case for equivalence of an alternative *sanitary measure*~~(s)~~ in a form ~~which~~ that facilitates evaluation ~~analysis~~ by an *importing country*;

4) the *exporting country* responds to any technical concerns raised by the *importing country* by providing relevant further information;

5) ~~judgement~~ determination of equivalence by the *importing country* should take~~s~~ into account as appropriate:

a) the impact of biological variability and uncertainty;

b) the expected effect of the alternative *sanitary measure*~~(s) on all relevant hazards~~;

c) OIE standards and guidelines;

d) ~~application of solely *qualitative* frameworks where it is not possible or reasonable to conduct *quantitative*~~ the results of a *risk assessment*;

6) the *importing country* notifies the *exporting country* of its judgement and its ~~the underlying~~ reasons within a reasonable period of time. The judgement:

a) ~~recognition~~ recognises ~~of~~ the equivalence of the *exporting country's* alternative *sanitary measure*~~(s)~~; or

b) requests ~~for~~ further information; or

c) ~~rejection~~ rejects ~~of~~ the case for equivalence of the alternative *sanitary measure*~~(s)~~;

7) an attempt should be made to resolve any differences of opinion over judgement of a case~~, either interim or final,~~ by using an agreed mechanism such as ~~to reach consensus (e.g.~~ the OIE informal procedure for dispute mediation~~), or by referral to an agreed expert~~ (Article 5.3.8.);

8) depending on the category of measures involved, the *importing country* and the *exporting country* may enter into a formal or informal agreement of equivalence ~~agreement~~ giving effect to the judgement ~~or a less formal acknowledgement of the equivalence of a specific measure(s) may suffice~~.

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

Article 5.3.7.

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

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

1. For zoning

a) The *exporting country* identifies a geographical area within its territory, which, based on *surveillance*, it considers to contain an animal *subpopulation* with a distinct health status with respect to a specific *disease*~~/specific diseases~~, *infection* or *infestation*~~, based on surveillance~~.

b) The *exporting country* describes in the *biosecurity plan* for the *zone* the measures ~~which are being, or will be,~~ applied to distinguish such an area epidemiologically from other parts of its territory, in accordance with the recommendations in the *Terrestrial Code*.

c) The *exporting country* provides:

i) the above information to the *importing country*, with an explanation of why the area can be treated as an epidemiologically separate *zone* for *international trade* purposes;

ii) access to enable the procedures or systems that establish the *zone* to be examined and evaluated upon request by the *importing country*.

d) The *importing country* determines whether it accepts such an area as a *zone* for the importation of *animals* ~~and~~ or animal products, taking into account:

i) an evaluation of the *exporting country's Veterinary Services*;

ii) the result of a *risk assessment* based on the information provided by the *exporting country* and its own research;

iii) its own animal health situation with respect to the *disease*~~(s)~~ concerned; and

iv) other relevant OIE standards or guidelines.

e) The *importing country* notifies the *exporting country* of its ~~determination~~ judgement and ~~the underlying~~ its reasons, within a reasonable period of time, being:

i) recognition of the *zone*; or

ii) request for further information; or

iii) rejection of the area as a *zone* for *international trade* purposes.

f) An attempt should be made to resolve any differences over recognition of the *zone*~~, either in the interim or finally,~~ by using an agreed mechanism ~~to reach consensus~~ such as the OIE informal procedure for dispute mediation (Article 5.3.8.).

g) The *Veterinary Authorities* of the *importing* and *exporting countries* should enter into an ~~formal~~ agreement recognising the *zone*.

2. For compartmentalisation

a) Based on discussions with the relevant industry, the *exporting country* identifies within its territory a *compartment* comprising an animal *subpopulation* contained in one or more *establishments* or other premises operating under common management practices and ~~related to~~ *biosecurity plan*. The *compartment* contains an identifiable animal *subpopulation* with a distinct health status with respect to a specific disease~~(s)~~. The *exporting country* describes how this status is maintained through a partnership between the relevant industry and the *Veterinary Authority* of the *exporting country*.

b) The *exporting country* examines the *compartment's biosecurity plan* and confirms through an audit that:

i) the *compartment* is epidemiologically closed throughout its routine operating procedures as a result of effective implementation of its *biosecurity plan*; and

ii) the *surveillance* and monitoring programme in place is appropriate to verify the status of such a *subpopulation* with respect to ~~such~~ the disease~~(s)~~ in question.

c) The *exporting country* describes the *compartment*, in accordance with ~~the recommendations in the *Terrestrial Code*~~ Chapters 4.3. and 4.4.

d) The *exporting country* provides:

i) the above information to the *importing country*~~,~~ with an explanation of why such a *subpopulation* can be treated as an epidemiologically separate *compartment* for *international trade* purposes; and

ii) access to enable the procedures or systems that establish the *compartment* to be examined and evaluated upon request by the *importing country*.

e) The *importing country* determines whether it accepts such a *subpopulation* as a *compartment* for the importation of *animals* or ~~and~~ animal products, taking into account:

i) an evaluation of the *exporting country's Veterinary Services*;

ii) the result of a *risk assessment* based on the information provided by the *exporting country* and its own research;

iii) its own animal health situation with respect to the disease~~(s)~~ concerned; and

iv) other relevant OIE standards or guidelines.

f) The *importing country* notifies the *exporting country* of its ~~determination~~ judgement and ~~the underlying~~ its reasons, within a reasonable period of time, being:

i) recognition of the *compartment*; or

ii) request for further information; or

iii) rejection of such a *subpopulation* as a *compartment* for *international trade* purposes.

g) An attempt should be made to resolve any differences over recognition of the *compartment*~~, either in the interim or finally,~~ by using an agreed mechanism ~~to reach consensus~~ such as the OIE informal procedure for dispute mediation (Article 5.3.8.).

h) The *Veterinary Authorities* of the *importing* and *exporting countries* should enter into an ~~formal~~ agreement recognising the *compartment.*

~~i) The *Veterinary Authority* of the *exporting country* should promptly inform *importing countries* of any occurrence of a *disease* in respect of which the *compartment* was defined.~~

Article 5.3.8.

The OIE informal procedure for dispute mediation

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

1) Both parties agree to give the OIE a mandate to assist them in resolving their differences.

2) If considered appropriate, the Director General of the OIE recommends an expert, or experts, and a chairman, as requested, agreed by both parties.

3) Both parties agree on the terms of reference and working programme, and to meet all expenses incurred by the OIE.

4) The expert or experts are entitled to seek clarification of any of the information and data provided by either country in the assessment or consultation processes, or to request additional information or data from either country.

5) The expert or experts ~~shall~~ submit a confidential report to the Director General of the OIE, who ~~will~~ then transmits it to both parties.

— Text deleted.

Annex 27

CHAPTER 2.X.

CRITERIA FOR ASSESSING THE SAFETY OF COMMODITIES

EU comment

The EU thanks the OIE and in general supports this draft new chapter. A comment is inserted in the text below.

Article 2.X.1.

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

General provisions

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

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

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

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

Article 2.X.2.

Criteria

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

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

EU comment

For reasons of consistency, please consider replacing the words "animal product" by the word "commodity" also in point 1 above, as well as in point 2 below.

OR

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

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

   or

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

   or

   c) biological (e.g. fermentation);

or

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

- - - - - - - - - - - - - -

— Text deleted.

Annex 28

DRAFT CHAPTER 6.X.

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

EU comment

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

Article 6.X.1.

Introduction

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

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

EU comment

At the end of the first sentence of the paragraph above, the EU suggests adding the words ", especially in case of infection with *S.* Dublin" after the words "may occur".

Indeed, clinical signs in cattle are common with *S.* Dublin infections.

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

EU comment

At the end of the paragraph above, the EU suggests deleting the words "and age", as age is not a factor related to the likelihood of introduction. Indeed, the age factor is not referred to when reading several articles and books describing risk factors for introduction of Salmonella (e.g. Salmonella in Domestic Animals, 2nd ed, Barrow P and Methner U, Chapter 12 Salmonella infections in Cattle, LaRagione R et al.).

However, age can be a risk-factor as regards influence on dissemination and persistence in a herd. For certain salmonella sero-types (*Salmonella* Dublin for example), dissemination and persistence is more likely among young calves.

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

EU comment

It is suggested to delete "the" before "producers" in the 2nd line of the paragraph above (language).

Article 6.X.2.

Definitions

For the purposes of this chapter:

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

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

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

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

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

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

Article 6.X.3.

Purpose and scope

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

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

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

EU comment

This chapter is about cattle, not pigs. Thus, the reference to guidelines regarding pork meat seems out of place.

Article 6.X.4.

Objectives of prevention and control measures

It is recommended that prevention and control measures be focused on those types of *Salmonella* of greatest consequence to cattle or public health.

EU comment

The sentence above seems to recommend focusing only on the serotypes of greatest consequences, while all *Salmonella* serotypes are pathogenic. Prevention of all *Salmonella* spp. should therefore not be discouraged. The EU thus suggests amending the sentence as follows:

"~~It is recommended that prevention and control measures be focused~~ Control measures may focus on those types of *Salmonella* of greatest consequence to cattle and public health. Preventive measures for those types will also contribute to the reduction of other types of *Salmonella*."

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

~~1) entering the *slaughterhouse/abattoir* and therefore decrease the *risk* of beef contamination during *slaughter* and dressing procedures;~~

~~2) in *milk* and *milk products*;~~

~~3) in the farm environment, thereby reducing the risk of dissemination of *Salmonella* and contact *infections* in humans.~~

Prevention and control measures in commercial cattle production systems may:

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

2) reduce the likelihood of *Salmonella* contamination in *milk;*

3) reduce *Salmonella* contamination of the environment via cattle faecal waste, which in turn will limit *infection* of *animals* (including *wildlife*);

4) reduce the likelihood of *infections* in humans through contact with infected cattle or contaminated material.

EU comment

At the end of point 4) above, the EU suggests adding the words "and contaminated irrigation water used for e.g. fruits and vegetables".

Indeed, as contamination of the environment might reach humans in different ways, irrigation water should be pointed out as a potential source.

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

Articles 6.X.5.to 6.X.~~14~~16. provide recommendations for the prevention and control of *Salmonella* in commercial cattle production systems.

These recommendations may also ~~have beneficial effects on the occurrence of~~ contribute to the prevention and control of some other *infections* ~~and *diseases*~~.

Article 6.X.5.

Biosecurity

Biosecurity is intended to assist with the prevention and control of *Salmonella*. A *biosecurity* management plan should be developed according to the commercial cattle production systems employed e.g. intensive or extensive. The applicability of the measures, described below, will vary according to the type of commercial cattle production system.

When including *Salmonella* as part of a *biosecurity* management plan it is recommended that the following be addressed:

1) location, design and management of the *establishment*;

2) veterinary supervision of cattle health;

3) management of the introduction and mixing of cattle;

4) training of personnel in their responsibilities and their role in animal health, human health and food safety;

5) maintenance of records including data on cattle health, production, movements, medications, *vaccination*, and mortality, and cleaning and *disinfection* of farm buildings and equipment;

6) availability of test results to the farm operator when *Salmonella surveillance* is conducted;

7) removal of unwanted vegetation and debris that could attract or harbour pests around cattle premises;

8) minimising the entry of *wild* birds into cattle buildings and feed stores;

9) cleaning and *disinfection* procedures for buildings in which cattle are handled or housed. For example, the cleaning and *disinfection* procedures for intensive calf housing, calving areas and sick pens after emptying may include feeders, drinkers, floor, walls, aisles, partitions between pens, and ventilation ducting. All visible organic material should be removed before *disinfection.*

EU comment

The choice of cleaning procedures is important, and it should be adapted to the situation. It is also important to consider the risk of spread to animals that might be present in the stables during cleaning, i.e. high-pressure cleaning may pose a considerable risk of infecting new animals via aerosols, which should therefore be avoided. In addition, depending on the methods used, it is important that all surfaces are allowed to dry after cleaning before disinfection is performed.

The EU therefore suggests amending point 9) above as follows:

"cleaning and disinfection procedures for buildings in which cattle are handled or housed. For example, the cleaning and disinfection procedures for intensive calf housing, calving areas and sick pens after emptying may include feeders, drinkers, floor, walls, aisles, partitions between pens, and ventilation ducting. To minimise the risk of infection for animals that might be present during cleaning operations, aerosols produced by high pressure cleaning methods should be avoided. All visible organic material should be removed and all surfaces should be allowed to dry before disinfection."

When chemical disinfectants are used, the effective concentration and contact time for *Salmonella* should be considered and the choice of disinfectant should take into account the cleaning process. Surfaces should be allowed to dry after *disinfection*. Disinfectants should be used in accordance with Chapter 4.13.;

EU comment

The EU suggests adding the words "and according to the manufacturer's instructions" at the end of the paragraph above, as it is indeed important to follow these instructions which are specific to each chemical disinfectant product.

10) control of pests such as rodents and arthropods and regular assessment of effectiveness;

11) control and hygienic procedures for entry and movement of persons and *vehicles*;

12) cleaning and *disinfection* of equipment and *vehicles* identified as posing a *risk*;

13) storage and disposal of dead animals, bedding, faeces and other potentially contaminated farm waste in a manner that minimises the likelihood of dissemination of *Salmonella* and prevents the direct or indirect exposure of humans, livestock and *wildlife* to *Salmonella*. Particular care should be taken when cattle bedding and faeces are applied to land used for horticultural crops intended for human consumption.

Article 6.X.~~5~~6.

Location and design of cattle establishments

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

It is recommended that the design of intensive cattle production systems consider the following:

1) management of faecal waste to minimise contamination of the *establishment*;

~~1~~2) adequate drainage for the site and control of run-off water and untreated waste water;

~~2~~3) use of materials for construction that facilitate effective cleaning and *disinfection*;

~~3~~4) control of ~~the points of~~ entry and movement of *vehicles*, equipment and persons;

5) preventing contamination of feed and water during storage and distribution;

EU comment

Contamination of water during storage and distribution seems not to be very relevant. The EU proposes to delete the words "and water" in the point 5) above, as water is also addressed in more detail under Article 6.X.10.

