Terrestrial Animal Health Standards Commission Report
September 2014

Revised Chapter showing proposed changes for comment

USA Comments

CHAPTER 8.7.

INFECTION WITH FOOT AND MOUTH DISEASE VIRUS

Article 8.7.1.

~~**Introduction**~~

1) Many different species belonging to diverse taxonomic orders are known to be susceptible to *infection* with foot and mouth disease virus (FMDV). Their epidemiological significance depends upon the degree of susceptibility, the husbandry system, the density and extent of populations and the contacts between them. Amongst *Camelidae* only Bactrian camels (*Camelus bactrianus*) are sufficiently susceptible to have potential for epidemiological significance. Infection of dromedaries and South American camelids has not been shown to be of epidemiological significance.

~~1~~ 2) For the purposes of the *Terrestrial Code*, foot and mouth disease (FMD) is defined as an *infection* of animals of the suborder *ruminantia* and of the family *suidae* of the order *Artiodactyla*, and *Camelus bactrianus* with any ~~foot and mouth disease virus (~~FMDV~~)~~.

~~2~~3) The following defines the occurrence of FMDV *infection*:

~~Detection in a sample from an animal listed above, of the virus, viral antigen, nucleic acid or virus-specific antibodies that are not a consequence of *vaccination* by a test as specified in the *Terrestrial Manual*.~~

a) FMDV has been isolated from a sample from an animal listed in point 2); or;

b) viral antigen or viral ribonucleic acid (RNA) specific to a serotype of FMDV has been identified in a sample from an animal listed in point 2), showing clinical signs consistent with FMD, or epidemiologically linked to a confirmed or suspected *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV; or

c) antibodies to structural or nonstructural proteins of FMDV that are not a consequence of vaccination, have been identified in a sample from an animal listed in point 2), showing clinical signs consistent with FMD, or epidemiologically linked to a confirmed or suspected *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV.

~~3~~4) ~~The following defines the occurrence of FMDV circulation:~~

Transmission of FMDV in a vaccinated population~~, as~~ is demonstrated by ~~clinical signs or~~ change in virological or serological evidence ~~status~~ indicative of recent *infection*, even in the absence of clinical signs.

~~4~~5) For the purposes of the *Terrestrial Code*, the *incubation period* ~~for~~ of FMD is 14 days.

~~5) Many different species belonging to diverse taxonomic orders are known to be susceptible to *infection* with FMDV. Their epidemiological significance depends upon the degree of susceptibility, the~~

~~husbandry system, the density and extent of populations and the contact between them. Amongst *Camelidae* only Bactrian camels (*Camelus bactrianus*) are of sufficient susceptibility to have potential for epidemiological significance. South American camelids and dromedaries are not considered of epidemiological importance significance.~~

~~For the purposes of this chapter, ruminants include *animals* of the family of Camelidae (except *Camelus dromedarius*).~~

~~For the purposes of this chapter, a *case* is an *animal* infected with FMD virus (FMDV).~~

6) *Infection* with FMDV can give rise to *disease* of variable severity and to FMDV ~~circulation~~transmission. FMDV may persist ~~*infection*~~ in the pharynx and associated lymph nodes of ~~in~~ ruminants ~~may persist~~ for a variable but limited period of time beyond 28 days. Such animals have been termed carriers ~~leading to carriers~~. However, the only persistently infected species from which ~~Although live FMDV can be recovered from carriers,~~ transmission of FMDV ~~from these carriers~~ has ~~not~~ been proven is the ~~except from for~~ African buffalo (*Syncerus caffer*).

7) The chapter deals not only with the occurrence of clinical signs caused by FMDV, but also with the presence of FMDV *infection* ~~with~~ and transmission.~~FMDV~~ in the absence of clinical signs.

~~The following defines the occurrence of FMDV *infection:*~~

~~1. FMDV has been isolated and identified as such from an *animal* or a product derived from that *animal*; or;~~

~~2. viral antigen or viral ribonucleic acid (RNA) specific to one or more of the serotypes of FMDV has been identified in samples from one or more *animals*, whether showing clinical signs consistent with FMD or not, or epidemiologically linked to a confirmed or suspected *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV; or~~

~~3. antibodies to structural or nonstructural proteins of FMDV that are not a consequence of vaccination, have been identified in one or more *animals* showing clinical signs consistent with FMD, or epidemiologically linked to a confirmed or suspected *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV.~~

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

Article 8.7.2.

FMD free country or zone where vaccination is not practised

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

Susceptible animals in the FMD free country or *zone* where *vaccination* is not practised should be protected ~~from neighbouring infected countries~~ by the application of animal health measures that ~~effectively~~ prevent the entry of FMDV ~~the virus~~ into the free country or *zone*~~,~~. ~~t~~Taking into consideration physical or geographical barriers with any neighbouring infected country or *zone*. ~~T~~These measures may include a *protection zone*.

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

1) have a record of regular and prompt animal *disease* reporting;

2) send a declaration to the OIE stating that during the past 12 months, within the proposed FMD free country or *zone*:

   a) there has been no *case* ~~*outbreak*~~ of FMD ~~during the past 12 months~~;

   b) no evidence of FMDV *infection* has been found ~~during the past 12 months~~;

c) no *vaccination* against FMD has been carried out ~~during the past 12 months~~;

~~d) no vaccinated *animal* has been introduced since the cessation of vaccination;~~

3) supply documented evidence that for ~~at least~~ the past 12 months:

a) *surveillance* ~~for FMD and FMDV *infection*~~ in accordance with Articles 8.7 .~~42~~40. to 8.7 ~~5~~ .~~47~~42. ~~and Article 8.5.49.~~ ~~is in operation~~ has been implemented to detect clinical signs of FMD and show absence of:

i) FMDV *infection* in non-vaccinated animals;

ii) FMDV transmission in previously vaccinated animals when transition is made from FMD free country or *zone* where *vaccination* is practised to FMD free country or *zone* where *vaccination* is not practised;

b) regulatory measures for the prevention and early detection, ~~prevention and control~~ of FMD have been implemented;

4) describe in detail and supply documented evidence that for ~~at least~~ the past 12 months the following ~~these~~ have been ~~are~~ properly implemented and supervised: ~~the boundaries and measures of a *protection zone*, if applicable.~~

a) in the case of a FMD free *zone*, the boundaries of the proposed FMD free *zone*;

b) the boundaries and measures of a *protection zone*, if applicable;

c) the system for preventing the entry of FMDV ~~the virus~~ into the proposed FMD free country or *zone*;

d) the control of the movement of susceptible animals, their *meat* and other products into the proposed FMD free country or *zone*, in particular ~~if~~ the measures ~~procedures~~ described in Articles 8.7 .8., 8.7 .9. and 8.7 .12. ~~are implemented~~;

e) no vaccinated animal has been introduced ~~during the past 12 months~~ except in accordance with Articles 8.7 .8. and 8.7 .9.

The Member Country or the proposed free *zone* will be included in the list of FMD free countries or *zones* where *vaccination* is not practised only after the submitted evidence, based on the provisions of Article 1.6.5., has been accepted by the OIE.

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

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

- the zoological collection has a primary purpose to exhibit *animals* or preserve rare species, ~~and should be~~ has been identified ~~in advance~~, including the boundaries of the facility, and ~~be~~ is included in the country's contingency plan for FMD;

- appropriate biosecurity measures are in place, including measures for zoological collection personnel and effective separation from other susceptible domestic populations or *wildlife*;

- the *animals* are identifiable as belonging to the collection and any movements can be traced;

- the vaccine used complies with the standards described in the *Terrestrial Manual*;

- *vaccination* is conducted under the supervision of the *Veterinary Authority*;

- the zoological collection is placed under ~~active~~ ~~clinical~~ clinical and serological *surveillance* for at least 12 months after *vaccination*.,

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

Comment & Rationale on 8.7.2:
-For ease of reference, we suggest that the zoological collection points be numbered or lettered in the section.
-Adding the phrase "including measures for zoological collection personnel" is an important specification that should be explicitly referenced to reduce risk **(second bullet).**
-Adding the words "clinical and serological" is an important specification. Surveillance is too broad a term, and could be interpreted to mean only observation; observing vaccinated zoo animals is insufficient as zoo animals may never show clinical illness **(sixth bullet).**

Article 8.7.3.

FMD free country or zone where vaccination is practised

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

Susceptible ~~*animals*~~ animals in the FMD free country or *zone* where *vaccination* is practised should be protected ~~from neighbouring infected countries~~ by the application of animal health measures that ~~effectively~~ prevent the entry of FMDV ~~the virus~~ into the free country or *zone*~~,~~. ~~t~~Taking into consideration physical or geographical barriers with any neighbouring infected country or *zone*.~~.~~ ~~T~~these measures may include a *protection zone*. Based on the epidemiology of FMD in the country, it may be decided to vaccinate only a defined *subpopulation* comprised of certain species or other subsets of the total susceptible population.

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

1) have a record of regular and prompt animal *disease* reporting;

2) send a declaration to the OIE stating that, based on the *surveillance* described in point 3, within the proposed FMD free country or *zone*:

   a) there has been no *case* ~~*outbreak*~~ of FMD during the past two years;

   b) there has been no evidence of FMDV ~~circulation~~transmission ~~has been found~~ during the past 12 months;

3) supply documented evidence that:

   ~~a) *surveillance* for FMD and FMDV circulation in accordance with Articles 8.56.4240. to 8.56.4746. and Article 8.5.49. is in operation;~~

   a) *surveillance* in accordance with Articles 8.7 .40. to 8.7 . 4 2 . has been implemented to detect clinical signs of FMD and show absence of:

      i) FMDV *infection* in non-vaccinated animals;

      ii) FMDV transmission in vaccinated animals;

b) regulatory measures for the prevention and early detection~~, prevention and control~~ of FMD have been implemented;

c) ~~routine~~ compulsory systematic *vaccination* in the target population ~~is~~ has been carried out to achieve adequate vaccination coverage and population immunity ~~for the purpose of the prevention of FMD~~;

d) the vaccine used complies with the standards described in the *Terrestrial Manual*, including appropriate vaccine strain selection;

4) describe in detail and supply documented evidence that ~~these~~ the following have been ~~are~~ properly implemented and supervised ~~the boundaries and measures of a *protection zone*, if applicable.~~:

a) in case of FMD free *zone*, the boundaries of the proposed FMD free *zone*;

b) the boundaries and measures of a *protection zone*, if applicable;

c) the system for preventing the entry of ~~the virus~~ EMDV into the proposed FMD free country or *zone*, ~~(~~in particular ~~if~~ the measures ~~procedure~~ described in Articles 8.7.8., 8.7.9.and 8.7.12. ~~is implemented)~~;

d) the control of the movement of susceptible ~~*animals*~~ animals and their products into the proposed FMD free country or *zone*.

