Japan's Comments on
The Code Commission Report of the February 2015 meeting

Japan would like to express appreciation to the Terrestrial Animal Health Standards Commission (TAHSC) and other relevant Commissions, Working Groups and ad hoc Groups for all the works they have done and thanks the TAHSC for giving us the opportunity of offering comments on proposed revisions to the text of Terrestrial Animal Health Code.

Please find our comments on the following texts:

1. Chapter 15.1. Infection with African Swine Fever Virus

2. (Chapter 4.16. High Health Status Horse Subpopulation)

   Model veterinary certificate for the international movement of not more than 90 days of a high health high performance horse for competition or races, and its explanatory document

3. Chapter 6.X. Prevention and Control of *Salmonella* in Commercial Cattle Production Systems

4. Chapter 11.4. Bovine Spongiform Encephalopathy

5. Chapter 8.7. Infection with Foot and Mouth Disease Virus

1. Chapter 15.1. Infection with African Swine Fever Virus

Article 15.1.1.

General provisions

Suids (the pig and its close relatives) are the only natural 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 giant forest hog (*Hylochoerus meinertzhageni*).

For the purposes of this chapter, a distinction is made among:

– 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 are not and may act as reservoirs of the virus. Ticks of the genus *Ornithodoros* are natural hosts of the virus and act as reservoirs and biological *vectors*.

Rationale

Edit for clarification.

~~A Member Country should not impose bans on the trade in *commodities* of domestic and *captive wild* pigs in response to a *notification* of *infection* with ASFV in *wild* and *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* shall be 15 days.

Rationale

Japan understands that the first draft text was prepared in April, 2014 by the ad hoc group, to update and possibly harmonize with the recently amended chapter 15.2 on classical swine fever (CSF), and this amendment was made under the hypothesis that the approach used for CSF is applicable to African swine fever (ASF).

However, ASF is totally different from CSF in terms of its difficulties in the prevention and control of the disease in pig population, especially in wild boars, due to (i) the role of recovered animals which may become persistently infected, acting as virus carriers for long period of times without any clinical signs, (ii) involvement of soft ticks as reservoirs and (iii) lack of vaccine (OIE Terrestrial Manual 2012).

In the current epidemics in the eastern EU, ASF continues to spread slowly through the wild boar populations in these countries (EFSA journal, 2015.13(7):4163, 14 July 2015), and it is clear that wild boars are important factor for the trans-boundary transmission of ASF in the region. In addition, observations related to the wild boar-domestic pig interface indicated that all ASF notifications in domestic pig holdings were situated in areas with suitable wild boar habitat (EFSA journal, 2015.13(7):4163).

Most outbreaks in domestic pig holdings have occurred in backyard farms (EFSA journal, 2015.13(7):4163), while the first outbreak observed in domestic pigs in Estonia on 18 July 2015 was in the farms with more than 100 pigs in the area where outbreaks in wild boars have been reported (WAHID, OIE).

From currently available data, it is clear that the risk of ASFV infection in domestic pigs is higher in the area where the wild boars exist and are infected, which justifies imposing higher risk mitigation measures for the import of commodities of domestic pigs in response to the outbreaks in wild population. And absence of the disease in wild boars is a critical factor for the determination of the free status of ASF of a country or zone.

Article 15.1.3.

Country or zone free from ASF

1. A country or *zone* may be considered historically free from ASF without formally applying a specific *surveillance* programme if the provisions of point 1 of Article 1.4.6. are complied with.

2. A country or *zone* which does not meet the conditions of point 1 above may be considered free from ASF when:
   a) there has been no *outbreak* of ASF in domestic and *captive wild* pigs during the past 12 months~~;~~

   b) *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;

   c) imported domestic and *captive wild* pigs and pig *commodities* comply with the requirements of Articles 15.1.5. to 15.1. 17.

   AND

   Based on *surveillance* in accordance with Articles 15.1.26, it has been demonstrated that:

   d) there has been no evidence of ASF *infection* in wild and *feral* pigs during the past 12 months;

Rationale

Please refer to the previous rationale described under second box of the amendment proposal under Article 15.1.1.

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.~~

Rationale

Japan suggests deleting both conditions a) and b), since scientific evidence was not observed in the references. The EFSA journal of 2010; 8(3):1556, Scientific Opinion on African Swine fever, quoted in the Sep. 2014 SCAD & April 2014 Ad Hoc Group report, only refers to Parma and Iberian hams having lower risk of virus survival post 100 days (p129).