~~4~~6) cattle handling and movements to minimise stress and spread of *Salmonella infection*;

~~5~~7) separation of cattle according to likelihood of ~~different~~ *infection* with, or susceptibility to, *Salmonella* ~~*risk* status~~;

EU comment

In point 7 above, the EU suggests replacing the word "separation" by the word "segregation", as this seems to better reflect the intended control measure of grouping animals in accordance with risk.

In addition, sick animals should be segregated, and it would also be good to implement a separation of animals by age. Therefore, the sentence could be amended as follows:

"segregation of cattle according to likelihood of infection with, or susceptibility to, Salmonella. In particular, sick animals should be segregated, and animals should be segregated according to age."

~~6~~8) restriction of entry of domestic animals, ~~*wild*~~ birds, rodents, flies and other relevant *wildlife*.

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

~~Article 6.X.6.~~

~~**Biosecurity management plan**~~

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

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

~~1) Veterinary supervision of cattle health.~~

~~2) Management of introduction and mixing of cattle.~~

~~3) Training of personnel in their responsibilities and their role in animal health, human health and food safety.~~

~~4) Maintenance of records including data on cattle health, production, movements, medications, *vaccination*, and mortality, and cleaning and *disinfection* of farm buildings and equipment.~~

~~5) Availability of test results to the farm operator when *Salmonella surveillance* is conducted.~~

~~6) Removal of unwanted vegetation and debris that could attract or harbour pests around cattle premises .~~

~~7) Minimising the entry of wild birds into cattle buildings and feed stores.~~

~~8) Cleaning and *disinfection* procedures for buildings in which cattle are handled or housed. For example, the cleaning and *disinfection* procedures for intensive calf housing, calving areas and sick pens after emptying may include feeders, drinkers, floor, walls, aisles, partitions between pens, and ventilation ducting.~~

~~When disinfectants are used they should be applied at an effective concentration after a complementary cleaning procedure.~~

~~9) Control of pests such as rodents and arthropods when required and regular assessment of effectiveness.~~

~~10) Control of persons and *vehicles* entering the *establishment*.~~

~~11) Cleaning and *disinfection* of *vehicles* and equipment identified as a *risk*.~~

~~12) Storage and disposal of cattle carcasses, bedding, faeces and other potentially contaminated farm waste in a safe manner to minimise the risk of dissemination of *Salmonella* and to prevent the direct or indirect exposure of humans, livestock and *wildlife* to *Salmonella*. Particular care to be taken when cattle bedding and faeces are used as fertiliser for horticultural crops intended for human consumption.~~

Article 6.X.7.

Management of cattle introductions

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

1) ~~There be~~ good communication within the cattle industry be encouraged to raise awareness of the ~~*risk*~~ likelihood of introducing *Salmonella* through cattle introductions~~.~~;

2) ~~The number of separate sources of cattle for breeding or rearing be kept to as few as possible. For example in a closed dairy *herd* it is possible to introduce new genetic material solely by semen or embryos.~~ consideration be given to minimising the number of sources of replacement cattle;

3) the introduction of new genetic material through the use of semen and embryos be considered whenever practicable;

~~3~~4) if possible, cattle be sourced directly from *herds* of origin because live animal markets or other places where cattle from multiple properties are mixed for resale may increase the ~~*risk*~~ likelihood of spread of *Salmonella* and other ~~*infections*~~ infectious agents among cattle~~.~~;

~~4~~5) newly introduced cattle be kept separate from the rest of the *herd* for a suitable period before mixing with other cattle, e.g. four weeks~~.~~;

~~5)~~ ~~Where appropriate, for example with cattle of unknown status, pooled faecal samples from introduced cattle could be taken to assess their *Salmonella* status.~~

6) where appropriate, testing of animals for *Salmonella* prior to introduction be considered to inform subsequent control measures, for example, when introducing cattle of unknown status.

Article 6.X.8.

On farm cattle management

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

1) cattle with suspected salmonellosis be separated from healthy cattle~~.~~;

2) care of healthy cattle be carried out prior to care of cattle with suspected salmonellosis~~.~~;

3) priority be given to the hygienic management of calving areas, for example keeping perinatal cattle separated from sick cattle and maintaining a clean environment~~.~~;

4) when possible, the 'all-in-all-out' principle for production cohorts be used. In particular, the unnecessary mixing of different age groups ~~during rearing~~, especially of calves, should be avoided~~.~~;

5) consideration be given to the potential for between-herd transmission of *Salmonella* via breeding, rearing and grazing of cattle from multiple sources on a single site, for example shared pasture, ~~and~~ heifer rearing~~.~~ or sharing of bulls;

6) consideration be given to the potential for between-herd transmission of *Salmonella* through direct contact between cattle across boundary lines or indirectly, for example through contamination of water courses.

Article 6.X.9.

Feed ~~and water~~

~~1.~~ ~~Compound feed~~ Feed and feed ingredients

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

~~a~~1) ~~Where~~ When appropriate, ~~compound~~ feed and feed ingredients be produced, handled, stored, transported and distributed according to Good Manufacturing Practices, considering Hazard Analysis Critical Control Points (HACCP) principles and recommendations in accordance with Chapter 6.3.

~~b~~2) ~~Compound~~ Where practical, feed and feed ingredients be transported, ~~and~~ stored and fed in a hygienic manner that minimises contamination by manure and access by domestic animals, ~~wild~~ birds, rodents and ~~other~~ *wildlife*.

~~2.~~ ~~Water~~

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

Article 6.X.10.

Water

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

EU comment

In the paragraph above, the EU suggests replacing the term "Drinking water" by the term "water for drinking" (or alternatively just "water") in order to avoid confusion with water for human consumption. Indeed, in EU legislation the term "drinking water" refers to water intended for human consumption which satisfies specific criteria, one of which being freedom from pathogenic agents. Therefore, saying that "drinking water

should be of appropriate quality" seems odd. Furthermore, water for animals does not need to satisfy the criteria for drinking water intended for human consumption, which is not always available on cattle farms, e.g. when wells are used as water supply.

In addition, the recommendations aimed at minimising the spread of *Salmonella* through water as detailed in Article 6.Y.10. (*Salmonella* in pigs) would be relevant also for cattle and should thus be included in the Article 6.X.10. above as well.

Article 6.X.~~10~~11.

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

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

~~1) *Antimicrobial agents* may modify normal flora in the gut and increase the likelihood of colonisation by *Salmonella*. If *antimicrobial agents* are used, they should be used in accordance with Chapter 6.9. *Antimicrobial agents* should not be used to control subclinical *infection* with *Salmonella* in cattle because the effectiveness of the treatment is limited, they may increase the risk of *Salmonella* colonisation, and their use can contribute to the development of antimicrobial resistance.~~

2) *Vaccination* may be ~~used~~ considered as part of a *Salmonella* control programme. Vaccine production and use should be in accordance with Chapter 1.1.6. of the *Terrestrial Manual*. The protective effect of vaccines is generally serotype specific ~~and few licensed vaccines are available for cattle~~ and is influenced by factors such as timing of *vaccination* in relation to exposure.

~~3) Use of probiotics may reduce colonisation of cattle by *Salmonella* and shedding of *Salmonella;* however, efficacy is variable.~~

4~~3~~) ~~Because conditions such as~~ A number of conditions, for example liver fluke and infection with bovine viral diarrhoea virus, may increase the susceptibility of cattle to *Salmonella*~~,~~; therefore, control of ~~these~~ such conditions is recommended.

~~5) The immune status of calves is important and therefore care should be taken to ensure that new-born calves consume adequate amounts of high quality colostrum.~~

4) *Antimicrobial agents* can be used for treatment of clinical salmonellosis and when administered, it should be in accordance with Chapter 6.9. However, *antimicrobial agents* should not be used to control subclinical *infection* with *Salmonella* in cattle because the effectiveness of the treatment is limited, they may increase the risk of *Salmonella* colonisation, and their use can contribute to the development of antimicrobial resistance.

EU comment

The EU does not support the first sentence of point 4 above, as it unduly encourages the use of antimicrobial agents for treatment of clinical salmonellosis. As antimicrobial agents can favour the persistence of *Salmonella* in the intestines after recovery, affect the intestinal flora, and increase the emergence of resistant strains, antimicrobials should not be used for routine management of enteric disease. Indeed, they should only be used upon veterinary prescription when absolutely necessary, e.g. for animal welfare reasons or to salvage valuable breeding animals. Reference is made to the relevant provision in Chapter 6.5. on *Salmonella* in poultry (Article 6.5.5.).. The EU thus suggests amending the text of point 4 as follows:

"~~Antimicrobial agents can be used for~~ The treatment of clinical enteric salmonellosis in cattle ~~and when administered, it should be in accordance with Chapter 6.9~~ with antimicrobial agents should be limited as much as possible, as it may favour the persistence of *Salmonella* in the intestines after recovery, affect the intestinal flora, and increase the emergence of antimicrobial-resistant strains. When used for example on animal welfare grounds or to salvage breeding animals with high genetic value, antimicrobial agents

should be prescribed by a veterinarian on a case by case basis after accurate diagnosis and in accordance with Chapter 6.9. ~~However~~ Furthermore, antimicrobial agents should not be used to control subclinical infection with *Salmonella* in cattle because the effectiveness of the treatment is limited, they may increase the risk of Salmonella colonisation, and their use can contribute to the development of antimicrobial resistance."

Article 6.X.~~11~~12.

Transportation

Hygienic maintenance of *vehicles* is recommended.

EU comment

The EU is of the opinion that the point above is too vague. There should be a specific recommendation to properly cleaning and disinfect vehicles after each use. The following wording is suggested:

"Hygienic maintenance of vehicles is recommended. In particular, proper cleaning and disinfection of vehicles is required after each use."

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

The relevant recommendations in Chapters 7.2., 7.3. and 7.4. apply.

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

Article 6.X.~~12~~13.

Lairage

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

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

Article 6.X.14.

Cleanliness of hides

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

Article 6.X.~~13~~15.

Surveillance ~~in cattle~~ for Salmonella in commercial cattle production systems

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

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

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

Article 6.X.~~14~~16.

Prevention and control in low prevalence regions

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

EU comment

The EU is of the opinion that in the sentence above, the previous wording "and possibly" is preferable as the role of carriers in *S*. Dublin herds is questioned. In addition, there is no reliable method to diagnose carriers, and removing carriers without taking any other preventive measures is not likely to be successful. The following alternative wording is thus suggested:

"[...] movement controls, ~~or~~ and possibly removal of persistent carriers in the case of *S*. Dublin infection."

- - - - - - - - - - - - - -

— Text deleted.

Annex 29

DRAFT CHAPTER 6.Y.

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

EU comment

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

Furthermore, the EU would like to draw OIE's attention on a Scientific Opinion of the European Food Safety Authority (EFSA) on *Salmonella* control in pigs published in 2010 (available here: https://www.efsa.europa.eu/en/press/news/biohaz100419). A number of relevant issues raised in that opinion are not included in this draft chapter. For example, it would be worth mentioning the following concepts:

- Focus on breeding pigs: It is indicated that in order to reduce *Salmonella* in pigs going to slaughter, decreasing the levels of *Salmonella* in holdings where pigs are bred would result in highest reduction. In countries which have high levels of *Salmonella* this would lead to the greatest reduction;

- Infected breeding pigs: probably one of the most difficult aspects of *Salmonella* control in pigs. The problem should at least be mentioned in this chapter.

Article 6.Y.1.

Introduction

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

EU comment

The last 2 sentences of the paragraph above are confusing, as the connection between variable prevalence of S. Enteritidis and S. Typhimurium in pigs on the one hand and the occurrence of S. infantis and S. Cholerasuis in humans in some countries on the other hand is not clear. The EU thus suggests either deleting the last sentence, or amending it as follows:

"~~For example~~ In some countries a high prevalence of e.g. S. Infantis and S. Choleraesuis in pigs can result in a high count of ~~may also cause~~ salmonellosis cases in humans."

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

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

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

EU comment

It is suggested to delete "the" before "producers" in the 2nd line of the paragraph above (language).

Article 6.Y.2.

Definitions

For the purpose of this chapter:

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

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

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

Article 6.Y.~~2~~3.

Purpose and scope

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

EU comment

To highlight the importance of pre-harvest control for reduction of environmental contamination, which could then also re-contaminate pigs, the following addition to the first sentence above is suggested:

"[...] reduce the burden of infection in pigs, contamination of the environment and the risk of human illness through [...].

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

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

~~Article 6.Y.3.~~

~~**Surveillance in pig herds for *Salmonella***~~

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

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

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

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

~~Article 6.Y.4.~~

~~**Definitions**~~

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

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

Article 6.Y.~~5~~4.

~~**Prevention**~~ **Objectives of prevention and control measures**

It is recommended that prevention and control measures be focused on those types of *Salmonella* of greatest consequence to pigs and public health.

EU comment

The sentence above seems to recommend focusing only on the serotypes of greatest consequences, while all *Salmonella* serotypes are pathogenic. Prevention of all *Salmonella* spp. should therefore not be discouraged. The EU thus suggests amending the sentence as follows:

"~~It is recommended that prevention and control measures be focused~~ Control measures may focus on those types of *Salmonella* of greatest consequence to pigs and public health. Preventive measures for those types will also contribute to the reduction of other types of *Salmonella*."

Prevention and control measures in commercial pig production systems may:

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

2) reduce *Salmonella* contamination of the environment via pig manure, which in turn will limit *infection* of *animals* (including *wildlife*);

3) reduce the likelihood of *infections* in humans through contact with infected pigs or contaminated material.

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

Articles 6.Y.65.to 6.Y.1814. provide recommendations for the prevention and control of *Salmonella* at in commercial pig production systems *herd* level. Contamination of pig *meat* can be reduced by measures taken during the *slaughter* process. Reduction of *Salmonella* in pigs entering the *slaughterhouse/abattoir* enhances the effectiveness of such measures.

These recommendations may will also contribute to the prevention and control of some have beneficial effects on the occurrence of other *infections* and *diseases*.

Article 6.Y.65.

Biosecurity measures

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

Biosecurity is intended to assist with the prevention and control of *Salmonella*. The choice of specific measures will vary according to the type of commercial pig production system.