The Member Country or the proposed free *zone* will be included in the list of FMD free countries or *zones* where *vaccination* is practised only after the submitted evidence, based on the provisions of Article 1.6.5., has been accepted by the OIE.

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

If a Member Country that meets the requirements of a~~n~~ FMD free country or *zone* where *vaccination* is practised wishes to change its status to FMD free country or *zone* where *vaccination* is not practised, it should notify the OIE in advance ~~on~~ of the intended date of cessation of *vaccination* and apply for the new status within 24 months. The status of this country or *zone* remains unchanged until compliance with Article 8.7.2. is approved by the OIE. If the dossier for the new status is not provided within 24 months then the status of the country or *zone* as being free with *vaccination* will be suspended. If the country does not comply with requirements of Article 8.7.2., evidence should be provided within ~~3~~ three months that it ~~they~~ comply~~ies~~ with Article 8.7.3. Otherwise the status will be withdrawn. ~~the status of this country remains unchanged for a period of at least 12 months after vaccination has ceased. Evidence should also be provided showing that FMDV *infection* has not occurred during that period.~~

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

~~Article 8.5.4.~~

~~**FMD free zone where vaccination is not practised**~~

~~An FMD free *zone* where vaccination is not practised can be established in either an FMD free country where vaccination is practised or in a country of which parts are infected. In defining such a *zones* the principles of Chapter 4.3. should be followed. Susceptible *animals* in the FMD free *zone* should be protected from the rest of the country and from neighbouring countries if they are of a different *animal health status* by the application of animal health measures that effectively prevent the entry of the virus, taking into consideration physical or geographical barriers. These measures may include a *protection zone*.~~

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

~~1. have a record of regular and prompt animal *disease* reporting;~~

~~2. send a declaration to the OIE stating that within the proposed FMD free *zone*:~~

~~a) there has been no *outbreak* of FMD during the past 12 months;~~

~~b) no evidence of FMDV *infection* has been found during the past 12 months;~~

~~c) no vaccination against FMD has been carried out during the past 12 months;~~

~~d) no vaccinated *animal* has been introduced into the *zone* since the cessation of vaccination, except in accordance with Article 8.5.10.;~~

~~3. supply documented evidence that:~~

~~a) *surveillance* for FMD and FMDV *infection* in accordance with Articles 8.5.42. to 8.5.47. and Article 8.5.49. is in operation;~~

~~b) regulatory measures for the early detection, prevention and control of FMD have been implemented;~~

~~4. describe in detail and supply documented evidence that these are properly implemented and supervised:~~

~~a) the boundaries of the proposed FMD free *zone*;~~

~~b) the boundaries and measures of a *protection zone*, if applicable;~~

~~c) the system for preventing the entry of the virus (including the control of the movement of susceptible *animals*) into the proposed FMD free *zone* (in particular if the procedure described in Article 8.5.10. is implemented).;~~

~~The proposed free *zone* will be included in the list of FMD free *zones* where vaccination is not practised only after the submitted evidence has been accepted by the OIE.~~

~~The information required in points 2, 3 and 4 b)-c) above should be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported to the OIE according to the requirements in Chapter 1.1.~~

~~Article 8.5.5.~~

~~FMD free zone where vaccination is practised~~

~~An FMD free *zone* where vaccination is practised can be established in either an FMD free country where vaccination is not practised or in a country of which parts are infected. In defining such *zones* the principles of Chapter 4.3. should be followed. Susceptible *animals* in the FMD free *zone* where vaccination is practised should be protected from neighbouring countries or *zones* if they are of a lesser *animal health status* by the application of animal health measures that effectively prevent the entry of the virus, taking into consideration physical or geographical barriers. These measures may include a *protection zone*.~~

~~To qualify for inclusion in the list of FMD free *zones* where vaccination is practised, a Member should:~~

~~1. have a record of regular and prompt animal *disease* reporting;~~

~~2. send a declaration to the OIE that within the proposed FMD free *zone*;~~

~~a) there has been no *outbreak* of FMD for the past two years;~~

~~b) no evidence of FMDV circulation has been found during the past 12 months;~~

~~3. supply documented evidence that:~~

~~a) *surveillance* for FMD and FMDV *infection*/circulation in accordance with Articles 8.5.42. to 8.5.47. and Article 8.5.49. is in operation;~~

~~b) regulatory measures for the early detection, prevention and control of FMD have been implemented;~~

~~c) routine vaccination is carried out for the purpose of the prevention of FMD;~~

~~d) the vaccine used complies with the standards described in the *Terrestrial Manual*;~~

~~4. describe in detail and supply documented evidence that these are properly implemented and supervised:~~

~~a) the boundaries of the proposed FMD free *zone*;~~

~~b) the boundaries and measures of a *protection zone*, if applicable;~~

~~c) the system for preventing the entry of the virus (including the control of the movement of susceptible *animals*) into the proposed FMD free *zone* (in particular if the procedure described in Article 8.5.10. is implemented).~~

~~The proposed free *zone* will be included in the list of FMD free *zones* where vaccination is practised only after the submitted evidence has been accepted by the OIE. The information required in points 2, 3 and 4 b)-c) above should be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3 b) and 4 should be reported to the OIE according to the requirements in Chapter 1.1.~~

~~If a Member that has a *zone* which meets the requirements of a FMD free *zone* where vaccination is practised wishes to change the status of the *zone* to FMD free *zone* where vaccination is not practised, the status of this *zone* remains unchanged for a period of at least 12 months after vaccination has ceased. Evidence should also be provided showing that FMDV *infection* has not occurred in the said *zone* during that period.~~

Article 8.7.4~~6~~.

FMD free compartment

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

A Member Country wishing to establish a~~n~~ FMD free *compartment* should:

1) have a record of regular and prompt animal *disease* reporting and if not FMD free, have an ~~official control programme~~ *official control programme* and a *surveillance* system for FMD in place according to Articles 8.7.~~42~~40. to 8.7.~~47~~42~~. and Article 8.5~~6.~~49~~46. that allows ~~an accurate~~ knowledge of the prevalence, distribution and characteristics of FMD in the country or *zone*;

2) declare for the FMD free *compartment* that:

   a) there has been no *case* ~~*outbreak*~~ of FMD during the past 12 months;

   b) no evidence of FMDV *infection* has been found during the past 12 months;

   c) *vaccination* against FMD is prohibited ~~either:~~

      ~~i) no *vaccination* against FMD has been carried out during the past 12 months; no vaccinated *animal* has been introduced during the past 12 months; or~~

      ~~ii) compulsory systematic *vaccination* is carried out and the vaccine used complies with the standards described in the *Terrestrial Manual*, including appropriate vaccine strain selection;~~

   d) no animal vaccinated against FMD within the past 12 months is in the compartment;

   ~~d) no *animal* vaccinated against FMD within the past 12 months is in the compartment;~~

   e~~de~~) animals, semen, ~~and~~ embryos and animal products should only enter the *compartment* in accordance with relevant articles in this chapter;

   f~~ef~~) documented evidence shows that *surveillance* in accordance with Articles 8.7.~~42~~40. to 8.7.~~47~~~~46~~42. ~~and Article 8.5.49.~~ is in operation ~~for FMD and FMDV *infection*~~;

   g~~fg~~) an *animal identification* and traceability system in accordance with Chapters 4.1. and 4.2. is in place;

3) describe in detail:

   a) the animal *subpopulation* in the *compartment*; ~~and~~

   b) the *biosecurity plan* ~~for FMD and FMDV *infection*~~ ~~and, where applicable, the *vaccination* plan,~~ to mitigate the risks identified by the *surveillance* carried out according to point 1 ~~of Article 8.7.4.~~

The *compartment* should be approved by the *Veterinary Authority*. The first approval should only be granted when no *case* ~~*outbreak*~~ of FMD has occurred within a ten-kilometre radius of the *zone* in which the *compartment* is situated, during the ~~last~~ past three months.

Rationale: Delete the word "last" … it is redundant.

Article 8.7.5 ~~7~~.

FMD infected country or zone

~~For the purposes of this chapter, when the requirements for acceptance as an FMD free country or *zone* where *vaccination* is not practised or an FMD free country or *zone* where *vaccination* is practised are not fulfilled, such country or *zone* shall be considered as FMD infected. an FMD infected country is a country that does not fulfil the requirements to qualify as either an FMD free country where vaccination is not practised or an FMD free country where vaccination is practised.~~

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

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

Article 8.7.6 ~~8~~.