The updated scientific opinion of EFSA Journal 2014; 12(4):3628, describes variation in the time of ASFV detection, some salted and dried meat beyond 180 days. If not salted, the curing procedure needs to be specified before discussing any of the curing time or other detailed conditions.

Japan also notes and agrees to the suggestion of the Ad Doc Group that there is a need for more scientific research to have updated information on the inactivating procedures.

>> p61 of September 2014, SCAD report
The Group considered that for the time being the data that are in the EFSA report are the only suitable figures and suggested that more scientific research is needed to have updated information on the inactivating procedures.

Article 15.1.24.

Surveillance strategies

1. Introduction

The population covered by *surveillance* aimed at detecting *disease* and *infection* should include domestic and *wild* pig populations within the country or *zone*. *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~~.

Rationale

There are guidelines for wildlife whereas those specific to African *wild* suids cannot be found in Chapter 1.4. The sentence can be either totally deleted as above or modified by inserting “wild and feral pigs” before “African wild suids”.

2. (Chapter 4.16. High Health Status Horse Subpopulation)

Model veterinary certificate for the international movement of not more than 90 days of a high health high performance (HHP) horse for competition or races, and its explanatory document

General comment

Japan appreciates the effort of OIE staff for preparing graphical description of the HHP concept and a decision tree on the OIE listed diseases, to facilitate the Member Countries and other stakeholders' understanding on the concept, while comments as follows:

2-1 Specified *listed diseases* which defines the high health status horse *subpopulation* (HHS) and grouping of the *listed diseases*

2-1-1 Equine viral arteritis (EVA)

According to Annex 2 of the explanatory document, EVA is listed in the *group of venereal diseases* and because breeding is not permitted, the disease is not considered in health regulations for HHP horses.

But respiratory transmission of EVA does occur* and therefore the disease needs to be considered in health regulations for HHP horses. For example, according to the explanatory document, during the 90 days before qualification as a compartment, there is no restriction on the source of "new entrants", and the horses can be introduced even from breeding farms and can become a source of infection. There needs to be a risk mitigation measures to establish compartment free from EVA.

Japan proposes to list EVA in the *group of disease of importance for the HHP concept,* and requests to revise the model certificate and explanatory document and its annexes respectively.

Model certificate needs to include result of diagnostic testing such as negative result for serological test.

* "Transmission of EAV (equine arteritis virus) can occur by respiratory, venereal and congenital routes. Respiratory spread is most important during the acute phase of the infection." (Source: chapter 2.5.10. Equine viral arteritis of OIE *Terrestrial Manual* 2013)

2-1-2 Equine piroplasmosis (EP)

EP sero-positive horses can be a source of infection**. Taking into account the difficulties in demonstrating freedom of ticks from entire environment, such as equestrian competition sites and turfs, only EP sero-negative horses can be introduced / imported to avoid an epizootic spread of the disease.

According to the explanatory document, there are neither risk mitigation measures nor examinations during the 90 days before qualification as a compartment. To avoid transmission of EP during the 90 days qualification period, not only HHP horses for export but all the horses in the premises need to be examined against EP and the

sero-negative horses need to be isolated from the positive ones and maintained free from ticks.

** ” Infected animals may remain carriers of these parasites for long periods and act as sources of infection for ticks, which act as vectors. The introduction of carrier animals into areas where tick vectors are prevalent can lead to an epizootic spread of the disease.”, ”Infections in carrier animals are best demonstrated by testing their sera for the presence of specific antibodies.” (Source: chapter 2.5.8. Equine piroplasmosis of OIE *Terrestrial Manual* 2014)

2-1-3 Equine infectious anemia (EIA)

According to the explanatory document, “free from EIA” is categorized as one of the health status being examined during the 90 days before qualification as a compartment. Japan requests the free status to be defined in the OIE code.

Secondly, the OIE code recommends EIA diagnostic testing to be implemented during the 90 days prior to shipment if imported on a temporary basis, while in the proposed model certificate (V10) the tests are recommended within 120 days of dispatch. The reason of the difference in the recommended dates of testing needs to be informed to Member Countries and stakeholders.

2-2 Biosecurity measures to create and maintain a functional separation between horses within the defined *subpopulation*

Japan reiterates the request at the 83rd General Session, for the circulation of the draft OIE Biosecurity Guidelines to Member Countries at the earliest opportunity, and expects it addresses the following:

- Whether the equestrian event can be held with only HHP horses or both with HHP horses and non-HHP horses under functional separation?