When including *Salmonella* as part of a *biosecurity* management plan, it is recommended that the following be addressed:

It is recommended that biosecurity measures include the following:

1) location, design and management of the *establishment*; Development and implementation of a *biosecurity plan* including management strategies for the prevention and control of *Salmonella*.

2) veterinary supervision of pig health;

3) management of the introduction and mixing of pigs;

24) training of personnel regarding in their responsibilities and the significance of their role in improving animal health, human health, and food safety.;

EU comment

Point 1) above seems to be elaborated in detail in Article 6.Y.6. A reference to that article could therefore be added at the end of that point.

Similarly, point 3) above is elaborated in Articles 6.Y.7s and 6.Y.8., so a reference to those articles could be added at the end of that point.

Points 2) and 4) above are not very specific and should be elaborated further in more concrete terms (e.g. bacteriological examination in case of suspicion in piglets for point 2).

35) maintenance of records including data on pig health, production, movements, medications, *vaccination*, mortality, *surveillance,* and cleaning and *disinfection* of farm buildings and equipment.;

6) availability of test results to the farm operator when *Salmonella surveillance* is conducted;

4) veterinary supervision of pighealth and *Salmonella* control.

57) removal of unwanted vegetation and debris that could attract or harbour pests around pig housing.;

68) prevention of minimising the entry of *wild* birds into pig houses and buildings and feed stores.;

79) cleaning and *disinfection* procedures for buildings in which pigs are handled or housed, including feeding systems, drinkers, floor, walls, aisles, walkways, partitions between pens, and ventilation ducting. Cleaning and *disinfection* procedures for pig housing, general equipment, transportation equipment and animal walkways. The cleaning and *disinfection* procedures for pig housing after emptying should include at least feeders, drinkers, floor, walls, aisles, partitions between pens, and ventilation ducting. All visible organic material should be removed before *disinfection* with a suitable *disinfectant* at an effective concentration. *Disinfectants* should be used in accordance with Chapter 4.13.

EU comment

The choice of cleaning procedures is important, and it should be adapted to the situation. It is also important to consider the risk of spread to animals that might be present in the stables during cleaning, i.e. high-pressure cleaning may pose a considerable risk of infecting new animals via aerosols, which should therefore be avoided. In addition, depending on the methods used, it is important that all surfaces are allowed to dry after cleaning before disinfection is performed.

The EU therefore suggests amending point 9) above as follows:

"cleaning and disinfection procedures for buildings in which pigs are handled or housed, including feeding systems, drinkers, floor, walls, aisles, walkways, partitions between pens, and ventilation ducting. To minimise the risk of infection for animals that might be present during cleaning operations, aerosols produced by high pressure cleaning methods should be avoided. All visible organic material should be removed and all surfaces should be allowed to dry before disinfection."

Furthermore, the EU suggests adding the following (which would be consistent with Chapter 6.X. and the EU comment on Article 6.X.5.):

"When chemical disinfectants are used, the effective concentration and contact time for Salmonella should be considered and the choice of disinfectant should take into account the cleaning process. Surfaces should be allowed to dry after disinfection. Disinfectants should be used in accordance with Chapter 4.13. and according to the manufacturer's instructions."

~~8~~10) control of pests such as rodents and arthropods, and regular assessment of effectiveness;~~Procedures for the control of vermin such as rodents and arthropods should be in place and regular checks should be carried out to assess effectiveness. When the presence of vermin is detected timely control actions should be taken to prevent the development of unmanageable populations; for example, the placement of baits for rodents where they are nesting.~~

~~9~~11) ~~Controlled access of persons and *vehicles* entering the *establishment*.~~control and hygienic procedures for entry and movement of persons and *vehicles*;

EU comment

For clarity reasons, the EU suggests slightly amending point 11) above as follows:

"control and hygienic procedures for entry into and movement within the establishment of persons and vehicles;".

~~10~~12) *biosecurity* ~~measures~~ applied to all personnel and visitors entering the *establishment.* ~~This~~ As a minimum, this should include hand washing and changing into clean clothes and footwear provided by the *establishment*. Similar precautions are recommended when ~~moving~~ they move between separate *epidemiological units* on large farms~~.~~;

~~11) *vehicles* and equipment identified as a *risk* in the *biosecurity plan* should be cleaned and *disinfected* before entering the *establishment*.~~

13) cleaning and *disinfection* of equipment and *vehicles* identified as posing a *risk*;

~~12~~14) ~~pig carcasses,~~ storage and disposal of dead animals, bedding, faeces and other potentially contaminated farm waste ~~should be stored and disposed of~~ in a ~~safe~~ manner ~~to~~ that minimises the ~~risk~~ likelihood of dissemination of *Salmonella* and ~~to~~ prevents the direct or indirect exposure of humans, livestock and *wildlife* to *Salmonella*. Particular care should be taken when pig bedding and faeces are applied to land used ~~to fertilise~~ for horticultural crops intended for human consumption.

Article 6.Y.~~7~~6.

~~Facility~~ Location and design of pig establishments

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

It is recommended that the design of commercial pig production systems consider the following:

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

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

1) ~~location~~ proximity of other livestock *establishments*, ~~in relation to~~ and *wild* bird and rodent populations;

2) management of faecal waste to minimise contamination of the *establishment*;

~~2~~3) adequate drainage for the site and control of run-off water and untreated waste water;

~~3~~4) use of smooth impervious materials for construction of pig houses to enable effective cleaning and *disinfection*;

~~4~~5) ~~surrounding~~ paving the area immediately surrounding ~~indoor~~ pig houses or indoor establishments with concrete or other impervious material. ~~to~~ This will facilitate rodent control and minimise recontamination after ~~facilitate~~ cleaning and *disinfection*;

~~5~~6) a control~~led~~ of entry and movement of *vehicles*, equipment and persons, ~~point to prevent the entry of unwanted *animals* and people;~~ for example, locate delivery and collection points away from pig housing or feed storage;

7) preventing contamination of feed and water during storage and distribution;

EU comment

Contamination of water during storage and distribution seems not to be very relevant. The EU proposes to delete the words "and water" in the point 7) above, as water is also addressed in more detail under Article 6.Y.10.

~~6) a sign indicating restricted entry at the entrance to the *establishment*;~~

~~7~~8) pig ~~flow~~ handling and movements to minimise stress and spread of *Salmonella infection*;

~~8~~9) ~~prevention of entry of *wild* birds, rodents and *feral animals*;~~ restriction of entry of domestic *animals*, *wild* birds, rodents, flies and other relevant *wildlife*.

~~9) location of delivery and collection points away from pig housing or feed storage.~~

EU comment

The EU suggests adding a point on the segregation of animals, consistent with Article 6.X.6., as follows:

"segregation of pigs according to likelihood of infection with, or susceptibility to, Salmonella. In particular, sick animals should be segregated, and animals should be segregated according to age."

Article 6.Y.7.

Management of new pig introductions into the establishment

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

EU comment

The EU suggests making the statement above stronger, as follows:

"Introduction of pigs into a herd is ~~an~~ the most important risk factor [...]".

1) good communication along the pig production chain be encouraged to raise awareness of the *risk* of introducing *Salmonella* through pig introductions;

2) consideration be given to minimising the number of sources for both replacement breeding stock and rearing pigs, and matching *Salmonella herd* status in terms of *Salmonella* freedom or occurrence of priority serotypes such as *S*. Typhimurium;

3) the introduction of new genetic material be through the use of semen whenever possible;

4) if possible, pigs be sourced directly from *herds* of origin because live animal markets or other places where pigs from multiple properties are mixed for resale may increase the likelihood of spread of *Salmonella* and other infectious agents among pigs;

4) newly introduced pigs be kept separate from the rest of the *herd* for a suitable period before mixing with other pigs, e.g. four weeks;

5) where appropriate, testing of pigs for *Salmonella* prior to introduction be considered to inform subsequent control measures, for example, when introducing pigs of unknown status.

Article 6.Y.8.

Moving and mixing of pigs

The moving and mixing of pigs increases the likelihood of spread of *Salmonella*. To minimise the spread of *Salmonella*, it is recommended that:

1) the number of pig movements and mixing of pigs between weaning and dispatch for *slaughter* be minimised;

2) if possible, the 'all-in-all-out' system with a single age group of pigs be used. In particular, the addition to younger groups of pigs held back from older groups should be avoided.

Article 6.Y.~~8~~9.

Feed and feed composition

1. Feed and feed ingredients

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

a) feed and feed ingredients be produced, handled, stored, transported and distributed in accordance with Chapter 6.3.;

b) where practical, feed and feed ingredients be transported, stored and fed in a hygienic manner that minimises contamination by manure and access by domestic animals, birds, rodents and *wildlife*;

c) feeds be treated with heat, bactericidal or bacteriostatic treatments e.g. organic acids.

EU comment

As it is in general preferable not to add any chemicals to feed, the EU would suggest the following amendments to point c) above:

"feeds be preferably be treated with heat, or, when not possible or as a complement, with approved bactericidal or bacteriostatic treatments e.g. organic acids.".

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

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

~~1) Feed and feed ingredients should come from monitored sources.~~

~~2) Heat treated feeds are used and may also include the addition of bactericidal or bacteriostatic treatments, e.g. organic acids. Where heat treatment is not possible, the use of bacteriostatic or bactericidal treatments or processes should be considered.~~

~~3) Cooling systems and dust control in feed ingredient processing plants and compound feed mills should be managed to avoid recontamination of feed and feed ingredients with *Salmonella*.~~

~~4) Feed should be stored and transported in a hygienic manner that prevents exposure to possible residual *Salmonella* contamination.~~

~~5) Access to feed by wild birds and rodents should be prevented.~~

~~6) Spilled feed should be cleaned up immediately to remove attractants for *wild* birds, rodents and other pests.~~

2. Feed composition

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

For the control of *Salmonella* it is recommended that the following be considered:

a) liquid feed that is fermented or containing *milk products* has a protective effect due to the presence of beneficial bacteria and lowered pH;

b) coarsely ground feed may reduce the occurrence of *Salmonella* by slowing gastric transit (thereby increasing exposure to gastric acid) and reducing dysbacteriosis. Coarsely ground feed ingredients may be fed alongside pelleted feed;

c) fine grinding needed to produce heat treated pellets may result in dysbacteriosis which favours the colonisation and multiplication of *Salmonella* in the intestine. Therefore, heat treated pellets are most appropriate for situations in which *Salmonella* is uncommon;

EU comment

Point c) above is a bit confusing, as it seems to suggest that heat treated feed could induce salmonella, when in fact heat treatment reduces *Salmonella* content of feed. The intention seems to be to point out that fine grinded feed turned into pellets favours dysbacteriosis, whereas the heat treatment is only for technological purposes for the stability of the pellets and is not related to *Salmonella* control. The EU therefore suggests amending the wording as follows:

"[...] Therefore, ~~heat treated~~ such pellets are [...]".

d) when wheat is the predominant feed ingredient, reducing the proportion of this ingredient may reduce the occurrence of *Salmonella* because the rapid fermentation of wheat promotes dysbacteriosis.

Article 6.Y.~~9~~10.

Water

~~For the effective control~~ Drinking water should be of an appropriate quality. To minimise the spread of *Salmonella* through water, it is recommended that:

1) the drinking water supply be monitored and controlled to maintain it free from *Salmonella* contamination~~.~~;

2) water holding tanks ~~are~~ be enclosed~~.~~;

3) the water delivery system ~~is~~ be regularly cleaned and disinfected. For example in an 'all-in-all-out' system this ~~would~~ occurs before restocking.

EU comment

In the article above, the EU suggests replacing the term "Drinking water" by the term "water for drinking" (or alternatively just "water") in order to avoid confusion with water for human consumption. Indeed, in EU legislation the term "drinking water" refers to water intended for human consumption which satisfies specific criteria, one of which being freedom from pathogenic agents. Therefore, saying that "drinking water should be of appropriate quality" seems odd. Furthermore, water for animals does not need to satisfy the criteria for drinking water intended for human consumption, which is not always available on pig farms, e.g. when wells are used as water supply.

~~Article 6.Y.10.~~

~~**Feed composition**~~

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

~~1) slower gastric transit time of ingested feed increases exposure of *Salmonella* to stomach acid resulting in decreased survival.~~

~~2) modified fermentation conditions in the gastrointestinal tract may enhance colonisation by protective bacteria and thereby suppress the colonisation and multiplication of *Salmonella*.~~

~~3) liquid feed that is fermented has a protective effect due to the presence of beneficial bacteria and low pH levels; for example, the inclusion of fermented *milk products*.~~

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

~~4) feed should be coarsely ground.~~

~~5) where feed is wheat based, reducing the proportion of wheat may reduce the occurrence of *Salmonella* in pigs.~~

~~6) coarsely ground material may be added to pelleted feed.~~

~~Article 6.Y.11.~~

~~**Pig flow management**~~

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

~~1) The number of pig movements and mixing of pigs between weaning and dispatch for *slaughter* should be minimised.~~

~~2) If possible, the 'all-in-all-out' single age group principle should be used. In particular, the addition to younger groups of pigs held back from older groups should be avoided.~~

~~Article 6.Y.12.~~

~~**Management of new pig introductions**~~

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

~~1) There is good communication along the pigproduction chain to ensure that steps are taken to minimise the introduction and dissemination of *Salmonella*.~~

~~2) A closed *herd* policy is applied with the introduction of new genetic material by semen only.~~

~~3) The number of separate sources for both replacement breeding stock and rearing pigs are as few as possible.~~

~~4) Newly introduced pigs are kept separate from the rest of the *herd* for a suitable period before incorporating with other pigs, e.g. four weeks.~~

~~5) Replacement breeding pigs are of a similar *Salmonella* status to that of the *herd*, for example a *Salmonella* free *herd* should source replacements from *Salmonella* free *herds*; or *herds* that are free of specific *Salmonella* serotypes such as S. Typhimurium should avoid introducing pigs from breeding *herds* infected with such serotypes.~~

~~6) Where appropriate, pooled faecal samples from introduced pigs are taken to assess their *Salmonella* status.~~

~~Article 6.Y.13.~~

~~**Stress reduction**~~

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

Article 6.Y.~~14~~11.