Establishment of a containment zone within a~~n~~ FMD free country or zone

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

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

1) ~~the boundaries of the *containment zone* are established taking into consideration that~~ the *outbreaks* ~~are limited based on the following factors:~~

   ~~a)~~ ~~immediately~~ on suspicion, standstill of animal movements has been imposed on the suspected *establishments* and animal movement control has been imposed in the country or *zone*, and effective controls on the movement of other *commodities* mentioned in this chapter are in place ~~a rapid response including notification has been made~~;

   2~~b)~~ on confirmation, standstill of susceptible animals has been imposed in the *containment zone* and movement controls have been reinforced; ~~standstill of animal movements has been imposed, and effective controls on the movement of other *commodities* mentioned in this chapter are in place;~~

   3~~c~~~~b~~) the boundaries of the *containment zone* may only be established once an epidemiological investigation (trace-back, trace-forward) ~~is able to~~ has demonstrated that the *outbreaks* are epidemiologically related and limited in number and geographic distribution ~~has been completed~~;

   ~~d)~~ ~~the *infection* has been confirmed~~;

   4~~e~~~~c~~) ~~the primary *outbreak* has been identified, and~~ investigations ~~on~~ into the likely source of the *outbreak* have been carried out;

   ~~f)~~ ~~all *cases* have been shown to be epidemiologically linked;~~

   ~~g)~~ ~~no new *cases* have been found in the *containment zone* within a minimum of two *incubation periods* as defined in Article 8.5.1. after the stamping-out of the last detected *case* is completed;~~

52) a *stamping-out policy*, with or without the use of emergency *vaccination*, has been applied;

63) no new *cases* have been found in the *containment zone* within a minimum of one two *incubation periods* as defined in Article 8.7.1. after the application of a *stamping-out policy* to the last detected *case*;

3.74) the susceptible domestic and *captive wild* animal populations within the *containment zones* should are be clearly identifiable as belonging to the *containment zone*;

4.85) increased passive and targeted *surveillance* in accordance with Articles 8.5.42.3 to 8.5.47. 8.7.40.to 8.7.42. and Article 8.5.4946. is in place in the *containment zone* and in the rest of the country or *zone* has been carried out is in place and has not detected any evidence of FMDV *infection*;

5.96) animal health measures that effectively prevent the spread of the FMDV to the rest of the country or *zone*, taking into consideration physical and geographical barriers, are in place.

6. ongoing *surveillance* in the *containment zone* is in place.

The free status of the areas outside the *containment zone* would be is suspended pending the establishment of while the *containment zone* is being established. The free status of these areas may could be reinstated irrespective of the provisions of Article 8.7.97., once the *containment zone* has been approved is clearly established, by complying with points 1 to 9 6 above. The *containment zone* should be managed in such a way that it can It should be demonstrated that *Cc*ommodities from susceptible animals for *international trade* can be shown to have originated should be identified as to their origin, either from inside or outside the *containment zone*.

In the event of recurrence of FMDV circulationtransmission in the *containment zone*, the approval of the *containment zone* is withdrawn. The FMD status of the whole country or *zone* is suspended until the relevant requirements of Article 8.7.7. are fulfilled.

The recovery of the FMD free status of the *containment zone* should follow the provisions of Article 8.7.97.

Article 8.7.7 9.

Recovery of free status (see Figures 1 and 2)

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

   a) three months after the disposal of the last *case* where a *stamping-out policy*, without emergency *vaccination*, and serological *surveillance* are applied in accordance with Articles 8.7.4240. to 8.7.432., 8. 56.45. and 8. 56.4946.; or

   b) three months after the disposal of the last case or the *slaughter* of all vaccinated animals whichever occurred last, where a *stamping-out policy*, emergency *vaccination* and serological *surveillance* in the remaining animals are applied in accordance with Articles 8.7.4240. to 8.7.432., 8. 56.45. and 8. 56.4946.; or

   c) six three months after the disposal of the last *case* or the last *vaccination* whichever occurred last, where a *stamping-out policy*, emergency *vaccination* not followed by the slaughtering of all vaccinated animals, and serological *surveillance* are applied in accordance with Articles 8.7.4240. to 8.7.423., 8. 5.4745. and Article 8. 56.4946.,. provided that However, this requires a serological survey based on the detection of antibodies to nonstructural proteins of FMDV to demonstrates the absence of *infection* in the remaining vaccinated population. This period can be reduced to three months if effectiveness of *vaccination* using vaccine compliant with *Terrestrial Manual* is demonstrated and additional serological *surveillance* for antibodies to nonstructural proteins is carried out in all vaccinated herds in accordance to Article 8. 56.45. point 2 is carried out. This includes sampling all vaccinated ruminants and their non-vaccinated offspring, and a representative number of animals of other species, based on an acceptable level of confidence.

Comment and Rationale:
-The change in risk between 6 months and 3 months is postulated to be so small as to be negligible (Geale et al 2013). Therefore, we suggest changing the time to 3 months.
- Serological surveillance is already required in the recommendations for 6 months according to Articles 8.7.40 to 8.7.42.
-The additional requirement for 3 months—serological surveillance in "all" vaccinated herds and sampling "all" vaccinated ruminants and their non-vaccinated offspring—is not based on scientific or epidemiological evidence of statistical confidence levels as currently phrased. There is no need to sample "all" herds or "all" ruminants. Strongly suggest removing this text.

-It is not clear what population refers to the "representative number of animals of other species", and whether or not it includes wildlife.

The country or *zone* will regain the status of FMD free country or *zone* where *vaccination* is not practised only after the submitted evidence, based on the provisions of Article 1.6.5., has been accepted by the OIE.

The time periods in points 1a) to 1c) are not affected if official emergency *vaccination* of zoological collections has been carried out following the relevant provisions of Article 8.7.2.

Where a *stamping-out policy* is not practised, the above waiting periods do not apply, and Article 8.7.2. applies.

2) When a~~n~~ FMD *case* ~~*outbreak* or FMDV *infection*~~ occurs in a~~n~~ 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: ~~6~~three months after stamping out of the disposal of the last *case* where a *stamping-out policy* has been applied and ~~adoption of~~ a continued *vaccination* policy has been adopted, provided that ~~serological~~ *surveillance* is applied in accordance with Articles 8.7.40. to 8.7.42. ~~and Articles 8.~~ 5~~6.44. to 8.~~ 5~~6.46~~, and a serological survey based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of FMDV ~~circulation~~transmission.

Comment & Rationale on 8.7.7.2
-Highlighted: In Figure 1, the box (flowing from stamping-out to vaccinate to live to continue vaccination), which cites this section (8.7.7.2) still says 6 months rather than 3 months.
-Should be 3 months.

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 1.6.5., 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.~~2~~3. applies.

~~2.~~3) When a~~n~~ FMD *outbreak* or FMDV ~~*infection* circulation~~transmission occurs in a~~n~~ FMD free country or *zone* where *vaccination* is practised, one of the following waiting periods is required to regain ~~the~~ this free status ~~of FMD free country or *zone* where *vaccination* is practised~~:

a) ~~6~~ six months after the disposal of the last *case* where a *stamping-out policy*, with emergency *vaccination*, and ~~serological~~ *surveillance* in accordance with Articles 8.7.~~42~~40. to 8.7.42. ~~and Articles 8. 56.44., 8.6.45 Point 1 and to 8. 56.46~~8.5.45. ~~and Article 8.5.49~~. are applied, provided that ~~the~~ serological *surveillance* based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of virus ~~circulation~~transmission; or

b) 1~~8~~2 months after the detection of the last *case* where a *stamping-out policy* is not applied, but where emergency *vaccination* and ~~serological~~ *surveillance* in accordance with Articles 8.7.~~42~~40. to 8.7.42. ~~and Articles 8. 56.44. , 8.6.45 Point 1 and to 8. 56.46.~~ ~~8.5.47. and Article 8.5.49~~. are applied, provided that ~~the~~ serological *surveillance* based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of virus ~~circulation~~transmission.

Where ~~an~~ 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 1.6.5., has been accepted by the OIE.

~~3.~~4) When a~~n~~ FMD *case* ~~*outbreak* or FMDV *infection*~~ occurs in a~~n~~ FMD free *compartment*, Article 8.7.~~6~~4. applies. ~~The waiting period in point 2a) and 2b) of Article 8.6.4. can be reduced to three months provided that the entire *compartment* has been depopulated, cleansed and disinfected.~~

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

Article 8.7.8 ~~10~~.

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

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

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

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

3) FMD has not occurred within a ten-kilometre radius of the *establishment* of origin for at least three months four weeks prior to movement;

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

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

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

The ~~*meat* should be derived from~~ animals ~~that~~ should have been subjected to ante- and post-mortem inspection for FMD, with favourable results, within 24 hours before and after *slaughter* and the *meat* derived from them treated according to point 2 of Article 8.-7.~~25~~22. or Article 8.7.~~26~~23. Other products obtained from the animals and any products coming into contact with them should be ~~considered infected, and~~ treated in such a way as to destroy any residual FMDV ~~virus~~ in accordance with Articles 8.7.~~34~~31. to 8.7.~~41~~38.

~~Animals moved into a free *zone* for other purposes should be moved under the supervision of the *Veterinary Authority* and comply with the conditions in Article 8.6.1412.~~

Article 8.7.9~~11~~.

Direct ~~T~~ transfer ~~directly to slaughter~~ of FMD susceptible animals from a containment zone for slaughter in ~~to~~ a free zone (where vaccination either is or is not practised) ~~within a country~~

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

1) the *containment zone* has been officially established according to the requirements in Article 8.7.~~8~~6.;

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

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

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

The ~~*meat* should be derived from~~ animals ~~that~~ should have been subjected to ante- and post-mortem inspection for FMD, with favourable results, within 24 hours before and after *slaughter* and the *meat* derived from them treated according to point 2 of Article 8.~~-~~7.~~25~~22. or Article 8.7.~~26~~23. Other products obtained from the animals and any products coming into contact with them should be treated in such a way as to destroy any residual FMDV ~~virus~~ in accordance with Articles 8.7.~~34~~31. to 8.~~-~~7.~~41~~38.

Article 8.7.10.~~12~~.

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

For FMD susceptible animals

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

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

2) were kept since birth or for at least the past three months in a~~n~~ FMD free country~~,~~ or ~~or~~ *zone* ~~or~~ ~~*compartment*~~ where *vaccination* is not practised~~; or a FMD free *compartment*~~ or a FMD free *compartment*;

3) ~~have not been vaccinated;~~

~~4)~~ if transiting an *infected zone*, were not exposed to any source of FMDV ~~*infection*~~ during transportation to the *place of shipment*~~.~~;

Article 8.7.11.~~13~~.