- According to the explanatory document, during the 90 days before qualification as a compartment, “all new entrants must be isolated from the other horses for at least two weeks”, but question arises at what level of isolation, whether it is at another HHS level or not?

- According to Annex 1 of the explanatory document, it gives idea for the HHP concept but not for the paddocks and training tracks and level of isolation between HHS and non-HHS.

3. Draft Chapter 6.X. Prevention and Control of *Salmonella* in Commercial Cattle Production Systems

Draft Chapter 6.X.

Prevention, Detection and Control of *Salmonella* in Commercial Cattle Production Systems

Rationale

Given that Article 6.X.13 on surveillance in cattle has been proposed, the modified title might be more consistent with Chapter 6.5. of the *Terrestrial Code.*

Article 6.X.1.

Introduction

~~Nontypoidal s~~Salmonellosis is one of the most common food-borne bacterial diseases in the world. The great majority of *Salmonella infections* in humans are food-borne with *Salmonella* Enteritidis and *S.* Typhimurium (including monophasic variants) , which are the predominant serotypes identified in most countries. In addition, a limited number of other serotypes associated with cattle may cause salmonellosis in humans, for example *S.* Dubline 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 occur. Subclinical *infection* can be of variable duration including a carrier state, which is significant as a potential zoonosis, and can play an important role in the spread of *Salmonella* within and between herds and pose a public health risk. *Salmonella* infection in humans can occur when contaminated meats or their products enter the food chain.

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

Salmonella serotypes and their *prevalence* in cattle may vary considerably between farms, localities, districts, countries and regions. It is important for *Veterinary Authorities* to consider types of *Salmonella*, their occurrence and the *disease* burden in cattle and human populations if ~~developing and implementing~~ they develop and implement strategies for the prevention and control of *Salmonella* in cattle.

Rationale

These modified texts might be more consistent with Article 6.5.1. of the *Terrestrial Code.*

Article 6.X.2.

Definitions

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

~~**Intensive cattle production systems**: means commercial systems where 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 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.~~

~~**Semi-intensive cattle production systems**: means commercial systems where 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.~~

Rationale

Each of the terms of 'commercial cattle production systems', 'intensive cattle (production) systems' and 'extensive cattle production systems' is used only once in an article: Article 6.X.4., Article 6.X.5. and Article 6.X.5., respectively. In addition, the term of 'semi-intensive cattle production systems' is not used in this chapter. It is unnecessary to define such terms in an independent article. However, the term of 'commercial cattle production systems' would be used in several modified texts proposed by Japan in several articles.

Article 6.X.4.

Objectives of prevention, detection and control ~~measures~~ of *Salmonella* in commercial cattle production systems

It is recommended that prevention, detection and control of *Salmonella* in commercial cattle production systems should be focused on those types ~~of *Salmonella*~~ of greatest consequence to cattle or public health.

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

1) Entering the *slaughterhouse/abattoir* and therefore ~~decrease~~ decreasing 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..

Article 6.X.5. to 6.X.13~~4~~. provide recommendations for the prevention, detection and control of *Salmonella* in commercial cattle production systems.

Rationale

These modified texts might be more defined and consistent with the Japan's proposed title of this chapter. The proposed Article 6.X.14 does not include any recommendations.

Article 6.X.5.

Location and design of cattle establishments

It is recommended to make ~~When making~~ decisions on the location and design of cattle *establishments*, considering ~~it is recommended that~~ mitigation of the ~~*risk*~~ risk 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 of *Salmonella* between *establishments* may involve c~~Carriage by wild birds, rodents, flies and other *wildlife* may be involved in transfer of *Salmonella* between

establishments.

It is recommended ~~that the~~ to design ~~of~~ intensive cattle production systems, where 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, considering the following:

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

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

3) control of the points of entry;

4) ~~cattle~~ handling and movement~~s~~ of cattle to minimise stress and spread of *Salmonella infection*;

5) separation of cattle of different *risk* status;

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

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

Rationale

These modified texts might be a little bit more natural and easy to read. According to the Glossary, '*risk*' means 'the likelihood of the occurrence and the likely magnitude of the biological and economic consequences of an adverse event or effect to animal or human health'. The definition of '*biosecurity measures*' was adopted at the 83rd OIE General Session.

Article 6.X.6.