~~**Pig treatments**~~ **Additional prevention and control measures**

1) *Vaccination* may be considered as part of a *Salmonella* control programme. Vaccine production and use should be in accordance with Chapter 1.1.6. of the *Terrestrial Manual*. The protective effect of vaccines is generally serotype-specific and is influenced by factors such as timing of *vaccination* in relation to exposure.

2) *Antimicrobial agents* can be used for treatment of clinical salmonellosis and when administered, it should be in accordance with Chapter 6.9. However, a*ntimicrobial agents* should not be used to control subclinical *infection* with *Salmonella* in pigs because the effectiveness of the treatment is limited, they may increase the risk of *Salmonella* colonisation, and their use can contribute to the development of antimicrobial resistance.

EU comment

The EU does not support the first sentence of point 2 above, as it unduly encourages the use of antimicrobial agents for treatment of clinical salmonellosis. As antimicrobial agents can favour the persistence of *Salmonella* in the intestines after recovery, affect the intestinal flora, and increase the emergence of resistant strains, antimicrobials should not be used for routine management of enteric disease. Indeed, they should only be used upon veterinary prescription when absolutely necessary, e.g. for animal welfare reasons or to salvage valuable breeding animals. Reference is made to the relevant provision in Chapter 6.5. on *Salmonella* in poultry (Article 6.5.5.). The EU thus suggests amending the text of point 4 as follows:

"~~Antimicrobial agents can be used for~~ The treatment of clinical enteric salmonellosis in pigs ~~and when administered, it should be in accordance with Chapter 6.9~~ with antimicrobial agents should be limited as much as possible, as it may favour the persistence of *Salmonella* in the intestines after recovery, affect the intestinal flora, and increase the emergence of antimicrobial-resistant strains. When used for example on animal welfare grounds or to salvage breeding animals with high genetic value, antimicrobial agents should be prescribed by a veterinarian on a case by case basis after accurate diagnosis and in accordance with Chapter 6.9. ~~However~~ Furthermore, antimicrobial agents should not be used to control subclinical infection with *Salmonella* in pigs because the effectiveness of the treatment is limited, they may increase the risk of Salmonella colonisation, and their use can contribute to the development of antimicrobial resistance."

~~*Antimicrobial agents* may modify normal flora in the gut and increase the likelihood of colonisation by *Salmonella*.~~ ~~If *antimicrobial agents* are used for the control of clinical *infections* in pigs, they should be used in~~

~~accordance with Chapters 6.7., 6.8., 6.9. and 6.10.~~

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

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

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

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

~~If live vaccines are used:~~

~~a) it is important that field and vaccine strains be easily differentiated in the laboratory;~~

~~b) the vaccine strain should not be present at the time of *slaughter*.~~

3) Where approved by the *Competent Authority*, ~~Organic~~ organic acids, probiotics and prebiotics may be added to feed or water to reduce shedding of *Salmonella* by pigs. However, efficacy is variable.

Article 6.Y.~~15~~12.

Transportation

Hygienic maintenance of *vehicles* is recommended.

EU comment

The EU is of the opinion that the point above is too vague. There should be a specific recommendation to properly cleaning and disinfect vehicles after each use. The following wording is suggested:

"Hygienic maintenance of vehicles is recommended. In particular, proper cleaning and disinfection of vehicles is required after each use."

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

The relevant recommendations in Chapters 7.2., 7.3. and 7.4. apply.

Article 6.Y.~~16~~13.

Lairage

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

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

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

Article 6.Y.14.

Surveillance for *Salmonella* in commercial pig production systems

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

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

EU comment

The EU suggests adding the following sentence to the description of limitations with using serology:

"[...] by means of serological testing. Serological testing also does not give an indication of actual excretion of *Salmonella* in the herd, i.e. it does not reflect how infectious the tested group is at the time of testing."

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

EU comment

In the paragraph above, the sentence starting with "Bacteriological sampling of individual pigs" is incorrect as it seems to suggest that the sensitivity increases by pooling of sample. This is not correct, as pooling will in fact decrease the sensitivity (and the cost) of the testing. The EU therefore suggests rewording the sentence as follows:

"Bacteriological sampling of individual pigs has low sensitivity. However on herd level the test has higher sensitivity as more samples are analysed. ~~but this can be overcome by r~~Repeated sampling will increase the sensitivity on individual animals.~~, by p~~ Pooling of samples (such as individual faecal samples or mesenteric lymph nodes) or sampling naturally pooled material (such as sampling of faeces from the floor of pig pens) will decrease the costs for testing.".

Article 6.Y.~~17~~15.

Prevention and control in low prevalence regions

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

EU comment

The EU is of the opinion that the role of persistent salmonella carriers in pigs is doubtful. The EU thus suggests that the last part of the sentence be amended to read as follows:

"[...] movement controls~~, or~~ and, if relevant and possible, removal of persistent carriers.".

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

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

Article 6.Y.~~18~~16.

Outdoor pig production

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

1) field rotation programmes be used to minimise *Salmonella* contamination and accumulation in soil and surface water and therefore ingestion by pigs;

2) systems used to provide feed, and where possible water, ~~be provided using troughs or bird proof hoppers~~ be designed to minimise attraction of, or access by, ~~of~~ *wild* birds;

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

~~Article 6.Y.19.~~

~~**Live animal markets**~~

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

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Text deleted.

Annex 32

CHAPTER 6.1.

THE ROLE OF THE VETERINARY SERVICES IN FOOD SAFETY SYSTEMS

EU comment

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

Article 6.1.1.

Introduction

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, regional, national and local in reach, especially in relation to the globalisation of the food supply, which requires a greater level of engagement and collaboration, in line with the One Health approach. 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.

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

Article 6.1.2.

Purpose and scope

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

This chapter should be read in conjunction with Chapters 4.1., 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 chapter should be read in conjunction with the Codex Alimentarius General Principles of Food Hygiene (CAC/RCP 1-1969), Code of Hygienic Practice for Meat (CAC/RCP 58-2005), Code of Practice on Good Animal Feeding (CAC/RCP 54-2004), Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food Producing Animals (CAC/GL 71-2009), and other relevant Codex texts 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

EU comment

The EU suggests slightly amending the title of point 1 above to read as follows:

"1. Farm to fork approach".

Indeed, this is the wording commonly used in the EU to describe the integrated food chain approach.

Food safety is best assured by an integrated, multidisciplinary approach, considering the whole 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 should include consideration of potential risks associated with each component of the food chain, namely primary production, transport, processing and distribution, and integrate these throughout the food 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.

EU comment

The EU suggests replacing the word "namely" by the words "such as" in the paragraph above. Indeed, the list is not exhaustive but merely represents examples, which would be clarified by the suggested change.

2. Risk-based food safety systems

Risk-based food safety systems include measures based on good practices (such as Good Agricultural Practice, Good Hygienic Practice), hazard analysis and critical control points (HACCP) and risk assessment. The design and application of this risk-based approach depend on the availability of scientific information and technical resources of the *Competent Authority*. Monitoring and review are essential to evaluate the performance of a risk-based food safety system.

EU comment

The EU suggests replacing "hazard analysis and critical control points (HACCP)" by "a system based on the hazard analysis and critical control points (HACCP) principles", to align with Codex Alimentarius terminology.

The EU suggests inserting the words "food business operators and" before the words "Competent Authority" in the 2nd sentence of the paragraph above. Indeed, the responsibility lies mainly with the food business operator, which would be clarified by the suggested change.

As an alternative, the words "and technical resources of the Competent Authority" could be deleted, as it could be understood that if no technical resources are available a risk-based approach is not needed.

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

3. Primary responsibilities of food business operators for food safety

Food business operators, including feed producers, farmers, processors, wholesalers, distributors, importers, exporters and retailers, have primary responsibility for ensuring the safety of their products and should be able to demonstrate that they comply with relevant food safety regulatory requirements. The food business operators have a responsibility to inform the *Competent Authority* 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 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* has the responsibility to develop national legislation and policies relevant to food safety. The *Competent Authority* should take steps to raise awareness of these both within the country and to trading partners.

EU comment

In point 4 above, it is not clear what the difference is between "legislation" and "policies". This is particularly confusing as the next sentence suggests raising awareness of these both to trading partners, however how can they be aware if not laid down in legislation. The EU thus suggests replacing "national legislation and policies relevant to food safety" by "food safety regulatory requirements", which would be consistent with the wording used in point 3 above.

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

EU comment

The EU suggests replacing the word "ensure" by the word "verify" in the first sentence of the paragraph above. Indeed, it is up to the food business operators to ensure adequate quality of their control systems, whereas verification is to be done by the competent authorities. This would be consistent with what is further described elsewhere in the text.

Furthermore, in the same sentence, the word "standards" should be replaced by the words "regulatory requirements", which is the wording used in point 3 above. Indeed, the responsibility of the Competent Authority is to control against applicable regulations or legislation, not standards which seems to be a broader concept.

Finally, the word "verified" should be replaced by "done" in the 2nd sentence of the paragraph above, as this seems more appropriate in this context.

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 of the Veterinary Services in a food safety system

1. Responsibilities of the Veterinary Services

The *Veterinary Authority* or other *Competent Authority* should provide an appropriate institutional environment to allow the *Veterinary Services* to implement the necessary policies and standards, and adequate resources for them to carry out their tasks in a sustainable manner. Within the *Veterinary Services* there should be a clear and well documented assignment of responsibilities 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, the design and implementation of national control programmes of a risk-based food safety system. Implementation includes verification, audit, assurance and certification. In the implementation of food safety systems for foods of *animal* origin, the *Veterinary Services* should retain responsibility for verification and audit and facilitate a flexible approach to operational activities.

Where food safety activities are delegated outside of the *Veterinary Services*, the *Veterinary Services* should retain responsibility for competency standards and performance of the delegated activities.

EU comment

The two last sentences above cannot be supported and should either be deleted or clarified. Indeed, according to EU legislation veterinarians retain responsibility in slaughterhouses, cutting plants and game handling establishments, but not in stages after these (further processing, distribution and retail). There needs to be consistency with the first paragraph of point 2 below.

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 should contribute to other food safety related activities such as investigations of foodborne disease outbreaks, food defence, disaster management, and emerging risks.

EU comment

The EU suggests amending the paragraph above as follows:

"<u>Where relevant,</u> ~~In view of the competencies within~~ the Veterinary Services~~, they~~ should contribute to other food safety related activities such as investigations of foodborne disease outbreaks, food defence, disaster management, and emerging risks."

Indeed, food safety is more than zoonoses; however some control programmes do not specifically require veterinary competence.

2. <u>Activities throughout the food chain</u>

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 hygienic conditions and in the early detection, *surveillance* and treatment of *animal diseases*, including conditions of public health significance. The *Veterinary Services* advise on *animal* husbandry practices, *biosecurity* and interventions that limit the transmission of *animal diseases*, including foodborne *zoonoses*.

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

The *Veterinary Services* assist farmers on how to minimise chemical hazards (e.g. 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 drugs, including *antimicrobial agents*, in *animal* husbandry. This helps to minimise the risk of developing antimicrobial resistance and unsafe levels of veterinary drug residues in foods of *animal* origin.

b) Processing and distribution

The *Veterinary Services* have an essential role in ensuring that 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 in both the *surveillance* network for *animal diseases* and *zoonoses* and 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* also play an important role in raising the awareness of food producers, processors and 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.

EU comment

As HACCP is not a quality assurance system, the wording of the paragraph above needs to be amended, either by deleting "other" or "quality".

c) Assurance schemes and certification of 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*).

EU comment

The EU suggests adding the words "<u>animal health and</u>" before "public health assurance" in the first sentence of the paragraph above, as this is an important component of the role of the Veterinary Services.

Furthermore, it is not clear what is meant by "meat hygiene". Perhaps this should be clarified (i.e. replaced by "ante- and post-mortem inspection"). Indeed, steps after the slaughterhouse/cutting plant might no longer be the responsibility of Veterinary Services, and could be understood to be included in "meat hygiene".

3. <u>Foodborne disease outbreaks</u>

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 such *outbreaks* throughout the food chain and in formulating and 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 health professionals, analysts, epidemiologists, food producers, processors and traders and others involved.

EU comment

The EU does not agree with the first sentence of the paragraph above. Indeed, some authors consider cross-contamination in the kitchen to be far more important. In other cases, inappropriate storage or preparation (undercooking) plays a much more important role in causing an outbreak. Thus, the EU suggests amending the sentence as follows:

"~~Most reported~~ Although outbreaks of foodborne disease in humans might be caused by inappropriate handling of food at any stage including the private kitchen, the initial ~~are due to~~ contamination of foods with zoonotic agents mostly occurs during primary production or processing".

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 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 35

NOTE:

The rationale for this new chapter is contained in the September 2014 report of the Scientific Commission and the *ad hoc* Group commissioned to develop it. (http://www.oie.int/fileadmin/Home/eng/Internationa_Standard_Setting/docs/pdf/ SCAD/A_SCAD_Sept2014.pdf)

DRAFT CHAPTER 8.X.

INFECTION WITH *MYCOBACTERIUM TUBERCULOSIS* COMPLEX

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.X.1.

General provisions

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

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

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

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

1) Bovids: this term means cattle (*Bos taurus*, *B. indicus, B. frontalis, B. javanicus* and *B. grunniens*), water buffaloes *(Bubalus bubalis)*, and bison (*Bison bison* and *B. bonasus*).

2) Cervids: this term means red deer *(Cervus elaphus elaphus)*, wapiti/elk *(C. elaphus canadensis)*, sika *(C. nippon)*, samba (C. unicolor unicolor), rusa (C. timorensis), roe deer (Capreolus capreolus), fallow deer *(Dama dama)*, white-tailed, black-tailed and mule deer (*Odocoileus* spp.) and reindeer/caribou *(Rangifer tarandus)*.

3) Goats *(Capra hircus)*.

~~4) New World Camelids (under study).~~

EU comment

The EU in general supports the deletion of New World Camelids, previously proposed for inclusion "under study". However, given the increasing international movement of this category of animals, the Code Commission should continue to assess their possible future inclusion in this chapter, especially in light of progress in the area of the

diagnostic tests described in the Terrestrial Manual, and the fact that these animals can indeed be infected with *Mycobacterium tuberculosis* complex pathogens.

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

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

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

OR

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

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

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

Article 8.X.2.