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

For domestic ruminants and pigs

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

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

2) were kept since birth or for at least the past three months in a~~n~~ FMD free country~~, or~~ or *zone* ~~or *compartment*~~ where *vaccination* is practised~~, since birth or for at least the past three months~~; ~~and~~

3) ~~when destined to an FMD free country or *zone* where *vaccination* is not practised, have not been vaccinated and~~ were subjected~~, with negative results,~~ to a test~~s~~ for ~~antibodies against~~ FMD with negative results ~~virus~~ ~~when destined to an FMD free country or *zone* where vaccination is not practised~~;

4) if transiting an *infected zone*, were not exposed to any source of FMDV ~~*infection*~~ during transportation to the *place of shipment*.

Article 8.7.12.~~14~~.

Recommendations for importation from FMD infected countries or zones

For domestic ruminants and pigs

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

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

2) prior to isolation, the animals were kept in the *establishment* of origin since birth, or; ~~since birth, or~~

   a) for the past ~~the past~~ 30 days~~, or since birth if younger than 30 days,~~ if a *stamping-out policy* is in force in the *exporting country* or *zone*, or

   b) for the past ~~the past~~ 3 months, ~~or since birth if younger than three months,~~ if a *stamping-out policy* is not in force in the *exporting country* or *zone*,

3) and that FMD has not occurred within ~~a ten-kilometre radius of~~ the *establishment* of origin for the relevant period as defined in points 2 a) and b) above;

~~3~~4) the animals were isolated in an *establishment* ~~or a *quarantine station*~~ for the 30 days prior to shipment, and all animals in isolation were subjected to diagnostic virological and serological tests ~~(virus detection on a probang sample in ruminants or on throat swabs in pigs and serology)~~ for evidence of FMDV ~~*infection*~~ with negative results on samples collected at least 28 days after the start of isolation ~~the end of that~~ period, and that FMD did not occur within a ten-kilometre radius of the *establishment* ~~or a *quarantine station*~~ during that period; ~~or~~

~~4) were kept in a *quarantine station* for the 30 days prior to shipment, all *animals* in quarantine were subjected to diagnostic tests (probang and serology) for evidence of FMDV *infection* with negative results at the end of that period, and that FMD did not occur within a ten-kilometre radius of the *quarantine station* during that period;~~

5) the animals were not exposed to any source of FMDV ~~*infection*~~ during their transportation from the *establishment* ~~or *quarantine station*~~ to the *place of shipment*.

Article 8.7.13.~~15~~.

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

For fresh semen of domestic ruminants and pigs

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

1) the donor animals:

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

b) were kept for at least three months prior to collection in a~~n~~ FMD free country~~,~~ or ~~or~~ *zones* ~~or compartments~~ where *vaccination* is not practised or FMD free *compartments* ~~or FMD free compartments~~;

c) were kept in an *artificial insemination centre* where none of the animals had a history of *infection;*

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

Article 8.7.14.~~16~~.

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

For frozen semen of domestic ruminants and pigs

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

1) the donor animals:

a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;

b) were kept for at least three months prior to collection in a~~n~~ FMD free country~~,~~ or ~~or~~ *zone* ~~or compartments~~ where *vaccination* is not practised or FMD free *compartments* ~~or FMD free compartments~~;

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

Article 8.7.15.~~17~~.

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

For frozen semen of domestic ruminants and pigs

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

1) the donor animals:

a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;

b) were kept for at least three months prior to collection in a~~n~~ FMD free country~~,~~ or ~~or~~ *zone* ~~or~~ ~~*compartment*~~ where *vaccination* is practised;

~~c) if destined to an FMD free country or *zone* where vaccination is not practised:~~

~~i)~~c) either

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

or

ii) ~~have not been vaccinated and~~ were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMDV ~~virus~~, with negative results~~; or~~

~~ii)~~d) ~~had been vaccinated at least twice, with the last *vaccination* not more than 612 and not less than one month prior to collection~~;

~~2) no other *animal* present in the *artificial insemination centre* has been vaccinated within the month prior to collection;~~

23) the semen:

a) was collected, processed and stored in ~~conformity~~ accordance with the provisions of Chapters 4.5. and 4.6.;

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

Article 8.7.16~~18~~.

Recommendations for importation from FMD infected countries or zones

For frozen semen of domestic ruminants and pigs

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

1) the donor animals:

a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;

b) were kept in an ~~*establishment*~~ *artificial insemination centre* where no animal had been added in the 30 days before collection, and that FMD has not occurred within ~~10 kilometres~~ a ten-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 than one month and not more than six month prior to collection~~, unless protective immunity has been proven for more than six months~~

or

ii) ~~have not been vaccinated and~~ were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMDV ~~virus~~, with negative results~~; or~~

~~ii)~~d) ~~had been vaccinated at least twice, with the last *vaccination* not more than 612 and not less than one month prior to collection.~~;

~~2. no other *animal* present in the *artificial insemination centre* has been vaccinated within the month prior to collection;~~

Rationale – re: Articles 8.7.15.1.c.i and 8.7.16.1.c.i:
We recommend deleting the phrase "unless protective immunity has been proven for more than six months."

- Currently no vaccine has been demonstrated to have immunity in all species for more than 6 months. Until there is an existing vaccine shown to provide protective immunity for more than 6 months in ruminants and swine, the statement is not relevant; hence our recommendation for deletion.

~~3.~~2) the semen:

a) was collected, processed and stored in ~~conformity~~ accordance with the provisions of Chapters 4.5. and 4.6.;

b) was subjected, with negative results, to a test for evidence of FMDV ~~*infection*~~ if the donor animal has been vaccinated within the 12 months prior to collection;

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

Article 8.7.17.~~19.~~

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

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

Article 8.7.18.~~20.~~

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

For *in vitro* produced embryos of cattle

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

1) the donor females:

a) showed no clinical sign of FMD at the time of collection of the oocytes;

b) were kept for at least three months prior to ~~at the time of~~ collection in a~~n~~ FMD free country~~,~~ or ~~or~~ *zones* ~~or *compartments*~~ where *vaccination* is not practised or FMD free *compartments* ~~or FMD free compartments~~;

2) fertilisation was achieved with semen meeting the conditions referred to in Articles 8.7.5.~~15~~13., 8.7.5.~~16~~14., 8.7.5.~~17~~15. or 8.7.5.~~18~~16., as relevant;

3) the oocytes were collected, and the embryos were processed and stored in ~~conformity~~ accordance with the provisions of Chapters 4.8. and 4.9., as relevant.

Article 8.7.19.~~21~~.

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

For *in vitro* produced embryos of cattle

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

1) the donor females:

a) showed no clinical sign of FMD at the time of collection of the oocytes;

b) were kept for at least three months prior to collection in a~~n~~ FMD free country~~,~~ or ~~or~~ *zones* ~~or~~ ~~*compartments*~~ where *vaccination* is practised;

~~c) if destined for an FMD free country or *zone* where vaccination is not practised or a FMD free *compartment*:~~

~~i)~~c) either

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

or

ii) ~~have not been vaccinated and~~ were subjected, not less than 21 days after collection, to tests for antibodies against FMDV ~~virus~~, with negative results~~; or~~

~~ii)d) had been vaccinated at least twice, with the last *vaccination* not more than 612 and not less than one month prior to collection~~;

~~2) no other *animal* present in the *artificial insemination centre* has been vaccinated within the month prior to collection~~;

2) fertilisation was achieved with semen meeting the conditions referred to in Articles 8.7 .~~15~~13., 8.7 .~~16~~14., 8.7 .~~17~~15. or 8.7 .~~18~~16., as relevant;

3) the oocytes were collected, and the embryos were processed and stored in ~~conformity~~ accordance with the provisions of Chapters 4.8. and 4.9., as relevant.

Article 8.7 .20.~~22~~.

Recommendations for importation from FMD free countries~~,~~ or ~~or~~ zones ~~or~~ ~~compartments~~ where vaccination is not practised or FMD free compartments ~~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 ~~the~~ FMD free country~~,~~ or ~~or~~ *zones* ~~or compartments~~ where *vaccination* is not practised or FMD free *compartments* ~~or FMD free compartments~~, or which have been imported in accordance with Article 8.7 .~~12~~10., Article 8.7 .~~13~~11. or Article 8.7 .~~14~~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.

Article 8.7. 21.~~23~~.

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

For fresh meat and meat products of ruminants and pigs ~~cattle and buffaloes (*Bubalus bubalis*) (excluding feet, head and viscera)~~

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

1) have been kept in the FMD free country~~,~~ or ~~or~~ *zone* ~~or *compartment*~~ where *vaccination* is practised, or which have been imported in accordance with Article 8.7 .~~12~~10., Article 8.7 .~~13~~11. or Article 8.7 .~~14~~12.;

2) have been slaughtered in an approved *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections for FMD with favourable results~~.~~;

3) for ruminants the head, including the pharynx, tongue and associated lymph nodes, ~~have~~ has been excluded from the shipment ~~removed~~.

~~Article 8.5.24.~~

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

~~For fresh meat or meat products of pigs and ruminants other than cattle and buffaloes~~

~~*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 the FMD free country or *zone* where vaccination is practised, or which have been imported in accordance with Article 8.5.12., Article 8.5.13. or Article 8.5.14.;~~

~~2) have been slaughtered in an approved *abattoir* and have been subjected to ante- and post-mortem inspections for FMD with favourable results.~~

Article 8.7.22.~~25~~.

Recommendations for importation from FMD infected countries or zones, where an official control programme ~~for FMD, involving compulsory systematic vaccination of cattle,~~ exists

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

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

1) comes from animals which:

   a) have remained, for at least three months prior to *slaughter*, in a *zone* of the *exporting country* ~~for at least three months prior to *slaughter*;~~

   ~~b) have remained, during this period, in a part of the country~~ where cattle and water buffaloes are regularly vaccinated against FMD and where ~~official controls are~~ an *official control programme* is in operation;

   b~~c~~) have been vaccinated at least twice with the last *vaccination* not more than six ~~6~~~~12~~ months, ~~unless protective immunity has been proven for more than six 6 months.~~ and not less than one month prior to *slaughter*;

Rationale re: Articles 8.7.19.1.c.i and 8.7.22.1.b: Like our previous comment, we recommend deleting the phrase "unless protective immunity has been proven for more than six months."