Biosecurity management plan

Biosecurity measures ~~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 the prevention and control of *Salmonella* in commercial cattle production systems.

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

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 harbor pests around cattle premises~~.~~;

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

8) Cleaning and *disinfection* procedures for cattle 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~~ cattle production systems may include feeders, drinkers, floor, walls, aisles, partitions between pens, and ventilation ducting~~.~~;

~~When d~~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 its 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 human, livestock and *wildlife* to *Salmonella*~~.~~; Particular care ~~to~~ should be taken when cattle bedding and faeces are used as ferteliser for horticultural crops intended for human consumption.

Rationale

The definition of '*biosecurity measures*' was adopted at the 83rd OIE General Session. The first modified text might be more defined and consistent with the title of this chapter. The second modified text might be a little bit more natural and easy to read. As for the 'minimising' of item 7, it is difficult to consider concrete measures for minimising the entry of wild birds into cattle buildings and feed stores but it could be possible to set up bird-proof measures. Regarding item 8, might the 'buildings in which cattle are handled or housed' be the same as 'cattle buildings' of item 7? In addition, could the second sentence of the first paragraph of this item generally apply to extensive cattle production systems? As for item 9, generally speaking, control of pests might be always required for prevention of *Salmonella*.

Article 6.X.7.

Management of cattle introductions

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

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

2) Cattle should be sourced ~~The number of separate sources of cattle~~ for breeding or rearing ~~be kept to~~ from as few *herds* of origin as possible~~.~~; For example in a closed dairy herd it is possible to introduce new genetic material solely by semen or embryos~~.~~;

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

4) Newly introduced cattle should 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~~ should be taken to assess their *Salmonella* status.

Rationale

According to the Glossary, '*risk*' means 'the likelihood of the occurrence and the likely magnitude of the biological and economic consequences of an adverse event or effect to animal or human health'. In British English, 'should' is usually needed in that-clause after 'recommended'. Japan would like to know the scientific rationale of the 'four weeks'.

Article 6.X.8.

On farm cattle management

To minimise the risk of transferring Salmonella among cattle, it is recommended that:

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

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

3) Priority should 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 should be used for production cohorts ~~be used.~~; In particular, it should be avoided to mix ~~the mixing of~~ different age groups during rearing of calves ~~should be avoided.~~;

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

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

Rationale

In British English, 'should' is usually needed in that-clause after 'recommended'. These modified texts might be a little bit more natural and easy to read.

Article 6.X.9.

Feed and water

1. Compound feed and feed ingredients

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

a) Where appropriate, compound 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.;

b) Compound feed and feed ingredients should be transported and stored in a hygienic manner that minimises access by wild birds, rodents and other *wildlife*.

2. Water

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

Rationale

In British English, 'should' is usually needed in that-clause after 'recommended'. It is advisable to take necessary measures in water management for the prevention and control of *Salmonella*, irrespective of the presence of the *risk*.

Article 6.X.10.

Prevention, treatment and control measures

1) *Antimicrobial agents* may modify normal flora in the gut and increase the likelihood of colonisation by *Salmonella*. ~~If a~~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, and because they may mask the *infection* at sampling, has the potential to produce residues in *meat* and *milk* and ~~increase the risk of *Salmonella* colonisation, and their use~~ can contribute to the development of antimicrobial resistance.

2) *Vaccination* may be ~~used~~ practised to cattle as part of a *Salmonella* control programme in order to prevent bovine salmonellosis or to reduce the risk of *Salmonella infection* in humans through beef consumption or contact with cattle. Vaccines against salmonellosis ~~production and use~~ should be produced in accordance with Chapter 2.9.9. of the *Terrestrial Manual*. The protective effect of the vaccines is generally serotype specific. Some vaccines are approved for bovine salmonellosis but ~~and~~ few licensed *Salmonella* vaccines are available for cattle for the prevention of human *infections*..

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

Rationale

The modified text of paragraph 1 might be more consistent with Article 6.5.5. of the *Terrestrial Code*. The 'increase the risk of *Salmonella* colonisation' is duplication with the first sentence. As for paragraph 2, generally speaking, while 'vaccine' is used, '*vaccination*' is practised. Vaccination against Salmonellosis might be practised to cattle for the following purposes: to prevent cattle from the infection of *Salmonella* (bovine salmonellosis) or to prevent humans from the infection of *Salmonella* through beef consumption or contact with cattle (human salmonellosis). We have some approved vaccines for bovine salmonellosis caused by, for example, *S.* Dublin and *S.* Typhimurium, but few vaccines approved to use to cattle against human salmonellosis, especially due to serotypes of *Salmonella* which are not pathogenic to cattle. Chapter 2.9.9. of the *Terrestrial Manual* does not include any standards for use of the vaccines.