Safe commodities

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

1) *fresh meat* and *meat products* originating from animals that have been subjected to ante- and post-mortem inspection as described in Chapter 6.2.;

2) cured hides, skins and trophies;

3) gelatine, collagen, tallow and *meat-and-bone meal*.

Article 8.X.3.

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

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

Article 8.X.4.

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

1) To qualify as free from *infection* with *M. tuberculosis* complex in bovids, a country or *zone* should satisfy the following requirements:

   a) *infection* in animals is a *notifiable disease* in the entire country;

   b) regular testing of all *herds* has been in place for at least three years and for the past three years this testing has demonstrated that *infection* with *M. tuberculosis* complex was not present in at least 99.8 % of the *herds* representing at least 99.9 % of the bovids in the country or *zone*;

EU comment

In point 1b) above, the EU suggests inserting the following wording for consistency with point 2b) below:

"<u>a surveillance programme based on</u> regular testing of [...]".

The same comment would also be valid for Article 8.X.5.

c) a *surveillance* programme is in place to detect *infection* with *M. tuberculosis* complex in the country or *zone* through ante- and post-mortem inspection <u>of bovids</u> as described in Chapter 6.2.;

EU comment

In point 1 c) above, the EU suggests referring also to Chapter 1.4. "Animal health surveillance". Indeed, point 1d) of Article 1.4.5. specifically addresses "ante-mortem and post-mortem inspections" as "structured non-random surveillance".

The same comment would also be valid for Article 8.X.5.

d) regulatory measures have been implemented for the early detection of *infection* with *M. tuberculosis* complex in bovids;

e) bovids and their germplasm introduced into the country or *zone* comply with the recommendations in Articles 8.X.7., 8.X.10. and 8.X.12.

2) To maintain the status as free from *infection* with *M. tuberculosis* complex in bovids, a country or *zone* should satisfy the following requirements:

a) the requirements in points 1a), 1c), 1d) and 1e) are met;

b) a *surveillance* programme based on regular testing of bovids is in place in the country or *zone* to detect *infection* with *M. tuberculosis* complex in accordance with Article 1.4.4.;

c) once the *surveillance* programme described in point b) has demonstrated that *infection* with *M. tuberculosis* complex has not been present in at least 99.8 % of the *herds* representing 99.9 % of the bovids in the country or *zone* for two consecutive years, *surveillance* may be maintained through ante- and post-mortem inspection as described in Chapter 6.2.;

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

Article 8.X.5.

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

1) To qualify as free from *infection* with *M. tuberculosis* complex in cervids, a country or *zone* should satisfy the following requirements:

a) *infection* with *M. tuberculosis* complex in animals is a *notifiable disease* in the entire country;

b) regular testing of all cervid *herds* has been in place for at least three years and for the past three years this testing has demonstrated that *infection* with *M. tuberculosis* complex was not present in at least 99.8 % of the *herds* representing at least 99.9 % of the cervids in the country or *zone*;

c) a *surveillance* programme is in place to detect *infection* with *M. tuberculosis* complex in the country or *zone* through ante- and post-mortem inspection <u>of cervids</u> as described in Chapter 6.2.;

d) regulatory measures have been implemented for the early detection of *infection* with *M. tuberculosis* complex in cervids;

e) cervids and their germplasm introduced into the country or *zone* comply with the recommendations in Articles 8.X.7., 8.X.11. and 8.X.12.

2) To maintain the status as free from *infection* with *M. tuberculosis* complex in cervids, a country or *zone* should satisfy the following requirements:

   a) the requirements in points 1a), 1c), 1d) and 1e) are met;

   b) a *surveillance* programme based on regular testing of cervids is in place in the country or *zone* to detect *infection* with *M. tuberculosis* complex in accordance with Article 1.4.4.;

   c) once the *surveillance* programme described in point b) has demonstrated that *infection* with *M. tuberculosis* complex has not been present in at least 99.8 % of the *herds* representing 99.9 % of the cervids in the country or *zone* for two consecutive years, *surveillance* may be maintained through ante- and post-mortem inspection as described in Chapter 6.2.;

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

Article 8.X.6.

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

1) To qualify as free from *infection* with *M. tuberculosis* complex, a *herd* of bovids or cervids should satisfy the following requirements:

   a) the *herd* is in a country or *zone* free from *infection* with *M. tuberculosis* complex in bovids or in cervids and is certified free by the *Veterinary Authority*;

   OR

   b) the *herd* meets the following conditions:

      i) *infection* with *M. tuberculosis* complex in animals is a *notifiable disease* in the entire country;

      ii) no evidence of *infection* with *M. tuberculosis* complex has been detected in the *herd* for at least the past 12 months;

      iii) bovids or cervids in the *herd* have shown no clinical signs of *infection* with *M. tuberculosis* complex or lesions at ante- or post-mortem inspection for at least the past 12 months;

      iv) two tests have been performed with negative results at a minimum interval of six months on all bovids or cervids over six weeks of age present in the *herd* at the time of testing. The first test was performed at least six months after the removal of the last *case*;

      v) bovids or cervids and their germplasm introduced into the *herd* comply with Articles 8.X.7., 8.X.10., 8.X.11. and 8.X.12.;

      vi) for at least the past 12 months, there has been no evidence of *infection* with *M. tuberculosis* complex in other *herds* of the same *establishments* or measures have been implemented to prevent any transmission of *infection* with *M. tuberculosis* complex from these other *herds*;

2) to maintain the free status, either:

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

   OR

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

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

      OR

      ii) showed a negative result to a test every two years to ensure the continuing absence of *infection* with *M. tuberculosis* complex if it has been confirmed that the annual percentage of *herds* infected

with *M. tuberculosis* complex is not more than 1% of all *herds* in the country or *zone* during the past two years;

OR

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

OR

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

OR

c) When there is a known *wildlife* reservoir of *M. tuberculosis* complex, all herds in the country or zone are covered by a *surveillance* programme in accordance with section 1c of Articles 8.X.4 and 8.X.5 and all herds identified as being at risk of *infection* with *M. tuberculosis* complex, based on;

i) a location associated with suspected or confirmed *infection* with *M. tuberculosis* complex in *wildlife*; or

ii) a history of *infection* with *M. tuberculosis* complex within last five years; or

iii) an epidemiological link with herds in c) i) or ii);

are subjected to a testing programme commensurate with the assessed epidemiological risk of *infection* with *M. tuberculosis* complex.

EU comment

The EU queries the relation between points 2a), b) and c) above, which are separated by an "or". Indeed, point 2c) is the only place in this article where the situation in wildlife is considered. This is most confusing, as it seems to suggest that for the rest of the article, the situation in wildlife does not play a role. Furthermore, the exact meaning of point 2c) is not clear and seems much less restrictive than the other options in point 2.

Thus, the EU suggests either replacing the "or" between points 2b) and 2c) by an "and" or to turn point 2c) into a separate point 3.

In addition, the location of the known wildlife reservoir could be clearer, as follows:

"When there is a known *wildlife* reservoir of *M. tuberculosis* complex in the country or zone, all herds in the country or zone are covered by [...]".

Finally, the EU suggests clarifying what is meant by "a testing programme" in point 2c). Indeed, there should either be a cross reference to points 2b) of Articles 8.X.4 and 8.X.5 or to Chapter 1.4.

Article 8.X.7.

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

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

1) showed no clinical signs of *infection* with *M. tuberculosis* complex on the day of shipment;

2) a) originate from a *herd* free from *infection* with *M. tuberculosis* complex that is in a country or *zone* free from *infection* with *M. tuberculosis* complex; or

b) originate from a *herd* free from *infection* with *M. tuberculosis* complex and have been tested for *infection* with *M. tuberculosis* complex with negative results within 30 days prior to shipment; or

c) have been isolated for at least ~~90 days~~ six months prior to shipment including protection from contact with ~~animal~~ any reservoirs of *M. tuberculosis* complex and all isolated animals showed negative results to at least two consecutive tests carried out at a six-month interval, with the second test performed within 30 days prior to shipment.

Article 8.X.8.

Recommendations for the importation of goats for breeding or rearing

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

1) *infection* with *M. tuberculosis* complex in animals is a *notifiable disease* in the entire country;

2) the goats showed no clinical signs of *infection* with *M. tuberculosis* complex on the day of shipment;

3) either:

a) the goats ~~were~~ have been kept since birth or for at least six months prior to shipment in *herds* in which no *case* of *infection* with *M. tuberculosis* complex has been detected for the past three years; or

b) have been isolated for at least six months prior to shipment including protection from contact with any reservoir of *M. tuberculosis* complex and all isolated animals showed negative results to at least two consecutive tests carried out at a six-month interval, with the second test performed within 30 days prior to shipment.

Article 8.X.9.

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

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

1) showed no clinical signs of *infection* with *M. tuberculosis* complex on the day of shipment;

2) a) originate from a country, *zone* or *herd* free from *infection* with *M. tuberculosis* complex; or

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

Article 8.X.10.

Recommendations for the importation of semen of bovids

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

1) the donor males showed no clinical signs of *infection* with *M. tuberculosis* complex on the day of collection of the semen;

2) the donor males ~~either~~:

a) were kept in an *artificial insemination centre* complying with the provisions of Chapter 4.5. and complied with Article 4.6.2.; or

b) were kept in a herd free from *infection* with *M. tuberculosis* complex that is in a country or zone free from *infection* with *M. tuberculosis* complex; or

~~b~~c) were kept in a *herd* free from *infection* with *M. tuberculosis* complex and showed negative results to a test~~s carried out annually and the semen~~ performed within 30 days prior to collection of the semen,

which was collected, processed and stored in ~~conformity~~ accordance with ~~the provisions of~~ Articles 4.5.~~3~~4.~~,~~ ~~to~~ 4.5.5.~~,~~ and ~~Articles~~ 4.6.5. to 4.6.7.

Article 8.X.11.

Recommendations for the importation of semen of cervids

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

1) the donor males showed no clinical signs of *infection* with *M. tuberculosis* complex on the day of collection of the semen;

2) the donor males either:

   a) were kept in a *herd* free from *infection* with *M. tuberculosis* complex in a country or *zone* free from *infection* with *M. tuberculosis* complex ~~and which only accepts cervids from free *herds* in a free country, or *zone*~~; or

   b) were kept in a *herd* free from *infection* with *M. tuberculosis* complex and showed negative results to a test~~s carried out annually and the semen~~ performed within 30 days prior to collection of the semen, which was collected, processed and stored in ~~conformity~~ accordance with ~~the provisions of~~ Articles 4.5.~~3~~4.~~,~~ ~~to~~ 4.5.5.~~,~~ and ~~Articles~~ 4.6.5. to 4.6.7.

Article 8.X.12.

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

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

1) the donor females either:

   a) originated from a *herd* free from *infection* with *M. tuberculosis* complex in a country or *zone* free from *infection* with *M. tuberculosis* complex; or

   b) were kept in a *herd* free from *infection* with *M. tuberculosis* complex, and were subjected to a test for *infection* with *M. tuberculosis* complex with negative results during an isolation period of 30 days in the *establishment* of origin prior to collection;

2) the semen used for embryo production complied with Article 8.X.10. or 8.X.11.

~~2~~3) the embryos were collected, processed and stored in accordance with the relevant provisions of Chapters 4.7. to 4.9.

Article 8.X.13.

Recommendations for the importation of milk and milk products of bovids

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

1) have been derived from bovids in a *herd* free from *infection* with *M. tuberculosis* complex; or

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

Article 8.X.14.

Recommendations for the importation of milk and milk products of goats

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

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

OR

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

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— Text deleted.

Annex 36

NOTE:

The rationale for the proposed new chapter is contained in the January 2016 report of the Scientific Commission and the ad hoc Group commissioned to develop it. (http://www.oie.int/en/international-standard-setting/specialists-commissions-groups/scientific-commission-reports/meetings-reports/)

CHAPTER 11.11.

INFECTION WITH LUMPY SKIN DISEASE VIRUS

EU comment

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

Article 11.11.1.

General provisions

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

EU comment

The use of the word "occasionally" seems odd in the sentence above. Indeed, either certain wild ruminants are susceptible, or they are not (i.e. they cannot be susceptible on occasion). The intended meaning (that not all, but some species of wild ruminants are susceptible) seems adequately reflected by the word "certain". The EU therefore suggests deleting the word "occasionally".

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

The following defines *infection* with LSDV:

1) LSDV has been isolated; or

EU comment

For clarity reasons, the EU suggests amending point 1) above as follows:

"1) LSDV has been isolated <u>from cattle or water buffaloes</u>; or".

2) antigen or nucleic acid specific to LSDV, excluding vaccine strains, has been identified in a sample from cattle or water buffaloes showing clinical signs consistent with LSD, or epidemiologically linked to a suspected or confirmed *case*, or giving cause for suspicion of previous association or contact with LSDV; or

3) antibodies specific to LSDV, which are not a consequence of vaccination, have been identified in a sample from cattle or water buffaloes that either show clinical signs consistent with LSD, or epidemiologically linked to a suspected or confirmed *case*.

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

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

Article 11.11.2

Safe commodities

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

1) skeletal muscle *meat*;

EU comment

The EU in general supports the listing of skeletal muscle meat as a safe commodity. At the same time, it is not clear why only skeletal muscle meat is listed here, i.e. certain organs (such as heart, liver etc.) are excluded (and require heat treatment as recommended in Article 11.11.12.). No explanation is provided for this in the *ad hoc* group report. As scientific information on the persistence of LSDV in meat seems to be scarce, further research should be conducted in this field.

2) casings;

3) gelatine and collagen;

4) tallow;

5) hooves;

6) horns.

Article 11.11.3.

Country or zone free from LSD

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

1) the country or *zone* is historically free as described in point 1 a) of Article 1.4.6.; or

2) the country or *zone* has prohibited *vaccination*, has not reported any *case* of *infection* with LSDV and a clinical *surveillance* programme in accordance with Article 11.11.14. has demonstrated no evidence of *infection* with LSDV in the country or *zone* for at least three years; or

3) the country or *zone* has prohibited *vaccination*, has not reported any *case* of *infection* with LSDV and a clinical, virological and serological *surveillance* programme in accordance with Article 11.11.14. has demonstrated no evidence of *infection* with LSDV in the country or *zone* for at least two years.