- Currently no vaccine has been demonstrated to have immunity in all species for more than 6 months. Until there is an existing vaccine shown to provide protective immunity for more than 6 months in ruminants and swine, the statement is not relevant; hence our recommendation for deletion.

c~~d~~) were kept for the past 30 days in an *establishment*, and that FMD has not occurred within a ten-kilometre radius of the *establishment* during that period;

d~~e~~) have been transported, in a *vehicle* which was cleansed and disinfected before the cattle and water buffaloes were loaded, directly from the *establishment* of origin to the approved *slaughterhouse/abattoir* without coming into contact with other animals which do not fulfil the required conditions for export;

e~~f~~) have been slaughtered in an approved *slaughterhouse/abattoir*:

i) which is officially designated for export;

ii) in which no FMD has been detected during the period between the last *disinfection* carried out before *slaughter* and the shipment for export has been dispatched;

f~~g~~) have been subjected to ante- and post-mortem inspections for FMD with favourable results within 24 hours before and after *slaughter*;

2) comes from deboned carcasses:

a) from which the major lymphatic nodes have been removed;

b) which, prior to deboning, have been submitted to maturation at a temperature above + 2°C for a minimum period of 24 hours following *slaughter* and in which the pH value was below 6.0 when tested in the middle of both the longissimus dorsi muscle.

Article 8.7.23.~~26~~.

Recommendations for importation from FMD infected countries or zones

For *meat products* of ~~domestic ruminants and pigs~~ FMD susceptible animals

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

1) the entire consignment of *meat products* come~~s~~ from animals which have been slaughtered in an *approved slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections for FMD with favourable results;

2) the *meat products* ha~~s~~ve been processed to ensure the destruction of ~~the~~ FMDV ~~virus~~ in accordance ~~conformity~~ with one of the procedures ~~referred to~~ in Article 8.7 .~~34~~31.;

3) the necessary precautions were taken after processing to avoid contact of the *meat products* with any potential source of FMDV ~~virus~~.

Article 8.7.24.~~27~~.

Recommendations for importation from FMD free countries~~,~~ or ~~or~~ zones ~~or compartments~~ ~~(~~where vaccination either is or is not practised~~)~~ or FMD free compartments ~~or FMD free compartments~~

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

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products come from animals which have been kept in a~~n~~ FMD free country, *zone* or *compartment*, or which have been imported in accordance with Article 8.7 .~~12~~10., Article 8.7 .~~13~~11. or Article 8.7 .~~14~~12.

Article 8.7.25.~~28~~.

Recommendations for importation from FMD infected countries or zones where an

official control programme exists

For *milk*~~, cream, milk powder~~ and *milk products*

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

1) these products:

   a) originate from *establishments* ~~*herds or flocks*~~ which were not infected or suspected of being infected with FMD at the time of *milk* collection;

   b) have been processed to ensure the destruction of ~~the~~ FMDV ~~virus~~ in accordance ~~conformity~~ with one of the procedures ~~referred to~~ in Article 8.7 .~~38~~35. and in Article 8.7 .~~39~~36.;

2) the necessary precautions were taken after processing to avoid contact of the products with any potential source of FMDV ~~virus~~.

Article 8.7.26.~~29~~.

Recommendations for importation from FMD infected countries

For blood-meal and meat-meals from FMD susceptible animals ~~(from domestic or wild ruminants and pigs)~~

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the manufacturing method for these products included heating to a minimum core temperature of 70°C for at least 30 minutes.

Article 8.7.27.~~30~~.

Recommendations for importation from FMD infected countries

For wool, hair, bristles, raw hides and skins from FMD susceptible animals ~~(from domestic or wild ruminants and pigs)~~

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

1) these products have been processed to ensure the destruction of ~~the~~ FMDV ~~virus~~ in accordance ~~conformity~~ with one of the procedures ~~referred to~~ in Articles 8.7 .~~35~~32., 8.7 .~~36~~33. and 8.7 .~~37~~34.;

2) the necessary precautions were taken after collection or processing to avoid contact of the products with any potential source of FMDV ~~virus~~.

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

Article 8.7.28.~~31~~.

Recommendations for importation from FMD infected countries or zones

For straw and forage

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

1) are free of grossly identifiable contamination with material of animal origin;

2) have been subjected to one of the following treatments, which, in the case of material sent in bales, has been shown to penetrate to the centre of the bale:

a) either to the action of steam in a closed chamber such that the centre of the bales has reached a minimum temperature of 80°C for at least ten minutes,

b) or to the action of formalin fumes (formaldehyde gas) produced by its commercial solution at 35–40 percent in a chamber kept closed for at least eight hours and at a minimum temperature of 19°C;

OR

3) have been kept in bond for at least ~~three~~ four months ~~(under study)~~ before being released for export.

Article 8.7.29.~~32~~.

Recommendations for importation from FMD free countries or zones (where vaccination either is or is not practised)

For skins and trophies derived from FMD susceptible *wildlife* ~~*animals*~~

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products are derived from animals that have been killed in such a country or *zone* or which have been imported from a country or *zone*, or *compartment* free ~~of~~ from FMD ~~(where *vaccination* either is or is not practised)~~.

Article 8.7.30.~~33~~.

Recommendations for importation from FMD infected countries or zones

For skins and trophies derived from FMD susceptible *wildlife* ~~*animals*~~

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products have been processed to ensure the destruction of ~~the~~ FMDV ~~virus~~ in accordance ~~conformity~~ with the procedures ~~referred to~~ in Article 8.7 .~~40~~37.

Article 8.7.31.~~34~~.

Procedures for the inactivation of ~~the~~ FMDV ~~virus~~ in meat and meat products

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

1. Canning

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

2. Thorough cooking

   Meat, previously deboned and defatted, and *meat products* ~~shall be~~ are subjected to a heat treatment ~~heating~~ that results in ~~so that~~ a core ~~an internal~~ temperature of 70°C or more ~~greater is maintained for a minimum of 30 minutes~~.

   After cooking, ~~it~~ they ~~shall~~ should be packed and handled in such a way they are not ~~that it cannot be~~ exposed to a source of FMDV ~~virus~~.

3. Drying after salting

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

'~~Drying~~ Completely dried' is defined ~~in terms of the~~ as a ratio between water and protein ~~which must~~ that is not ~~be~~ greater than 2.25:1.

Article 8.7.32.~~35~~.

Procedures for the inactivation of ~~the~~ FMDV ~~virus~~ in wool and hair

For the inactivation of FMDV ~~viruses~~ 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 in a series of baths of water, soap and sodium hydroxide (soda) or potassium hydroxide (potash);

2) chemical depilation by means of slaked lime or sodium sulphide;

3) fumigation with ~~in~~ formaldehyde in a hermetically sealed chamber for at least 24 hours. ~~The most practical method is to place potassium permanganate in containers (which must NOT be made of plastic or polyethylene) and add commercial formalin; the amounts of formalin and potassium permanganate are respectively 53 ml and 35 g per cubic metre of the chamber~~;

4) industrial scouring which consists of the immersion of wool in a water-soluble detergent held at 60–70°C;

5) storage of wool at ~~18°C for four weeks, or~~ 4°C for four months, 18°C for four weeks or 37°C for eight days.

Article 8.7.33.~~36~~.

Procedures for the inactivation of ~~the~~ FMDV ~~virus~~ in bristles

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

1) boiling for at least one hour;

2) immersion for at least 24 hours in a one percent aqueous solution of formaldehyde ~~prepared from 30 ml commercial formalin per litre of water~~.

Article 8.7.34.~~37~~.

Procedures for the inactivation of ~~the~~ FMDV ~~virus~~ in raw hides and skins

For the inactivation of FMDV ~~viruses~~ present in raw hides and skins for industrial use, the following procedure should be used: treatment ~~salting~~ for at least 28 days ~~in~~ with ~~sea~~ salt (NaCl) containing 2 percent sodium carbonate (Na_2CO_3).

Article 8.7.35.~~38~~.

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

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

1) a ~~sterilisation~~ process applying a minimum temperature of 132°C for at least one second (ultra-high temperature [UHT]), or

2) if the *milk* has a pH less than 7.0, a ~~sterilisation~~ process applying a minimum temperature of 72°C for at least 15 seconds (high temperature – short time pasteurisation [HTST]), or

3) if the *milk* has a pH of 7.0 or greater ~~over~~, the HTST process applied twice.

Article 8.7.36.~~39~~.

Procedures for the inactivation of ~~the~~ FMDV ~~virus~~ in milk for animal consumption

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

1) the HTST process applied twice;

2) HTST combined with another physical treatment, e.g. maintaining a pH 6 for at least one hour or additional heating to at least 72°C combined with desiccation;

3) UHT combined with another physical treatment referred to in point 2 above.

Article 8.7.37~~40~~.

Procedures for the inactivation of ~~the~~ FMDV ~~virus~~ in skins and trophies from wild animals susceptible to the disease

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

1) boiling in water for an appropriate time so as to ensure that any matter other than bone, horns, hooves, claws, antlers or teeth is removed;

2) gamma irradiation at a dose of at least 20 kiloGray at room temperature (20°C or higher);

3) soaking, with agitation, in a four percent (~~w/v~~ weight/volume) solution of ~~washing soda (~~sodium carbonate ~~–~~ ((Na_2CO_3) maintained at pH 11.5 or greater ~~above~~ for at least 48 hours;

4) soaking, with agitation, in a formic acid solution (100 kg salt [NaCl] and 12 kg formic acid per 1,000 litres water) maintained at below pH 3.0 for at least 48 hours; wetting and dressing agents may be added;

5) in the case of raw hides, treating ~~salting~~ for at least 28 days with ~~sea~~ salt (NaCl) containing two percent ~~washing soda (~~sodium carbonate ~~–~~ ((Na_2CO_3).

Article 8.7.38.~~41~~.

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

For the inactivation of FMDV ~~viruses~~ present in casings of ruminants and pigs, the following procedures should be used: treating ~~salting~~ for at least 30 days either with dry salt (NaCl) or with saturated brine (NaCl, ~~Aw~~ a_w< 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), either dry or as a saturated brine (a_w< 0.80), and kept at a temperature of greater than 12°C during this entire period.

Article 8.7.39.