4) It is recommended to control ~~Because~~ the conditions ~~such as liver fluke and infection with bovine viral diarrhoea virus~~ that may increase the susceptibility of cattle to *Salmonella*, such as liver fluke and bovine viral diarrhoea ~~control of these conditions is recommended~~.

Rationale

This modified text might be a little bit more natural and easy to read. Infection with bovine viral diarrhoea virus is described as ‘bovine viral diarrhoea’ in *Terrestrial Code*.

Article 6.X.11.

Transportation

The relevant recommendations in Chapters 7.2.,7.3. and 7.4. apply to prevention and control of *Salmonella* during transportation of cattle.

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

Rationale

The relevant recommendations in Chapter 7.3 as well as 7.2 and 7.4 apply to prevention and control of *Salmonella* during transport of cattle. The second modified text might be a little bit more natural and easy to read.

Article 6.X.12.

Lairage

~~Relevant aspects of *l*~~*Lairage* should be managed ~~management include consideration of~~ taking into consideration effective cleaning and *disinfection* between groups, as well as minimising mixing of separate groups and managing stress.

In addition the relevant recommendations in Article 7.5.1., 7.5.3. and 7.5.4. apply to prevention and control of *Salmonella* of cattle in *lairage*.

Rationale

The text should be a recommendation.

Article 6.X.13.

Surveillance in cattle

~~*Surveillance* data provide information to assist the *Competent Authorities* in their decision making regarding the requirement for, and design of, control programmes.~~ Where justified by *risk assessment*, *surveillance* should be carried out to identify infected *herds* in order to take measures that will reduce the prevalence in cattle and the risk of transmission of *Salmonella* to humans. Sampling and testing methods, frequency and type of samples required should be determined by the *Veterinary Services* based on a *risk assessment*.

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~~ *herd* or individual animal status. Boot swab samples from communal areas in cattle housing, slurry samples or lymph nodes collected post-mortem can also be useful for microbiological testing. Some types of *Salmonella* such as *S.* Dublin can be difficult to detect through microbiological methods.

If *vaccination* is ~~used~~ practised, it may not be possible to distinguish between vaccinated and infected cattle by

means of serological testing.

Rationale

The first sentence of the first paragraph of the original texts is unnecessary for the recommendation. The modified text might be more consistent with Article 6.5.4. of the *Terrestrial Code*.

4. Chapter 11.4 Bovine Spongiform Encephalopathy

1) Comments on the adopted Chapter 11.4

Japan would like to express its warmest regards to the leadership and excellent decision made by President of the Code Commission and Director General of the OIE at the discussion about 'atypical BSE' during the 83rd OIE General Session. We have supported the revised BSE Code adopted, which provides "for the purpose of official BSE risk status recognition, BSE excludes 'atypical BSE'".

On the other hand, as commented by plural Member Countries and to avoid confusion, Japan requests the OIE to clarify the case definition of classical and atypical BSE in either OIE Code or Manual, as well as their diagnostic methods in the Manual.

2) Comments on the ad hoc group reports

Japan would like to comment on the report of the OIE ad hoc group meetings on BSE in November 2014 stating that 'the Group agreed that import of ruminants other than cattle is not considered to be a risk and therefore proposed to replace ruminants by cattle or bovine in the entire chapter, except in reference to the ruminant-to-ruminant feed ban'.

Japan requests the OIE to clarify the kind of ruminants other than cattle, import of which was not considered to be a risk of BSE. If goat included, we would like to confirm that for what reason the import of goats was not considered to be a risk although two cases of BSE infected goats had been reported so far.

3) Comments on the ad hoc group reports and the report of the joint meeting between the Scientific Commission and the Code Commission

Japan would like to recall that the report of the OIE ad hoc group meetings on BSE in November 2014 states that 'The Group also considered the risk posed by atypical BSE and proposed a recommendation ensuring that the products were not contaminated with tissues listed in the newly proposed point 4 of Article 11.4.14. (brain, eye, spinal cord and skull from cattle aged more than 96 months)'.