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

EU comment

For clarity reasons, the EU suggests replacing the word "area" by the words "country or zone" in the sentence above. This would also be in line with the relevant recommendation in the chapter on bluetongue.

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

EU comment

The EU suggests adding provisions to the article above for regaining freedom. Indeed, it would be very important to have clear recommendations on how and when a previously free country or zone would regain freedom after having successfully eradicated an LSD incursion, with or without use of vaccination. In addition, regaining freedom after using preventive vaccination without disease incursion should be addressed as well.

Article 11.11.4.

Recommendations for importation from countries or zones free from LSD

For domestic cattle and water buffaloes

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

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

Article 11.11.5.

Recommendations for importation from countries or zones not free from LSD

For domestic cattle and water buffaloes

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

1) showed no clinical sign of LSD on the day of shipment;
2) were kept since birth, or for the past 60 days prior to shipment, in an *epidemiological unit* where no *case* of LSD occurred during that period;
3) were vaccinated against LSD according to manufacturer's instructions at least 60 days prior to shipment;
4) were demonstrated to have antibodies at least 30 days after *vaccination*;

EU comment

While in general supporting point 4) above, the EU would like to point out that currently there are no commercially available serological tests for LSD, and that according to the Terrestrial Manual, all existing serological tests have limitations.

5) were kept in a *quarantine station* for the 28 days prior to shipment.

Article 11.11.6.

Recommendations for importation from countries or zones free from LSD

For semen of cattle and water buffaloes

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

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

Article 11.11.7.

Recommendations for importation from countries or zones not free from LSD

For semen of cattle and water buffaloes

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

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

      OR

      iii) were subjected to a serological test to detect antibodies specific to LSDV, with negative results, at least every 14 days throughout the collection period and one test 14 days after the final collection for this consignment; and
      iv) were subjected to agent detection by PCR conducted on blood samples collected at commencement and conclusion of, and at least every 14 days during, semen collection for this consignment, with negative results; and
      v) the semen to be exported was subjected to agent detection by PCR;
2) the semen was collected, processed and stored in accordance with Chapters 4.5. and 4.6.

Article 11.11.8.

Recommendations for importation from countries or zones free from LSD

For embryos of cattle and water buffaloes

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

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

Article 11.11.9.

Recommendations for importation from countries or zones not free from LSD

For embryos of cattle and water buffaloes

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

1) the donor females:
   a) showed no clinical sign of LSD on the day of collection and the following 28 days;
   b) were kept in an *establishment* where no *case* of LSD occurred during the 60 days prior to collection;

c) and EITHER:

i) were regularly vaccinated against LSD according to manufacturer's instructions, the first vaccination being administrated at least 60 days prior to the first collection; and

ii) were demonstrated to have antibodies against LSDV at least 30 days after vaccination;

OR

iii) were subjected to a serological test to detect antibodies specific to LSDV, with negative results, on the day of collection and at least 21 after collection; and

iv) were subjected to agent detection by PCR with negative results on a blood sample on the day of collection;

2) the semen used for the production of the embryos complied with Articles 11.11.6. or 11.11.7. as relevant;

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

Article 11.11.10.

Recommendations for the importation of milk and milk products

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

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

OR

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

Article 11.11.11.

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

EU comment

It is unclear what products are covered by this article, and what is meant by "agricultural or industrial use". Therefore, this should preferably be clarified; at least it should be stated that these would be non-food and non-feed uses.

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

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

EU comment

The EU is of the opinion that the guarantees given in the option 1 above are not sufficient. Indeed, the animals from which these products have been derived should be free from clinical signs, and the residence period seems too short as it corresponds to the incubation period, whereas the infectivity is longer than that. Thus, 40 days as referred to in Article 11.11.13. of the current version of the chapter would be preferable also here.

2) these products have been processed to ensure the destruction of the LSDV.

Article 11.11.12.

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

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

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

2) a) the products were processed using heat treatment to a minimum internal temperature of 65°C for at least 30 minutes;

   b) the necessary precautions were taken after processing to avoid contact of the *commodities* with any potential source of LSDV.

Article 11.11.13.

Recommendations for importation of hides of cattle and water buffaloes

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

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

EU comment

As for the EU comment above, the EU is of the opinion that the guarantees given in the option 1 of this article are not sufficient. Indeed, the animals from which these products have been derived should be free from clinical signs, and the residence period seems too short as it corresponds to the incubation period, whereas the infectivity is longer than that. Thus, 40 days as referred to in Article 11.11.13. of the current version of the chapter would be preferable also here.

2) these products had been processed to ensure the destruction of LSDV, in premises controlled and approved by the *Veterinary Authority* of the *exporting country*.

Article 11.11.14.

Surveillance

1. General principles of surveillance

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

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

In particular Member Countries should have in place:

a) a formal and ongoing system for detecting and investigating *outbreaks* of *disease*;

b) a procedure for the rapid collection and transport of samples from suspected *cases* of *infection* with LSDV to a *laboratory* for diagnosis;

c) a system for recording, managing and analysing diagnostic and *surveillance* data.

2) Clinical surveillance

Clinical *surveillance* requires the physical examination of susceptible animals.

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

3) Virological and serological surveillance

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

The study population used for a serological survey should be representative of the population at risk in the country or *zone* and should include susceptible unvaccinated animals.

4. Surveillance in high risk areas

Disease specific enhanced *surveillance* in a free country or *zone* should be carried out over an appropriate distance from the border with an infected country or *zone*, based upon geography, climate, history of *infection* and other relevant factors. The *surveillance* should be carried out over a distance of at least 20 kilometres from the border with that country or *zone*, but a lesser distance could be acceptable if there are relevant ecological or geographical features likely to interrupt the transmission of LSDV. A country or *zone* free from LSD may be protected from an adjacent infected country or *zone* by a *protection zone*.

— Text deleted.

Annex 37

CHAPTER 15.1.

INFECTION WITH AFRICAN 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 15.1.1.

General provisions

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

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

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

– *wild* and *feral* pigs;

– African *wild* suid species.

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

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

The following defines *infection* with ASFV:

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

OR

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

OR

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

~~A Member Country should not impose bans on the trade in *commodities* of domestic and or *captive wild* pigs in response to a *notification* of *infection* with ASFV in *wild* and or *feral* pigs or African *wild* suids provided that Article 15.1.2. is implemented.~~

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

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

Article 15.1.2.

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

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

1) ASF ~~should be~~ is a *notifiable* *disease* in the entire ~~whole~~ country, and all suids showing clinical signs suggestive of ASF are subjected to appropriate field and *laboratory* investigations;

2) an ongoing awareness programme is in place to encourage reporting of all ~~cases~~ suids showing signs suggestive of ASF;

3) the *Veterinary Authority* has current knowledge of, and authority over, all domestic and *captive wild* pig *herds* in the country, *zone* or *compartment*;

4) the *Veterinary Authority* has current knowledge of ~~about~~ the species of *wild* and *feral* suids present, their distribution, ~~population~~ and habitat ~~of wild suids pigs~~ in the country or *zone*~~.~~;

5) for domestic and *captive wild* pigs, an appropriate *surveillance* programme in accordance with Articles 15.1.22. to 15.1.25. and 15.1.27. is in place;

6) for *wild* and *feral* pigs, and for African *wild* suids, if present in the country or *zone*, a *surveillance* programme is in place ~~according to~~ in accordance with Article 15.1.26., ~~taking into account~~ considering the presence of natural and artificial boundaries, the ecology of the *wild* and *feral* pig and African *wild* suid populations and an assessment of the ~~*risk*~~ likelihood of ~~*disease*~~ ASF spread including taking into account the presence of *Ornithodoros* ticks;

7) based on the assessed ~~*risk*~~ likelihood of spread within the *wild* and *feral* pig and African *wild* suid populations, and ~~according to~~ *surveillance* in accordance with Article 15.1.26., the domestic and *captive wild* pig population should be separated by appropriate *biosecurity* ~~measures~~, effectively implemented and supervised, from the *wild* and *feral* pig and African *wild* suid populations and protected from *Ornithodoros* ticks ~~by appropriate measures~~.

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

EU comment

For clarity reasons, the EU suggests slightly amending the wording of the sentence above, by replacing the words "according to" by the words "in accordance with". Indeed, it is important to emphasise the intended meaning, i.e. that trade is safe as long as the OIE recommendations are complied with.

Article 15.1.3.

Country or zone free from ASF ~~free country, zone or compartment~~

1. ~~Historically free status~~ Historical freedom

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

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

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

   a) *surveillance* in accordance with Articles 15.1.22. to 15.1.27. has been in place for the past three years;

   b) there has been no *case* of *infection* with ASFV during the past three years; this period can be reduced to 12 months when the *surveillance* demonstrates no evidence of presence of *Ornithodoros* ticks;

   c) pig *commodities* are imported in accordance with Articles 15.1.5. to 15.1.17.

3. Freedom in domestic and captive wild pigs

   A country or *zone* which does not meet the conditions of point 1 or 2 above ~~or a *compartment*~~ may be

considered free from ASF in domestic and *captive wild* pigs when it complies with all the criteria of Article 15.1.2. and when:

a) *surveillance* in accordance with Articles 15.1.22. to 15.1.27. has been in place for the past three years;

~~a~~b) there has been no ~~*outbreak*~~ *case* of *infection* with ASF~~V~~ in domestic ~~and~~ or *captive wild* pigs during the past ~~12 months~~ three years; this period can be reduced to 12 months when ~~there is no evidence of tick involvement in the epidemiology of the *infection*~~ the *surveillance* demonstrates no evidence of presence of *Ornithodoros* ticks;

~~b) no evidence of ASFV *infection* with ASFV in domestic and *captive wild* pigs has been found during the past 12 months~~;

~~bc) *surveillance* in accordance with Articles 15.1.22. to 15.1.27. has been in place in domestic and *captive wild* pigs for the past 12 months;~~

~~d~~c) ~~imported domestic and *captive wild*~~ pigs and pig *commodities* are imported in accordance ~~comply~~ with ~~the requirements of~~ ~~in~~ Article~~s~~ 15.1.5. ~~or~~ to ~~Article~~ 15.1.~~6~~17.

~~AND~~

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

~~e) there has been no clinical evidence, nor virological evidence of ASF in wild pigs during the past 12 months;~~

~~f) no seropositive wild pigs have been detected in the age class 6–12 months during the past 12 months;~~

~~g) imported wild pigs comply with the requirements in Article 15.1.7.~~

Article 15.1.3bis.

Compartment free from ASF

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

Article 15.1.3ter.

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

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

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

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

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

Article 15.1.4.

Recovery of free status

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

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

1) ~~three months after the last *case* where~~ a *stamping-out policy* ~~is~~ has been implemented ~~practised and in the case where ticks are suspected to be involved in the epidemiology of the *infection*~~, followed by ~~acaricide~~

~~treatment and~~ the use of sentinel pigs in the infected *establishments* for two months; ~~or~~

EU comment

The EU reiterates its comment submitted previously that sentinel pigs would only be appropriate in regions where ticks are involved in the epidemiology of the disease. Indeed, ASFV is a highly resistant virus, however only when protected in a protein rich matrix such as meat or blood. ASFV survives also in faeces and urine but only during limited periods of time (≤1-2 weeks; Davies *et al*. Transbound Emerg Dis. 2015 Jun 24. doi: 10.1111/tbed.12381). On the other hand, survival in the environment after thorough cleansing and disinfection of an infected premise as required as part of the stamping-out policy is limited.

Thus, the EU does not agree with the changes to point 1 above, which should be reverted back to the previous wording as regards tick involvement, as follows:

"1) a stamping-out policy has been implemented and in the case where ticks are suspected to be involved in the epidemiology of the infection followed by acaricide treatment and the use of sentinel pigs in the infected establishments for two months; "

2) *surveillance* in accordance with Article 15.1.25. has been carried out with negative results.

~~2)~~ ~~where a *stamping-out policy* is not practised~~ Otherwise, the provisions of point 2 of Article 15.1.3. apply ~~should be followed~~.

~~AND~~

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

Article 15.1.5.

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

For domestic and *captive wild* pigs

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

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

2) the animals were kept in a~~n ASF free~~ country, *zone* or *compartment* free from ASF since birth or for at least the past ~~40 days~~ three months.

3) if the animals are exported from a free *zone* or *compartment* within an *infected* country or *zone*, necessary precautions were taken to avoid contact with any source of ASFV.

Article 15.1.6.

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

For domestic and *captive wild* pigs

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

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

2) and either:

a) were kept since birth or for the past ~~40 days~~ three months in a~~n ASF free~~ *compartment* free from ASF~~.~~; or

b) were kept in a *quarantine station*, isolated for 30 days prior to shipment, and were subjected to a virological test and a serological test performed at least 21 days after entry into the *quarantine station*, with negative results.

~~Article 15.1.7.~~

~~**Recommendations for importation from ASF free countries or zones**~~

~~For wild pigs~~

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

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

~~2) have been captured in an ASF free country or *zone*;~~

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

~~3) were kept in a *quarantine station* for 40 days prior to shipment, and were subjected to a virological test and a serological test performed at least 21 days after entry into the *quarantine station*, with negative results.~~

EU comment

The EU reiterates its previous editorial comment: as Article 15.1.7. above (as well as Article 15.1.15. below) is being deleted, the numbering of subsequent articles should be changed accordingly.

Article 15.1.8.

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

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~~n ASF free~~ country, *zone* or *compartment* free from ASF since birth or for at least ~~40 days~~ three months prior to collection;

   b) showed no clinical sign of ASF on the day of collection of the semen;

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

Article 15.1.9.

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

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 an ASF free *establishment* *compartment* free from ASF~~ since birth or for at least ~~40 days~~ three months prior to collection in an *establishment*, in which *surveillance* in accordance with Articles 15.1.22. to 15.1.24 demonstrates that no *case* of ASF has occurred in the past three years; this period can be reduced to 12 months when the *surveillance* demonstrates that there is no evidence of tick involvement in the epidemiology of the *infection*;

   b) showed no clinical sign of ASF on the day of collection of the semen ~~and for the following 40~~ 30 ~~days~~;

   ~~c) were subjected to a serological test performed at least 21 days after collection, with negative results;~~

2) the semen was collected, processed and stored in ~~conformity~~ accordance with ~~the provisions of~~ Chapters

4.5. and 4.6.