OIE endorsed official control programme for FMD

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

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

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

Country should:

1) have a record of regular and prompt animal *disease* reporting according to the requirements in Chapter 1.1.;

2) submit documented evidence of ~~on~~ the capacity of the *Veterinary Services* to control FMD; one way of providing this evidence ~~can be provided by countries following~~ is through the OIE PVS Pathway;

3) submit a detailed plan of ~~on~~ the programme to control and eventually eradicate FMD in the country or *zone* including:

   a) the timeline;

   b) the performance indicators for assessing ~~to assess~~ the efficacy of the control measures to be implemented;

   c) ~~submit~~ documentation indicating that the *official control programme* for FMD is applicable to the entire country;

4) submit a dossier on the epidemiology of FMD in the country describing the following:

   a) the general epidemiology in the country highlighting the current knowledge and gaps and the progress that has been made in controlling FMD;

   b) the measures implemented to prevent introduction of *infection*, the rapid detection of, and response to, all FMD *outbreaks* in order to reduce the incidence of FMD *outbreaks* and to eliminate FMDV ~~virus circulation~~transmission ~~in domestic ruminants~~ in at least one *zone* in the country;

   c) the main livestock production systems and movement patterns of FMD susceptible animals and their products within and into the country;

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

   a) taking into account provisions in Chapter 1.4. and the provisions on *surveillance* of this chapter;

   b) have diagnostic capability and procedures, including regular submission of samples to a *laboratory* that carries out diagnosis and further characterisation of strains;

6) where *vaccination* is practised as a part of the *official control programme* for FMD, provide:

   a) evidence (such as copies of legislation) that *vaccination* of selected populations is compulsory;

   b) detailed information on *vaccination* campaigns, in particular on:

      i) target populations for *vaccination*;

      ii) monitoring of *vaccination* coverage, including serological monitoring of population immunity;

      iii) technical specification of the vaccines used, including matching with the circulating FMDV strains, and description of the licensing procedures in place;

      iv) the proposed timeline for the transition to the use of vaccines fully compliant with the standards and methods described in the *Terrestrial Manual*;

7) provide an emergency preparedness and response plan to be implemented in case of *outbreaks*.

The Member Country's *official control programme* for FMD will be included in the list of programmes endorsed by the OIE only after the submitted evidence has been accepted by the OIE. Retention on the list requires an annual update on the progress of the *official control programme* and information on significant changes concerning the points above. Changes in the epidemiological situation and other significant events

should be reported to the OIE according to the requirements in Chapter 1.1.

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

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

Article 8.7.40.~~42~~.

General principles of ~~S~~surveillance~~: introduction~~

Articles 8.7~~5~~.~~42~~40. to 8.7~~5~~.~~47~~~~4~~62. ~~and Article 8.5.49.~~ define the principles and provide a guide for the *surveillance* of FMD in accordance with Chapter 1.4. applicable to Member Countries seeking establishment, maintenance ~~and~~ or recovery of freedom from FMD at the country, *zone* or *compartment* level~~, either with or without the use of *vaccination*~~ ~~and~~ or Member Countries seeking endorsement by the OIE of their *official control programme* for FMD, in accordance with Article 8.7~~5~~.39. *Surveillance* aimed at identifying *disease* and FMDV *infection* or ~~Avirus circulation~~ transmission should cover ~~all the susceptible~~ domestic and *wildlife* species indicated in Article 8.7.1. point 2 ~~, including *wildlife*, if applicable~~, within the country, *zone* or *compartment*. ~~Guidance is provided for Members seeking reestablishment of freedom from FMD for the entire country or for a *zone*, either with or without vaccination, or a *compartment*, following an *outbreak* and for the maintenance of FMD status.~~

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

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

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

A Member Country wishing to demonstrate FMD freedom where *vaccination* is not practised should show absence of FMDV *infection*.

A Member Country wishing to demonstrate FMD freedom where *vaccination* is practised should show that FMDV has not been transmitted in any susceptible populations. Within vaccinated populations, serological surveys to demonstrate the absence of FMDV transmission should target animals that are less likely to show vaccine-derived antibodies to nonstructural proteins, such as young animals vaccinated a limited number of times, or unvaccinated animals. Absence of FMDV *infection* should be demonstrated in any unvaccinated *subpopulations*.

Surveillance strategies employed for establishing and maintaining a *compartment* should ~~also~~ identify the prevalence, distribution and characteristics of FMD outside the *compartment* ~~in the country or *zone*~~.

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

~~There is~~ Therefore considerable latitude is available to Member Countries to design and implement *surveillance* ~~on the one hand~~ to establish that the whole territory or part of it is free from FMDV *infection* and ~~/circulation~~transmission and ~~on the other~~ to understand the epidemiology of FMD as part of the *official control programme* ~~official FMD control programmes~~.

It is incumbent upon the Member Country to submit a dossier to the OIE in support of its application that not only explains the epidemiology of FMD in the region concerned but also demonstrates how all the risk factors, including the role of *wildlife*, are identified and managed. This should include provision of scientifically based supporting data. ~~There is therefore considerable latitude available to Members to provide a well-reasoned argument to prove that the absence of FMDV *infection* (in non-vaccinated populations) or circulation (in vaccinated populations) is assured at an acceptable level of confidence.~~

Surveillance for FMD should be in the form of a continuing programme. ~~The design of S~~*surveillance* programmes to prove the absence of FMDV *infection* and ~~/ circulation~~transmission ~~needs to~~ should be carefully designed and implemented ~~followed~~ to avoid producing results that are ~~either~~ insufficient~~ly reliable~~ to be accepted by the OIE or ~~international~~ trading partners, or being excessively costly and logistically complicated. ~~The design of any *surveillance* programme, therefore, requires inputs from professionals competent and experienced in this field.~~

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

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

An effective *surveillance* system will identify suspected cases that require immediate follow-up and investigation to confirm or exclude that the cause of the condition is FMDV. Samples should be taken and submitted for diagnostic testing, unless the suspected case can be confirmed or ruled out by epidemiological and clinical investigation. Details of the occurrence of suspected cases and how they were investigated and dealt with should be documented. This should include the results of diagnostic testing and the control measures to which the animals concerned were subjected during the investigation.

~~Irrespective of the survey design selected,~~ T~~t~~he sensitivity and specificity of the diagnostic tests employed, including the performance of confirmatory tests, are key factors in the design, sample size determination and interpretation of the results obtained. ~~Ideally,~~ T~~t~~he sensitivity and specificity of the tests used should be validated for the *vaccination*~~/~~ or *infection* history and production class of animals in the target population.

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

Laboratory results should be examined in the context of the epidemiological situation. Corollary information needed to complement the serological survey and assess the possibility of viral ~~circulation~~transmission

includes but is not limited to:

- characterisation of the existing production systems;
- results of clinical *surveillance* of the suspects and their cohorts;
- ~~quantification~~ description of number of, and protocol for, ~~of~~ *vaccinations* performed in the area under assessment ~~on the affected sites~~;
- biosecurity ~~sanitary protocol~~ and history of the *establishments* with positive reactors;
- control of *animal identification* and traceability of movements;

Rationale for Article 8.7.40: The control of animal identification does not equate to traceability. The suggested change improves the specificity and clarity of the statement.

- other parameters of regional significance in historic FMDV transmission.

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

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

The entire investigative process should be documented as standard operating procedure within the *surveillance* programme.

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

~~*Surveillance* for FMD should be in the form of a continuing programme designed to establish that the whole territory or part of it is free from FMDV *infection*/circulation.~~

~~For the purposes of this chapter, virus circulation means transmission of FMDV as demonstrated by clinical signs, serological evidence or virus isolation.~~

Article 8.7.41.~~43~~.

Methods of s~~S~~urveillance: ~~**general conditions and methods**~~ ~~**general principles**~~

~~1)~~ ~~A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. A procedure should be in place for the rapid collection and transport of samples from suspect *cases* of FMD to a *laboratory* for FMD diagnose~~is ~~as described in the *Terrestrial Manual*. This requires that sampling kits and other equipment are available for those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in FMD diagnosis and control.~~

12) The FMD *surveillance* programme should:

a) include structured non-random *surveillance* activities as described in Article 1.4.5. with particular reference to an early warning system throughout the production, marketing and processing chain for reporting suspicious suspect *cases*. Farmers and workers who have day-to-day contact with livestock, as well as diagnosticians, should report promptly any suspicion of FMD. They should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. All suspect *cases* of FMD should be investigated immediately. Where suspicion cannot be resolved by epidemiological and clinical investigation, sSamples should be taken and submitted for diagnostic testing a *laboratory*, unless the suspect *case* can be confirmed or ruled out by epidemiological and clinical investigation. This requires that sampling kits and other equipment are available for those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in FMD diagnosis and control. Any *epidemiological unit* within which suspicious *animals* are detected should be classified as infected until contrary evidence is produced;

b) implement, when relevant, regular and frequent clinical inspection and serological testing of high-risk groups of *animals*, such as those adjacent to an FMD infected country or *infected zone* (for example, bordering a game park in which infected *wildlife* are present).

b) implement structured population-based surveys, when appropriate, as described in Article 1.4.4.

3) The *surveillance* programme above should:

a) identify the nature of risk factors, including the role of *wildlife*, to inform targeted *surveillance* strategies when appropriate;

b) implement, when relevant, an appropriate combination of clinical investigation and other diagnostic procedures in high risk groups.

34) An effective *surveillance* system should will periodically identify suspicious suspect *cases* that require follow-up and investigation to confirm or exclude that the cause of the condition is FMDV. Details of the occurrence of suspect *cases* and how they were investigated and dealt with should be documented. The rate at which such suspicious *cases* are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from FMDV *infection*/circulation should, in consequence, provide details of the occurrence of suspicious *cases* and how they were investigated and dealt with. This should include the results of diagnostic *laboratory* testing and the control measures to which the *animals* concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

Article 8. 5.42.44.

Surveillance: methods strategies

1. Introduction

The target population for *surveillance* aimed at identifying *disease* and *infection* should cover all the susceptible species within the country, *zone* or *compartment*.