In addition, Japan would like to recall that the report of the joint meeting between the OIE Scientific Commission for animal diseases and the OIE Terrestrial Animal Health Standards Commission in February 2015 states that 'The Commissions agreed that the revision of Chapter 11.4. on BSE follow sequential steps with regards to surveillance and specified risk materials, the first focusing on minimising the impact of atypical BSE on disease status'.

While Japan understands that the Scientific Commission is going to discuss the surveillance and specified risk materials (SRMs) at the meeting to be held in September 2015, Japan suggests that, regarding the specification of SRMs, enough discussion based on the risk posed by atypical BSE be held.

5. Chapter 8.7 Infection with Foot and Mouth Disease Virus

As Japanese delegation noted at the 83rd OIE General Session, Japan would like to submit some editorial comments as follow:

Article 8.7.2.

FMD free country or zone where vaccination is not practised

4) describe in detail ~~and supply~~ with documented evidence that ~~the following have been properly implemented and supervised~~:

a) in case of FMD free *zone*, the boundaries of the proposed FMD free *zone* have been properly established and supervised;

b) the boundaries ~~and measures~~ of a *protection zone* have been properly established and supervised and appropriate measures have been implemented and supervised, if applicable;

c) the system for preventing the entry of FMDV into the proposed FMD free country or zone has been properly in place and supervised;

d) the control of the movement of susceptible animals, their *meat* and other products into the proposed FMD free country or *zone* have been properly in place and supervised; in particular the measures described in Article 8.7.8., 8.7.9. and 8.7.12. have been applied;.

e) it has been ensured that no vaccinated animal has been introduced except in accordance with Article 8.7.8. and 8.7.9.

Rationale

Improved syntax and readability

Article 8.7.3.

FMD free country or zone where vaccination is practised

4) describe in detail ~~and supply~~ with documented evidence that ~~the following have been properly implemented and supervised~~:

a) in case of FMD free *zone*, the boundaries of the proposed FMD free *zone* have been properly established and supervised;

b) the boundaries ~~and measures~~ of a *protection zone* have been properly established and supervised and appropriate measures have been implemented and supervised, if applicable;

c) the system for preventing the entry of FMDV into the proposed FMD free country or *zone* has been properly in place and supervised~~, in particular the measures described in Article 8.7.8., 8.7.9. and 8.7.12~~;

d) the control of the movement of susceptible animals, their *meat* and ~~their~~ other products into the proposed FMD free country or *zone* have been properly in place and supervised; in particular the measures described in Article 8.7.8., 8.7.9. and 8.7.12. have been applied;

Rationale

Improved syntax and readability

Article 8.7.7.

Recovery of free status (see Figures 1 and 2)

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

a) three months after the disposal of the last animal killed where a *stamping-out policy*, without emergency *vaccination*, and *surveillance* in accordance with Article 8.7.40. to 8.7.42. are applied ~~in accordance with Article 8.7.40. to 8.7.42.~~; or

2) When a FMD *case* occurs in a FMD free country or *zone* where *vaccination* is not practised, the following waiting period is required to gain the status of FMD free country or zone where vaccination is practised: six months after the disposal of the last animal killed where a *stamping-out policy* has been applied and a continued *vaccination* policy has been adopted, provided that *surveillance* is applied in accordance with Articles 8.7.40. to 8.7.42., and serological survey based on the detection of antibodies to nonstructural proteins of FMDV demonstrates no evidence of FMDV transmission.

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

Where a *stamping-out policy* is not practised, the above waiting periods do not apply, and Article 8.7.3. applies.

3) When a *case* of FMD occurs in a FMD free country or *zone* where *vaccination* is practised, one of the following waiting periods is required to regain this free status:

a) six months after the disposal of the last animal killed where a *stamping-out policy*, with emergency *vaccination* and *surveillance* in accordance with Article 8.7.40. to 8.7.42. are applied, provided that serological *surveillance* based on the detection of antibodies to nonstructural proteins of FMD demonstrates no evidence of ~~virus~~ FMDV transmission; or

b) 12 months after the detection of the last case where a *stamping-out policy* is not applied, but where emergency *vaccination* and surveillance in accordance with Article 8.7.40. to 8.7.42. are applied, provided that serological *surveillance* based on the detection of antibodies to nonstructural proteins of FMD demonstrates no evidence of ~~virus~~ FMDV transmission.

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

Where emergency *vaccination* is not applied, the above waiting periods do not apply, and Article 8.7.3. applies.