Article 15.1.10.

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

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 an ASF free country, *zone* or *compartment* since birth or for at least 40 days prior to collection;~~

   a) were kept in a country, *zone* or *compartment* free from ASF since birth or for at least three months prior to collection;

   b) showed no clinical sign of ASF on the day of collection of the embryos;

2) the embryos were collected, processed and stored in ~~conformity~~ accordance with the relevant provisions of Chapters 4.7. and 4.9.~~, as relevant.~~

Article 15.1.11.

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

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 an ASF free *compartment* free from ASF~~ since birth or for at least ~~40 days~~ three months prior to collection in an *establishment,* in which *surveillance* in accordance with Articles 15.1.22. to 15.1.24 demonstrates that no *case* of ASF has occurred in the past three years; this period can be reduced to 12 months when the *surveillance* demonstrates that there is no evidence of tick involvement in the epidemiology of the *infection*;

   b) showed no clinical sign of ASF on the day of collection of the embryos ~~and for the following 40~~ 30 days;

   c) were subjected to a serological test performed at least 21 days after collection, with negative results;

2) the embryos were collected, processed and stored in ~~conformity~~ accordance with the relevant provisions of Chapters 4.7. and 4.9.~~, as relevant.~~

Article 15.1.12.

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

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 which:

1) have been kept in a~~n ASF free~~ country, *zone* or *compartment* free from ASF since birth ~~or for at least the past 40 days,~~ or ~~which~~ have been imported or introduced in accordance with Article 15.1.5. or Article 15.1.6.;

2) have been slaughtered in an approved *slaughterhouse*/*abattoir*, where they have been subjected with favourable results to ante- and post-mortem inspections in accordance with Chapter 6.2.~~, and have been found free of~~ from ~~any sign suggestive of ASF.~~

Article 15.1.12.bis

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

For fresh meat of domestic and *captive wild* pigs

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

1) ~~the entire consignment of *fresh meat* comes from animals which have been slaughtered in an approved *slaughterhouse/abattoir*, have been subjected with favourable results to ante- and post-mortem inspections in accordance with Chapter 6.2., and have been found free from any sign suggestive of ASF;~~

~~2)~~

~~a)~~ the entire consignment of *fresh meat* comes from animals which originated from *herds* in which *surveillance* in accordance with Articles 15.1.22. to 15.1.24 demonstrates that no *case* of ASF has occurred in the past three years. This period can be reduced to 12 months when the *surveillance* demonstrates that there is no evidence of tick involvement in the epidemiology of the *infection*. ~~and~~ In addition, samples from a statistically representative number of animals were tested for ASF, with negative results; ~~or~~

~~b) appropriate samples have been collected from every animal killed slaughtered and been tested subjected to a virological test and a serological test for ASF, with negative results.~~

2) the entire consignment of *fresh meat* comes from animals which have been slaughtered in an approved *slaughterhouse/abattoir*, have been subjected with favourable results to ante- and post-mortem inspections in accordance with Chapter 6.2.;

3) necessary precautions have been taken after *slaughter* to avoid contact of the *fresh meat* with any source of ASFV

Article 15.1.13.

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

~~For fresh meat of wild pigs~~

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

~~1)~~ the entire consignment of *fresh meat* comes from animals which:

~~a~~1) ~~have been killed in an ASF free country or *zone*~~ have been killed in a country or *zone* free from ASF in accordance with point 1) or 2) of Article 15.1.3.;

~~b~~2) have been subjected with favourable results to a post-mortem inspection in accordance with Chapter 6.2. in an ~~approved~~ examination ~~centre~~ facility approved by the *Veterinary Authority* for export purposes, ~~and have been found free of any sign suggestive of ASF~~;

~~and,~~

~~2) if the country or the *zone* where the *animal* has been killed does not comply with the conditions of point 1 of Article 1.4.6., or is adjacent to a country or *zone* with an unknown infection status or with *infection* in *wild* or *feral* pigs or African wild suids,~~

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

Article 15.1.14.

Recommendations for the importation of meat products of pigs ~~(either domestic or wild), or for products of animal origin (from fresh meat of pigs) intended for use in animal feeding, for agricultural or industrial use, or for pharmaceutical or surgical use, or for trophies derived from wild pigs~~

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

1) have been prepared:

a) exclusively from *fresh meat* meeting the relevant conditions ~~laid down~~ in Articles 15.1.12. 15.1.12.bis ~~or~~ and 15.1.13.~~, as relevant~~;

b) in a processing ~~establishment~~ facility:

i) approved by the *Veterinary Authority* for export purposes;

ii) processing only *meat* meeting the relevant conditions ~~laid down~~ in Articles 15.1.12. or 15.1.13.~~, as relevant~~;

OR

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

~~Article 15.1.15.~~

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

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

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

~~a) exclusively from *fresh meat* meeting the conditions laid down in Articles 15.1.12. or 15.1.13., as relevant;~~

~~b) in a processing establishment:~~

~~i) approved by the *Veterinary Authority* for export purposes;~~

~~ii) processing only *meat* meeting the conditions laid down in Articles 15.1.12. or 15.1.13., as relevant;~~

~~OR~~

~~2) have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the ASFV, for swill in accordance with Article 15.1.18., and that the necessary precautions were taken after processing to avoid contact of the product with any source of ASFV.~~

Article 15.1.16.

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

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

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

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

~~Article 15.1.17.~~

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

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

~~1) come from an ASF free country, *zone* or *compartment*; or~~

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

Article 15.1.17. (Reinstated)

Recommendations for the importation of litter and manure from pigs

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

1) originated from domestic or *captive wild* pigs in a country, *zone* or *compartment* free from ASF; or

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

Article 15.1.17bis.

Recommendations for the importation of skins and trophies from suids

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

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

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

Article 15.1.17ter.

Recommendations for the importation of other pig products

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

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

OR

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

Article 15.1.18.

Procedures for the inactivation of ASFV in swill

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

1) the swill ~~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 ASFV.

Article 15.1.19.

Procedures for the inactivation of ASFV in meat

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

1. Heat treatment

Meat should be subjected to one of the following ~~treatments~~:

a) heat treatment in a hermetically sealed container with a Fo value of 3.00 or more; or

b) heat treatment for at least 30 minutes at a minimum temperature of 70°C, which should be reached throughout the *meat*.

2. Dry cured pig meat (under study)

a) if salted, *meat* should be cured and dried for a minimum of six months; or

b) if not salted, *meat* should be cured and dried for a minimum of 12 months.

Article 15.1.20.

Procedures for the inactivation of ASFV in casings of pigs

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

Article 15.1.21.

Procedures for the inactivation of ASFV in skins and trophies

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

1) boiling in water for an appropriate time so as to ensure that any matter other than bone, tusks or teeth is removed; or

2) soaking, with agitation, in a 4 % ~~percent~~ (w/v) solution of washing soda (sodium carbonate – Na_2CO_3) maintained at pH 11.5 or above for at least 48 hours; or

3) soaking, with agitation, in a formic acid solution (100 kg salt [NaCl] and 12 kg formic acid per 1,000 litres water) maintained at below pH 3.0 for at least 48 hours; wetting and dressing agents may be added; or

4) in the case of raw hides, treating for at least 28 days with salt (NaCl) containing 2 % ~~percent~~ washing soda (sodium carbonate – Na_2CO_3); or

5) treatment with 1 % ~~percent~~ formalin for a minimum of six days.

Article 15.1.21bis.

Procedures for the inactivation of ASFV in bristles

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

1) boiling for at least 30 minutes;

2) immersion for at least 24 hours in a 1% solution of formaldehyde prepared from 30 ml commercial formalin per litre of water.

Article 15.1.21ter.

Procedures for the inactivation of ASFV in litter and manure ~~and litter~~ from pigs ~~(under study)~~

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

1) moist heat treatment for at least one hour at a minimum temperature of 55°C

2) moist heat treatment for at least 30 minutes at a minimum temperature of 70°C

Article 15.1.22.

Introduction to surveillance

Articles 15.1.22. to 15.1.27. ~~define the principles and~~ provide ~~a~~ recommendations for ~~guide on the~~ *surveillance* for ASF, and are complementary to Chapter 1.4. and Chapter 1.5.~~, applicable to Member Countries seeking to determine their ASF status. This may be for the entire country or a *zone*. Guidance is also provided for Member Countries seeking recovery of ASF free status for the entire country or for a *zone* following an *outbreak* and for the maintenance of ASF free status.~~

The impact and epidemiology of ASF may vary in different regions of the world~~.~~, as does the routine *biosecurity* ~~measures~~ in different production systems. The *surveillance* strategies employed for determining ~~demonstrating freedom from~~ ASF status should be adapted to the ~~regional or sub-regional~~ situation. ~~For example,~~ ~~the~~ The approach used should take into account ~~be tailored in order to demonstrate freedom from ASF for a country or *zone* where~~ the presence of *wild* ~~and~~ or *feral* pigs or African *wild* suids, the presence of *Ornithodoros* ticks, ~~provide a potential reservoir of *infection*,~~ ~~or~~ and the presence of ~~where~~ ASF ~~is present~~ in adjacent countries or *zones*. ~~The method should examine the epidemiology of ASF 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 demonstrate that absence of *infection* with ASFV is assured at an acceptable level of confidence.~~

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

– the role of swill feeding;

– the impact of different production systems;

– the role of *wild* and *feral* pigs and African *wild* suids on the maintenance and spread of the *disease*;

– whether *Ornithodoros* ticks are present and the role they may play in the maintenance and spread of the *disease*;

– ~~the role of semen in transmission of the ASFV;~~

– the lack of pathognomonic gross lesions and clinical signs;

– the occurrence of ~~apparently healthy~~ carriers;

– the genotypic variability of ASFV.

Article 15.1.23.

General conditions and methods for surveillance

1) A *surveillance* system in accordance with Chapter 1.4. and under the responsibility of the *Veterinary Authority* should address the following:

   a) a formal and ongoing system for detecting and investigating *outbreaks* of ASF;

   b) a procedure for the rapid collection and transport of samples from suspected *cases* to a *laboratory* ~~for ASF diagnosis~~;

   c) appropriate *laboratory* testing capability for ASF diagnosis;

   d~~e~~) a system for recording, managing and analysing diagnostic and *surveillance* data.

2) The ASF *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 ASF 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 para-professionals*) by government or private sector ~~information~~ awareness programmes targeted to all relevant stakeholders. Personnel responsible for *surveillance* should be able to seek expertise in ASF diagnosis, epidemiological evaluation and control;

b) conduct, when relevant, regular and frequent clinical inspections and *laboratory* testing of high-risk groups (for example, where swill feeding is practised), or those adjacent to an ASF infected country or *zone* (for example, bordering areas where infected *wild* and *feral* pigs or African *wild* suids are present).

Article 15.1.24.

Surveillance strategies

1. Introduction

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

~~The practicality of *surveillance* in African *wild* suids should be considered following the guidelines in Chapter 1.4.~~

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

a) specific high-risk *wild* and *feral* suid ~~pig~~ populations and their proximity;

b) farms which feed swill;

c) pigs reared outdoors.

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

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

– an emergence or an increase in the prevalence of ASF in countries or *zones* from which live pigs or products are imported;

– an increase in the prevalence of ASF in *wild* or *feral* suids ~~pigs~~ in the country or *zone*;

– an increase in the prevalence of ASF in adjacent countries or *zones*;

– an increased entry of, or exposure to, infected *wild* or *feral* suid ~~pig~~ populations ~~of~~ from adjacent countries or *zones*;

– evidence of involvement of ticks in the epidemiology of ASF as demonstrated by *surveillance* implemented in accordance with Chapter 1.5.

2. Clinical surveillance

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

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

Wild and *feral* suids ~~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 antibodies.

3. Virological surveillance

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

a) to investigate clinically suspected *cases*;

b) to monitor at risk populations;

c) to follow up positive serological results;

d) to investigate increased mortality when ASF cannot be ruled out;~~.~~

e) to confirm eradication after a *stamping-out policy* has been applied.

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

4. Serological surveillance

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

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

Article 15.1.25.

Surveillance procedures for recovery of free status

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

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

This *surveillance* programme should include:

1) *establishments* in the proximity of the *outbreaks*;

2) *establishments* epidemiologically linked to the *outbreaks*;

3) animals moved from or used as sentinels or to repopulate affected *establishments*;

4) all *establishments* where contiguous culling has been carried out;

5) *wild* and *feral* suid ~~pig~~ populations in the area of the *outbreaks*.

Article 15.1.26.

Surveillance for ASFV in wild and feral pigs and African wild suids

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

~~A similar approach should be taken with respect to African *wild* suids where appropriate. While the same principles apply, *surveillance*~~ *Surveillance* in *wild* and *feral* suids ~~pigs~~ presents additional challenges including:

a) determination of the distribution, size and movement patterns ~~associated with~~ of the *wild* and *feral* suid ~~pig~~ population;

b) relevance and practicality of assessing the possible presence of *infection* with ASFV ~~within~~ in the population;

c) determination of the practicability of establishing a *zone* taking into account the degree of interaction with domestic and *captive wild* pigs within the proposed *zone*.

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

2) For implementation of the *surveillance* programme, the limits of the area over which *wild* and *feral* pigs range should be defined. *Subpopulations* of *wild* and *feral* suid ~~pig~~ may be separated from each other by natural or artificial barriers.

3) The *surveillance* programme may ~~should~~ include animals found dead, road kills, animals showing abnormal behaviour and ~~or~~ hunted animals, and may also include awareness campaigns targeted at hunters and farmers.

4) There may be situations where a more targeted *surveillance* programme can provide additional assurance. The criteria to define high risk areas for targeted *surveillance* include:

a) areas with past history of ASF;

b) subregions with large populations of *wild* or ~~and~~ *feral* pigs or African *wild* suids;

c) border regions with ASF-affected countries or *zones*;

d) interface between *wild* and *feral* pig populations, and domestic and *captive wild* pig populations;

e) areas with farms with free-ranging and outdoor pigs;

f) areas with a high level of hunting activity, where animal dispersion and feeding as well as inappropriate disposal of waste can occur;

g) other risk areas determined by the *Veterinary Authority* such as ports, airports, garbage dumps and picnic and camping areas.