The design of *surveillance* programmes to prove the absence of FMDV *infection*/circulation needs to be carefully followed to avoid producing results that are either insufficiently reliable to be accepted by the OIE or international trading partners, or excessively costly and logistically complicated. The design of any *surveillance* programme, therefore, requires inputs from professionals competent and experienced in this field.

~~The strategy employed may be based on randomised sampling requiring *surveillance* consistent with demonstrating the absence of FMDV *infection*/circulation at an acceptable level of statistical confidence. The frequency of sampling should be dependent on the epidemiological situation. Targeted *surveillance* (e.g. based on the increased likelihood of *infection* in particular localities or species) may be an appropriate strategy. The Member should justify the *surveillance* strategy chosen as adequate to detect the presence of FMDV *infection*/circulation in accordance with Chapter 1.4. and the epidemiological situation. It may, for example, be appropriate to target clinical *surveillance* at particular species likely to exhibit clear clinical signs (e.g. cattle and pigs). If a Member wishes to apply for recognition of a specific *zone* within the country as being free from FMDV *infection*/circulation, the design of the survey and the basis for the sampling process would need to be aimed at the population within the *zone*.~~

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

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

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

1~~2.~~ Clinical surveillance

~~The detection of clinical signs by farmers, *veterinary para-professionals* and *veterinarians* is the foundation of an early warning system and of clinical *surveillance*.~~

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

Clinical *surveillance* ~~aims at detecting clinical signs of FMD by~~ requires close physical examination of susceptible animals. ~~Whereas~~ Although significant emphasis is placed on the diagnostic value of mass serological screening, *surveillance* based on clinical inspection ~~should not be underrated.~~ . ~~It may~~ ~~as it can~~ ~~be able to~~ may provide a high level of confidence of detection of *disease* if a sufficient~~ly~~ ~~large~~ number of clinically susceptible animals is examined at an appropriate frequency and investigations are recorded and quantified.

Clinical examination ~~*surveillance*~~ and ~~*laboratory*~~ diagnostic testing should ~~always~~ be applied ~~in series~~ to clarify the status of ~~FMD~~ suspected cases detected by either of these complementary diagnostic approaches. ~~*Laboratory*~~ Diagnostic testing may confirm clinical suspicion, while clinical *surveillance* may contribute to confirmation of positive ~~serology~~ laboratory test results. ~~Any sampling unit within which suspicious *animals* are detected should be classified as infected until contrary evidence is produced.~~ Clinical *surveillance* may be insufficient in ~~case of~~ wildlife and domestic species that usually do not show clinical signs or husbandry systems that do not permit sufficient observations. In such situations ~~cases~~, serological ~~sero-~~surveillance should be used. Hunting, capture and non-invasive sampling and observation methods can be used to obtain information and diagnostic samples from wildlife species.

~~A number of issues must be considered in clinical *surveillance* for FMD. The often underestimated~~

~~labour intensity and the logistical difficulties involved in conducting clinical examinations should not be underestimated and should be taken into account.~~

~~Identification of clinical *cases* is fundamental to FMD *surveillance*. Establishment of the molecular, antigenic and other biological characteristics of the causative virus, as well as its source, is dependent upon disclosure of such *animals*. It is essential that FMDV isolates are sent regularly to the regional reference *laboratory* for genetic and antigenic characterization.~~

~~3~~2. Virological surveillance

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

Virological *surveillance* ~~using tests described in the *Terrestrial Manual* should be conducted~~ aims to:

~~a)~~ ~~to monitor at risk populations;~~

~~b)~~a) ~~to~~ confirm clinically suspected cases;

~~c~~b) ~~to~~ follow up positive serological results;

c) characterise isolates for epidemiological studies and vaccine matching;

~~d)~~ ~~to test 'normal' daily mortality, to ensure early detection of *infection* in the face of vaccination or in *establishments* epidemiologically linked to an *outbreak*.~~

d) monitor ~~at risk~~ populations at risk.

~~4~~3) Serological surveillance

Serological *surveillance* aims at detecting antibodies ~~against FMDV caused by~~ resulting from *infection* or *vaccination* using ~~either,~~ nonstructural protein ~~(NSP)~~ tests ~~that detect all FMD types~~ or ~~type-specific tests that detect~~ structural protein~~s~~ tests. ~~Positive FMDV antibody test results can have four possible causes:~~

Serological *surveillance* ~~with tests described in the *Terrestrial Manual*~~ ~~is~~ may be used to:

a) estimate the prevalence or substantiate freedom from ~~demonstrate the absence of~~ FMDV *infection*~~*l*~~ or ~~circulation~~transmission;

b) monitor population immunity.

~~a)~~ ~~natural *infection* with FMDV;~~

~~b)~~ ~~*vaccination* against FMD;~~

~~c)~~ ~~maternal antibodies derived from an immune dam (maternal antibodies in cattle are usually found only up to six months of age but in some individuals and in some species, maternal antibodies can be detected for considerably longer periods);~~

~~d)~~ ~~heterophile (cross) reactions.~~

It is important that serological tests, where applicable, contain antigens appropriate for detecting antibodies against viral variants (types, subtypes, lineages, topotypes, etc.) that have recently occurred in the region concerned. Where the probable identity of FMDVs is unknown or where exotic viruses are suspected to be present, tests able to detect representatives of all serotypes should be employed (e.g. tests based on nonstructural viral proteins – see below).

It may be possible to use sSerum collected for other survey purposes can be used for FMD *surveillance*.. provided However, the principles of survey design described in this chapter are met. and the requirement for a statistically valid survey for the presence of FMDV should not be compromised.

The discovery of clustering of seropositive reactions should be foreseen. It may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or the presence of field strain *infection*. As clustering may signal field strain *infection*, the investigation of all instances must be incorporated in the survey design. If *vaccination* cannot be excluded as the cause of positive serological reactions, diagnostic methods should be employed that detect the presence of antibodies to nonstructural proteins (NSPs) of FMDVs as described in the *Terrestrial Manual*.

The results of random or targeted serological surveys are important in providing reliable evidence that FMDV *infection* is not present in a country, *zone* or *compartment* of the FMD situation in a country, *zone* or *compartment*. It is therefore essential that the survey be thoroughly documented.

Article 8. 5.43.45.

Members applying for recognition of freedom from FMD for the whole a country, or a zone or compartment where vaccination is not practised: additional surveillance procedures

The strategy and design of the *surveillance* programme will depend on the historical epidemiological circumstances including whether or not *vaccination* has been used. In addition to the general conditions described in the above-mentioned articles, a A Member applying for recognition of FMD freedom for the country, or a *zone* or *compartment* where *vaccination* is not practised should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances will be planned and implemented according to general conditions and methods in this chapter, to demonstrate absence of FMDV circulation in previously vaccinated *animals* and absence of FMDV *infection* in non-vaccinated *animals*., during the preceding 12 months in susceptible populations. This requires the support of a national or other *laboratory* able to undertake identification of FMDV *infection* through virus/antigen/genome detection and antibody tests described in the *Terrestrial Manual*.

Article 8.5.44.46.

Members applying for recognition of freedom from FMD for the whole a country, or a zone or compartment where vaccination is practised: additional surveillance procedures

In addition to the general conditions described in the above-mentioned articles, a Member applying for recognition of country or *zone* freedom from FMD with *vaccination* should show evidence of an effective *surveillance* programme planned and implemented according to general conditions and methods in this chapter. Absence of clinical *disease* in the country or *zone* for the past two years should be demonstrated. Furthermore, s*Surveillance* should demonstrate that FMDV has not been circulating in any susceptible populations during the past 12 months. This will require serological *surveillance* incorporating tests able to detect antibodies to NSPs as described in the *Terrestrial Manual*. Serological surveys to demonstrate the absence of FMDV circulation should target within vaccinated populations, unvaccinated *animals* or *animals* that are less likely to show vaccine-derived antibodies to NSPs, such as young *animals* vaccinated a limited number of times, or unvaccinated *subpopulations*. Vaccination to prevent the transmission of FMDV may be part of a disease control programme. The level of *herd* immunity required to prevent transmission will depend on the size, composition (e.g. species) and density of the susceptible population. It is therefore impossible to be prescriptive. However, the aim should be for at least 80 percent of the *animals* in each vaccinated population to have protective immunity. The vaccine must comply with the *Terrestrial Manual*. Evidence to show the effectiveness of the *vaccination* programme such as adequate *vaccination* coverage and population immunity should be provided.

In designing serosurveys to estimate population immunity, blood sample collection should be stratified by

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

Based on the epidemiology of FMD in the country or *zone*, it may be that a decision is reached to vaccinate only certain species or other subsets of the total susceptible population. In that case, the rationale should be contained within the dossier accompanying the application to the OIE for recognition of status.

Evidence to show the effectiveness of the vaccination programme should be provided.

Article 8.56.45.47.

Members re-applying for recognition of freedom from FMD for the whole a country, or a zone or compartment where vaccination is either practised or not practised, following an outbreak: additional surveillance procedures

In addition to the general conditions described in the above-mentioned articles, aA country re-applying for country, or *zone* or *compartment* freedom from FMD where *vaccination* is practised or not practised should show evidence of an active *surveillance* programme for FMD as well as absence of FMDV *infection/* circulation. This will require serological surveillance incorporating, in the case of a country or a zone practising vaccination or a country or a zone practising tests able to detect antibodies to NSPs, as described in the *Terrestrial Manual*.

Four strategies are recognised by the OIE in a programme to eradicate FMDV *infection/*circulation following an *outbreak*:

1. *slaughter* of all clinically affected and in-contact susceptible *animals*;

2. *slaughter* of all clinically affected and in-contact susceptible *animals* and vaccination of at-risk *animals*, with subsequent *slaughter* of vaccinated *animals*;

3. *slaughter* of all clinically affected and in-contact susceptible *animals* and vaccination of at-risk *animals*, without subsequent *slaughter* of vaccinated *animals*;

4. vaccination used without *slaughter* of affected *animals* or subsequent *slaughter* of vaccinated *animals*.

The time periods before which an application can be made for re-instatement of freedom from FMD depends on

which of these alternatives is followed. The time periods are prescribed in Article 8.5.9.