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

5) Member Countries applying for the recovery of status should do so only when the respective requirements for the recovery of status are met. When a *containment zone* has been established, the restrictions within the *containment zone* should be lifted in accordance with the requirements of ~~this article~~ Article 8.7.6. only when ~~the *disease*~~ FMD has been successfully eradicated within the *containment zone*.

For Member Countries not applying for recovery within 24 months after suspension, the provisions of Article 8.7.2., Article 8.7.3. or Article 8.7.4. apply.

~~For Member Countries not applying for recovery within 24 months after suspension, the provisions of Article 8.7.2., Article 8.7.3. or Article 8.7.4. apply.~~

Rationale

These modified texts might be more consistent with other paragraphs of this article. This article might not include any requirements for the containment zone. According to the Glossary, *'disease'* means 'the clinical and/or pathological manifestation of *infection*', and is not limited to FMD.

Article 8.7.8.

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

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

1) for at least 30 days prior to movement, no FMD susceptible animal should have ~~has~~ been introduced into the *establishment* of origin and no animal in the *establishment* of origin should have ~~has~~ shown clinical signs of FMD

~~for at least 30 days prior to movement~~;

2) the animals should have been ~~were~~ kept in the *establishment* of origin for at least three months prior to movement;

3) FMD ~~has~~ should not have occurred within a 10 kilometre radius of the *establishment* of origin for at least four weeks prior to movement;

4) the animals should be transported under the supervision of the *Veterinary Authority* in ~~*a vehicle*~~ *vehicles*, which ~~was~~ were cleansed and disinfected before *loading*, directly from the *establishment* of origin to the *slaughterhouse/abattoir* without coming into contact with other susceptible animals;

5) such a *slaughterhouse/abattoir* ~~is~~ should not be approved for the export of *fresh meat* ~~during the time it is~~ while handling the *meat* of animals from the *infected zone*;

6) *vehicles* and the *slaughterhouse/abattoir* should be subjected to thorough cleansing and *disinfection* immediately after use.

Article 8.7.9.

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

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

1) the *containment zone* should have ~~has~~ been officially established according to the requirements in Article 8.7.8.;

2) the animals should be transported under the supervision of the *Veterinary Authority* in ~~*a vehicle*~~ *vehicles*, which ~~was~~ were cleansed and disinfected before *loading*, directly from the *establishment* of origin to the *slaughterhouse/abattoir* without coming into contact with other susceptible animals;

3) such a *slaughterhouse/abattoir* ~~is~~ should not be approved for the export of *fresh meat* ~~during the time it is~~ while handling the *meat* of animals from the *containment zone*;

4) *vehicles* and the *slaughterhouse/abattoir* should be subjected to thorough cleansing and *disinfection* immediately after use.

Rationale

According to the Glossary, '*slaughter*' means 'any procedure which causes the *death* of an *animal* by bleeding', and then it is a noun. In British English, 'should' is usually needed in that-clause after the noun of 'condition'. It is unnecessary to limit the number of vehicles for the transport to one.

Article 8.7.15.

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

For frozen semen of domestic ruminants and pigs

1) the donor males:

c) either

i) have been vaccinated at least twice~~,~~ with the last *vaccination* not ~~less~~ more than ~~one~~ six months ~~and not more than six months prior to collection~~, unless protective immunity has been demonstrated for more than six months, and not less than one month prior to collection;

2) the semen:

b) was stored in the country of origin for a period of at least one month following collection, and during this period no animal on the *establishment* where the donor ~~animals~~ males were kept showed any sign of FMD.

Rationale

The first modified text might be more consistent with item b of the first paragraph of Article 8.7.22.

Article 8.7.16

Recommendations for importation from FMD infected countries or zone

For frozen semen of domestic ruminants and pigs

1) the donor males:

b) were kept in an *artificial insemination centre* ~~where~~ in which no animal had been added ~~in~~ for the 30 days before collection, and within a 10 kilometre radius of which, ~~that~~ FMD has not occurred ~~within a 10 kilometre radius of the *artificial insemination centre*~~ for the 30 days before and after collection;

c) either

i) have been vaccinated at least twice~~,~~ with the last *vaccination* not ~~less~~ more than ~~one~~ six months ~~and not more than six months prior to collection~~, unless protective immunity has been demonstrated for more than six months, and not less than one month prior to collection;

Rationale

It might be difficult for us to correctly interpret the item b of the first paragraph due to the phrase of 'an *artificial insemination centre* that FMD has not occurred within a 10 kilometre radius of the *artificial insemination centre*'. The second modified text might be more consistent with item b of the first paragraph of Article 8.7.22.