Article 15.1.27.

Surveillance for arthropod vectors

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

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

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

Sampling methods include CO_2 trapping and flagging, and vacuuming of burrows or structures.

EU comment

It is unclear to the EU what is meant by the term "flagging". The EU asks the OIE clarify that term in this connection.

— Text deleted.

Annex 38

NOTE:

The rationale for this new chapter is contained in the February 2014 and September 2015 Scientific Commission meeting reports. (http://www.oie.int/en/international-standard-setting/ specialists-commissions-groups/scientific-commission-reports/meetings-reports/)

CHAPTER 15.X.

INFECTION WITH PORCINE REPRODUCTIVE AND RESPIRATORY SYNDROME VIRUS

EU comment

The EU thanks the OIE for having taken some of its previous comments into account and in general supports this new chapter. However, important comments regarding fresh meat should be taken into account (see EU comment on Article 15.X.2. below). Further comments are inserted in the text below.

Article 15.X.1.

General provisions

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

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

The following defines *infection* with PRRSV:

1) a strain of PRRSV has been isolated from samples from a domestic or *captive wild* pig;

OR

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

OR

3) antigen or ribonucleic acid specific to a PRRSV vaccine strain has been detected in samples from a domestic or *captive wild* pig that is unvaccinated, or has been vaccinated with an inactivated vaccine, or with a different vaccine strain;

OR

~~3~~4) ~~virus-specific~~ antibodies specific ~~against~~ to PRRSV that are not a consequence of *vaccination*~~,~~ have been identified in samples from a domestic or *captive wild* pig in a *herd* showing clinical signs consistent with PRRS, or epidemiologically linked to a confirmed or suspected *outbreak* of PRRS, or giving cause for suspicion of previous association or contact with PRRSV.

~~OR~~

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

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

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

EU comment

For clarity reasons, the EU suggests slightly amending the wording of the sentence above, by replacing the words "according to" by the words "in accordance with". Indeed, it is important to emphasise the intended meaning, i.e. that trade is safe as long as the OIE recommendations are complied with.

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

Article 15.X.2.

Safe commodities

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

1) hides, skins and trophies;
2) bristles;
3) *meat products*;
4) *meat-and-bone meal*;
5) ~~blood by-products;~~
6) casings;
7) gelatine.

EU comment

The EU requests that fresh meat derived from pigs that have passed ante- and post-mortem inspections be included in the list of safe commodities, and consequently Article 15.X.12. be deleted.

The relevant scientific opinion of the European Food Safety Authority (http://www.efsa.europa.eu/en/efsajournal/pub/239) states that "*Historically, pig meat from PRRSv-infected countries has been imported into PRRSv free countries [...] over the past decade without any evidence of dissemination of PRRSv. [...] Thus, there is to date no documented field evidence to support or quantify the overall risk of importing PRRSv infected meat*".

Indeed, there is no scientific information suggesting that fresh meat poses a risk of transmission of PRRS under field conditions, and to date there is no evidence that trade in meat ever resulted in the introduction or spread of PRRSv. As regards spread across countries and continents, the OIE Manual chapter on PRRS rather states that "*it is assumed these viruses were introduced through the movement of swine or semen*"; however potential transmission via meat is not mentioned.

This is in line with the draft criteria for safe commodities as proposed by the OIE in Chapter 2.X. ("*There is strong evidence that the pathogenic agent is not present in the tissues from which the animal product is derived at a dose able to cause infection in a human or animal by a natural exposure route*"), and fresh meat should thus be listed in the article above.

Furthermore, the OIE ad hoc group on PRRS as well as the Scientific Commission for Animal Diseases had reached the same conclusion. The EU queries why the Code Commission has not proposed fresh meat to be included in the list of safe commodities, as this is not explained in the introduction to the report.

Article 15.X.3.

Country, zone or compartment free from PRRS

A country, *zone* or *compartment* may be considered free from PRRS when:

1) PRRS is a *notifiable disease* in the country;

2) an *early detection system* is in place;

3) *surveillance* in accordance with Articles 15.X.~~15~~13. to 15.X.~~18~~16. has been in place for at least 12 months, capable of detecting the presence of *infection* with PRRSV even in the absence of clinical signs;

4) no ~~evidence of~~ *infection* with PRRSV has been found in domestic and *captive wild* pigs during the past 12 months;

5) no *vaccination* against PRRS with inactivated vaccines has been carried out during the past 12 months;

6) no *vaccination* against PRRS with modified live vaccines has been carried out during the past 24 months;

~~6)~~7) measures are in place to prevent the introduction of PRRSV;

~~7)~~8) imported pigs and pig *commodities* comply with the requirements in Articles 15.X.5. to 15.X.~~14~~12.

Article 15.X.4.

Recovery of free status

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

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

EU comment

Since according to the latest glossary definition cleaning and disinfection are part of the stamping-out policy, there is a slight contradiction in the first indent above, as it seems to suggest that the stamping-out policy would be followed by cleaning and disinfection of the establishments, while the latter is indeed already part of the stamping-out policy itself. In order to remove all ambiguity, the EU suggests removing the comma after the words "infected herds".

– *surveillance* ~~is~~ has been carried out in accordance with Articles 15.X.~~15~~13. to 15.X.~~18~~16. with negative results.

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

Article 15.X.5.

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

For domestic and captive wild pigs

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

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

2) were kept in a country, *zone* or *compartment* free from PRRS since birth or for at least the past three months.

Article 15.X.6.

Recommendations for importation from countries or zones not free from PRRS

For domestic and captive wild pigs for breeding or rearing

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

1) were kept, since birth or for at least three months prior to isolation in an *establishment,* in which no *infection* with PRRSV was detected within that period;

2) showed no clinical sign of PRRS on the day of shipment;

~~2~~3) have not been vaccinated against PRRS nor are they the progeny of vaccinated sows;

~~3~~4) were isolated by application of *biosecurity* and subjected to a serological test for *infection* with PRRSV, with negative results, on two occasions, at an interval of not less than 21 days, the second test being performed within 15 days prior to shipment.

Article 15.X.7.

Recommendations for importation from countries or zones not free from PRRS

For domestic and captive wild pigs for slaughter

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

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

~~Article 15.X.8.~~

~~**Recommendations for importation of wild and feral pigs**~~

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

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

~~2) were isolated in a *quarantine station*, and were subjected to a serological test for PRRS, with negative results, on two occasions, at an interval of not less than 21 days, the second test being performed within 15 days prior to shipment;~~

~~3) have not been vaccinated against PRRS.~~

Article 15.X.~~9~~8.

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

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 PRRS since birth or for at least three months prior to collection;

   b) showed no clinical sign of PRRS on the day of collection of the semen;

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

Article 15.X.~~10~~9.

Recommendations for importation from countries or zones not free from PRRS

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 have not been vaccinated against PRRS and either:

   a) ~~and either~~:

      i) were kept, since birth or for at least three months prior to entry into the pre-entry isolation facility in an *establishment*, in which no *infection* with PRRSV was detected within that period ~~without any evidence of PRRS~~;

ii) showed no clinical sign of PRRS and were ~~serologically tested~~ subjected to a serological test with negative results on the day of entry into the pre-entry isolation facility;

iii) were kept in the pre-entry isolation facility for at least 28 days and were subjected to a serological test with negative results ~~at least~~ no less than 21 days after entry;

iv) have been kept in an *artificial insemination centre* where a statistically representative sample of all donor males is subjected ~~are all boars are subjected~~, ~~at least every month,~~ to a serological test for *infection* with PRRSV with negative results, at least every month. Donor males should be tested every 12 months and at least once during their stay;

EU comment

The EU is of the opinion that the way in which point 1 a) iv) above is drafted is a bit confusing. Indeed, from the 1st sentence it is not clear whether all donor males need to be subjected to the test at least every month, or if a subset of donor males needs to be tested every month (the latter is understood as the intended meaning, which would reflect the previous EU comment). Furthermore, from the 2nd sentence it is not clear whether all donor males should be tested at least once per year (or at least once during their stay if staying less than a year), and how this connects with the 1st sentence. Indeed, requiring each donor male to be tested at least once would seem overly prescriptive, given that already a statistically representative subset is being tested on a monthly basis. Consequently, the 1st sentence should be reworded for clarity reasons, and the 2nd sentence should be deleted.

The following alternative wording is suggested:

"iv) have been kept in an artificial insemination centre where at least every month a statistically representative sample of all donor males is subjected to a serological test for infection with PRRSV with negative results. ~~, at least every month. Donor males should be tested every 12 months and at least once during their stay.~~"

or

b) ~~or~~ have been kept in an *artificial insemination centre* where all pigs

i) ~~have been kept in an *artificial insemination centre* where all boars~~ were subjected to serologcial and virological examinations for *infection* with PRRSV, on serum samples taken ~~seronegative for PRRS~~ on the day of collection;

ii) ~~a sample of semen from each collection for export has been tested for PRRSV nucleic acid with negative results or~~

EU comment

The EU reiterates its comment submitted previously relating to point 1b) above, which is still relevant. Indeed, the whole of option 1b) above should be deleted because these conditions are unsound. This is because the health status of a porcine artificial insemination centre cannot be created instantly and tests for PRRS are not 100% sensitive and specific. These conditions could be significantly flawed especially if applied to a small population, and if it is intended that semen will be traded from an AI centre, then it is unlikely that such trade will be an isolated event. Moreover, it is impractical to test all boars serologically each day of semen collection. Option 1b) would have to be accompanied with recommendations for pre-entry isolation to be acceptable and would then essentially be identical to option 1a).

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

Article 15.X.~~11~~10.

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

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

1) the donor females were kept in a country, *zone* or *compartment* free from PRRS since birth or for at least three months prior to collection;

2) the donor females showed no clinical sign of PRRS on the day of collection ~~of the embryos~~;

3) the embryos were collected, processed and stored ~~in conformity with the relevant provisions of~~ in accordance with Chapters 4.7. ~~and~~ or 4.9., as relevant;

4) the semen used for the production of embryos complied with the provisions of Article 15.X.~~9~~8. or 15.X.~~10~~9.

Article 15.X.~~12~~11.

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

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

1) the donor females:

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

   b) were subjected to a serological test for *infection* with PRRSV, with negative results, on two occasions, at an interval of not less than 21 days, the second test being performed within 15 days prior to embryo collection;

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

3) the semen used for the production of embryos complied with the provisions of Article 15.X.~~9~~8. or 15.X.~~10~~9.

Article 15.X.12.

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

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

1) either:

   a) comes from pigs that were kept in a country, *zone* or *compartment* free from PRRS since birth or for at least the past three months;

   or

   b) does not contain:

      – tonsils;

      – thymus;

      – lymph nodes of the head, neck, or thoracic or abdominal viscera;

2) comes from pigs that have been slaughtered in a *slaughterhouse*/*abattoir* and have been subjected to ante- and post-mortem inspections in accordance with Chapter 6.2. with favourable results.

EU comment

As indicated in the EU comment on Article 15.X.2. above, the EU requests that fresh meat be included in the list of safe commodities. Indeed, there is no scientific justification to exclude the commodities listed in point 1b) above. Furthermore, it would be very difficult if not impossible to comply with the requirement of that point to remove all lymph nodes from the head and neck, resulting in a very negative impact on currently ongoing international trade that would not be justified. The article above should thus be deleted.

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

~~2) comes from *animals* which:~~

a) showed no clinical signs suggestive of PRRS within 24 hours before *slaughter*;

b) have been slaughtered in a *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections in accordance with Chapter 6.2.

Article 15.X.13.

Recommendations for importation of fresh meat of wild and feral pigs

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

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

2) comes from *animals* which:

a) have been subjected to a post-mortem inspection in accordance with Chapter 6.2. in an approved examination centre;

b) have been found free from any sign suggestive of PRRS.

Article 15.X.14.

Recommendations for importation of offal

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

Article 15.X.1513.

Introduction to surveillance

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

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

– the role of pig-to-pig contact;

– the role of semen in transmission of the virus;

– the existence occurrence of aerosol transmission over short distances;

– the existence of two distinct genotypes of PRRSV, also with antigenic and virulence variability among strains of both genotypes;

– the frequency of clinically inapparent *infections*, particularly in older *animals* pigs;

– the occurrence of long-term virus-shedding even in the presence of antibodies;

– the lack of a differentiating test for vaccinal antibodies and the inherent risks associated with the use of modified live vaccines for PRRS.

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

Article 15.X.1614.

General conditions and methods for surveillance

1) A *surveillance* system in accordance with Chapter 1.4. and under the responsibility of the *Veterinary Authority* should be in place and ~~including~~ include the following ~~aspects~~ elements:

   a) formal and on-going system for detecting and investigating *outbreaks* of PRRS;

   b) a system for recording, managing and analysing diagnostic and *surveillance* data.

2) ~~The~~ Any PRRS *surveillance* programme should:

   a) include ~~a system for~~ the reporting and investigation of suspected *cases*. Diagnosticians and those with regular contact with pigs should report promptly any suspicion of PRRS to the *Veterinary Authority*;

   b) implement, when relevant, regular and frequent clinical inspections and *laboratory* testing of populations at high risk of contracting or spreading *disease*, such as *artificial insemination centres* and nucleus *herds*, *establishments* in high pig density areas or with ~~low~~ lax *biosecurity* ~~measures~~.

Article 15.X.~~17~~15.

Surveillance strategies

1. Introduction

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

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

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

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

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

2. Clinical surveillance

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

3. Virological surveillance

   Virological *surveillance* should be conducted:

   a) to monitor at risk populations;

   b) to investigate clinically suspected cases;

   c) to follow up positive serological results.

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

4. Serological surveillance

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

Article 15.X.~~18~~16.

Additional surveillance requirements for recovery of free status

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

This *surveillance* programme should cover:

1) *establishments* in the proximity of the *outbreaks*;

2) *establishments* epidemiologically linked to the *outbreaks*;

3) ~~*animals*~~ pigs moved from or used to repopulate affected *establishments*.

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

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