Article 8.7.19.

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

For *in vitro* produced embryos of cattle

1) the donor females:

c) either

i) have been vaccinated at least twice~~,~~ with the last *vaccination* not ~~less~~ more than ~~one~~ six months ~~and not more than six months prior to collection~~, unless protective immunity has been demonstrated for more than six months, and not less than one month prior to collection

Rationale

The modified text might be more consistent with item b of the first paragraph of Article 8.7.22.

Article 8.7.20

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

For fresh meat or meat products of FMD susceptible animals

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

1) have been kept in a FMD free country or *zone* where *vaccination* is not practised or FMD free *compartment,* or ~~which~~ have been imported in accordance with Article 8.7.10., Article 8.7.11. or Article 8.7.12.;

Rationale

Since the main clause ends at 'which**:',** the 'which' in the first item might be unnecessary or could be replaced by '**;**'.

Article 8.7.21.

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

For fresh meat or meat products of ruminants and pigs

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

1) have been kept in a FMD free country or *zone* where *vaccination* is practised*,* or ~~which~~ have been imported in accordance with Article 8.7.10., Article 8.7.11. or Article 8.7.12.;

2) have been slaughtered in an approved slaughterhouse/ abattoir and have been subjected to ante- and post-mortem inspections ~~for FMD with favourable results~~ with no evidence of FMD;

Rationale

Since the main clause ends at 'which**:**', the 'which' in the first item might be unnecessary or could be replaced by '**;**'. The second modified text might be more consistent with item f of the first paragraph of Article 8.7.22.

Article 8.7.22.

Recommendations for importation from FMD infected countries or zones where an official control programme exists

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

1) comes from animals which:

c) were kept for the past 30 days in an *establishment*, within a 10 kilometre radius of which ~~and that~~ FMD has not occurred ~~within a 10 kilometre radius of the *establishment*~~ during that period, or ~~the *establishment* is~~ in a quarantine station;

Rationale

Improved clarity and readability

Article 8.7.23

Recommendations for importation from FMD infected countries or zones

For meat products of FMD susceptible animals

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

1) the entire consignment of *meat products* come from animals which have been slaughtered in an approved *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections ~~for FMD with favourable results~~ with no evidence of FMD;

Rationale

The modified text might be more consistent with item f of the first paragraph of Article 8.7.22.

Article 8.7.29

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

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

Rationale

The modified title might be more consistent with ones of Article 8.7.8. and 8.7.9. The modified text might be more consistent with other articles of this chapter.

Article 8.7.32

Procedures for the inactivation of FMDV in wool and hair

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

1) industrial washing, which consists of the immersion of the wool or the hair in a series of baths of water, soap and sodium hydroxide (soda) or potassium hydroxide (potash);

Rationale

This article is for procedures for the inactivation of FMDV not only in wool but also in hair.

Article 8.7.36

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

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

Rationale

These modified title and text might be more consistent. We, however, prefer '*feral* and *wild animals*' to '*wildlife*'.

Article 8.7.39

OIE endorsed official control programme for FMD

5) submit evidence that ~~FMD *surveillance* is in place~~:

a) FMD *surveillance* is in place, taking into account provisions in Chapter 1.4 and the provisions on surveillance of this chapter;

b) the Member Country has ~~have~~ diagnostic capability and procedures, including regular submission of samples to a *laboratory* that carries out diagnosis and further characterization of strains;

Rationale

It might be more appropriate to put 'the Member Country' as the subject of item b of this paragraph.

Article 8.7.40.

General principles of surveillance

2. Demonstration of freedom

(The third paragraph of this clause)

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

3. OIE endorsed official control programme

Rationale

More consistent with other articles of this chapter

Article 8.7.42

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

(The third paragraph of this article)

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

Procedure in case of positive test results

(The third paragraph of this part)

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

Follow-up field and laboratory findings:

(The second paragraph of this part)

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

Rationale

The term of '*case*' is defined in the Glossary. On the other hand, the term of '*laboratory*' is also found in the Glossary but, in this case, 'laboratory confirmed reactor' is one term. We can find the term of 'laboratory confirmed reactor' in the first paragraph of this part. The third modification is for improved syntax and readability.