1. Additional *surveillance* using NSP tests is required to reduce the time period from six to three months in case of *slaughter* of all clinically affected and in-contact susceptible *animals* and *vaccination* of at-risk *animals*, without subsequent *slaughter* of vaccinated *animals* as mentioned in point 1c) of Article 8.5.7., Additional. This includes serosurveillance of all *herds* with vaccinated *animals* by sampling all vaccinated ruminants and their non-vaccinated offspring and a representative number of *animals* of other species based on an acceptable level of confidence.

~~In all circumstances, a Member re-applying for country or *zone* freedom from FMD with vaccination or without vaccination should report the results of an active *surveillance* programme implemented according to general conditions and methods in this chapter.~~

~~Article 8.5.48.~~

~~**OIE endorsed official control programme for FMD**~~

~~The overall objective of an OIE endorsed *official control programme* for FMD is for countries to progressively improve the situation and eventually attain free status for FMD.~~

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

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

1. ~~submit documented evidence on the capacity of the *Veterinary Services* to control FMD; this evidence can be provided by countries following the OIE PVS Pathway;~~

2. ~~submit documentation indicating that the *official control programme* for FMD is applicable to the entire territory;~~

3. ~~have a record of regular and prompt animal *disease* reporting according to the requirements in Chapter 1.1.;~~

4. ~~submit a dossier on the epidemiology of FMD in the country describing the following:~~

   a) ~~the general epidemiology in the country highlighting the current knowledge and gaps;~~

   b) ~~the measures to prevent introduction of *infection*;~~

   c) ~~the main livestock production systems and movement patterns of FMD susceptible animals and their products within and into the country;~~

5. ~~submit a detailed plan on the programme to control and eventually eradicate FMD in the country or *zone* including:~~

   a) ~~the timeline;~~

   b) ~~the performance indicators to assess the efficacy of the control measures to be implemented;~~

6. ~~submit evidence that FMD *surveillance*, taking into account provisions in Chapter 1.4. and the provisions on *surveillance* of this chapter, is in place;~~

7. ~~have diagnostic capability and procedures, including regular submission of samples to a laboratory that carries out diagnosis and further characterisation of strains in accordance with the *Terrestrial Manual*;~~

8. ~~where vaccination is practised as a part of the *official control programme* for FMD, provide evidence (such as copies of legislation) that vaccination of selected populations is compulsory;~~

9. ~~if applicable, provide detailed information on vaccination campaigns, in particular on:~~

   a) ~~target populations for vaccination;~~

   b) ~~monitoring of vaccination coverage, including serological monitoring of population immunity;~~

c) technical specification of the vaccines used and description of the licensing procedures in place;

d) the proposed timeline for the transition to the use of vaccines, fully compliant with the standards and methods described in the *Terrestrial Manual*;

10. provide an emergency preparedness and response plan to be implemented in case of *outbreaks*.

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

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

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

Article 8.7.462.49.

The use and interpretation of serological tests (see Figure 123)

The recommended serological tests for FMD *surveillance* are described in the *Terrestrial Manual*. The selection and interpretation of serological tests should be considered in the context of the epidemiological situation. Information should be provided on the Test protocols, reagents, performance characteristics and validation of all tests used should be known. Where combinations of tests are used, the overall test system performance characteristics should also be known. The selection and interpretation of serological tests should be considered in the context of the epidemiological situation.

Animals infected with FMDV produce antibodies to both the structural proteins (SP) and the nonstructural proteins (NSP) of the virus. Tests for SP antibodies to include SP-ELISAs and the virus neutralisation test (VNT). Vaccinated animals produce antibodies mainly or entirely to the SP structural proteins of the virus depending upon vaccine purity. The SP structural protein tests are serotype specific and for optimal sensitivity one should select utilise an antigen or virus closely related to the field strain expected against which antibodies are being sought. Tests for NSP antibodies include NSP I-ELISA 3ABC and the electro-immunotransfer blotting technique (EITB) as recommended in the *Terrestrial Manual* or equivalent validated tests. In unvaccinated populations, SP structural protein tests may be used to screen sera for evidence of FMDV *infection*/ or circulationtransmission or to detect the introduction of vaccinated animals. In areas where animals have been vaccinated populations, SP structural protein antibody tests may be used to monitor the serological response to the *vaccination* and can help to identify *infection* since vaccinated-and-infected animals may have higher SP- antibody titres than vaccinated-only animals.

In contrast to SP tests, Nonstructural protein NSP tests may be used to screen sera for evidence of can detect antibodies due to *infection*/ or circulationtransmission of for to all serotypes of FMDV virus regardless of the *vaccination* status of the animals provided the vaccines comply with the standards of the *Terrestrial Manual* insofar as with respect to purity is concerned. However, although aAnimals vaccinated and subsequently infected with FMDV virus develop antibodies to nonstructural proteins NSP s, but in some, the titre levels may be lower than that those found in infected animals that have not been vaccinated. To ensure that all animals that had contact with the FMDV have seroconverted it is recommended that for each *vaccination* area to take samples for nonstructural protein NSP antibody testing are taken not earlier than 30 days after the last case and in any case not earlier than 30 days after the last *vaccination*.

Both the NSP I-ELISA 3ABC and EITB tests have been extensively used in cattle. Validation in other species is ongoing. Vaccines used should comply with the standards of the *Terrestrial Manual* insofar as purity is concerned to avoid interference with NSP antibody testing.

Serological testing is a suitable tool for FMD *surveillance*. The choice of a serosurveillance system will

~~depend on, amongst other things, the vaccination status of the country. A country, which is free from FMD without vaccination, may choose serosurveillance of high-risk subpopulations (e.g. based on geographical risk for exposure to FMDV). SP tests may be used in such situations for screening sera for evidence of FMDV *infection*/circulation if a particular virus of serious threat has been identified and is well characterised. In other cases, NSP testing is recommended in order to cover a broader range of strains and even serotypes. In both cases, serological testing can provide additional support to clinical *surveillance*. Regardless of whether SP or NSP tests are used in countries that do not vaccinate, a diagnostic follow-up protocol should be in place to resolve any presumptive positive serological test results. In areas where *animals* have been vaccinated, SP antibody tests may be used to monitor the serological response to the vaccination. However,~~

~~NSP antibody tests should be used to monitor for FMDV *infection*/circulation. NSP-ELISAs may be used for screening sera for evidence of *infection*/circulation irrespective of the vaccination status of the *animal*.~~

Positive FMDV antibody test results can have four ~~five~~ possible causes:

a) *infection* with FMDV;

b) *vaccination* against FMD;

c) maternal antibodies ~~derived from an immune dam~~ (maternal antibodies in cattle are usually found only up to six months of age but in some individuals and in some other species, maternal antibodies can be detected for longer periods);

d) non-specific reactivity of the serum in the tests used~~;~~

~~e) lack of specificity of the diagnostic tests used~~.

Procedure in case of positive test results:

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

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

All *herds* with ~~seropositive~~ at least one *laboratory* confirmed reactor~~s~~ should be investigated ~~immediately~~. ~~Epidemiological and supplementary *laboratory* investigation results should document the status of FMDV *infection*/circulation for each positive *herd*.~~ The investigation should examine all evidence, including the results of virological 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 ~~virus circulation~~transmission and should document the status ~~of FMDV *infection*/ circulation~~ for each positive *herd*. Epidemiological investigation should be continued concurrently ~~in parallel~~.

Clustering of seropositive reactions should be investigated as it may reflect any of a series of events, including ~~but not limited to~~ the demographics of the population sampled, vaccinal exposure or the presence of *infection*~~/~~ or ~~circulation~~transmission. As clustering may signal *infection*~~/~~ or ~~circulation~~transmission, the investigation of all instances should ~~must~~ be incorporated in the survey design.

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

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

In some circumstances, s~~S~~entinel animals ~~can~~ may also be used. These can be young, unvaccinated animals or animals in which maternally conferred immunity has lapsed and preferably ~~belonging to~~ of the same species as ~~resident with~~in the ~~initial~~ positive sampling units. If other susceptible, unvaccinated animals are present, they could act as sentinels to provide additional serological evidence. The sentinels should be kept in close contact with the animals of the *epidemiological unit* under investigation for at least two *incubation periods* and should remain serologically negative if ~~virus~~ FMDV is not circulating.

~~Tests used for confirmation should be of high diagnostic specificity to eliminate as many false positive screening test reactors as possible. The diagnostic sensitivity of the confirmatory test should approach that of the screening test. The EITB or another OIE-accepted test should be used for confirmation.~~

~~Information should be provided on the protocols, reagents, performance characteristics and validation of all tests used.~~

~~1.~~ ~~The follow-up procedure in case of positive test results if no vaccination is used in order to establish or re-establish FMD free status without vaccination country or, zone where vaccination is not practised~~

~~Any positive test result (regardless of whether SP or NSP tests were used) should be followed up immediately using appropriate clinical, epidemiological, serological and, where possible, virological investigations of the reactor *animal* at hand, of susceptible *animals* of the same *epidemiological unit* and of susceptible *animals* that have been in contact or otherwise epidemiologically associated with the reactor *animal*. If the follow-up investigations provide no evidence FMDV infection, the reactor *animal* shall be classified as FMD negative. In all other cases including the absence of such follow-up investigations, the reactor *animal* should be classified as FMD positive.~~

Follow-up of field and laboratory findings:

If ~~circulation~~transmission is proven then an ~~the~~ *outbreak* is declared.

~~In the absence of FMDV circulation, an *outbreak* can be ruled out, but t~~The significance of small numbers of ~~FMD~~ seropositive animals in the absence of current FMDV transmission is difficult to determine~~classify~~. Such findings ~~can~~ may be an indication of past ~~acute~~ *infection* followed by recovery or by the development of a ~~the~~ carrier state, in ruminants, or due to non-specific serological reactions ~~or lack of specificity of the diagnostic tests used~~. Antibodies to nonstructural proteins ~~NSP~~ 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 ~~for~~ countries~~.~~ or *zones* ~~or *compartments*~~ 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.

However, if the number of seropositive animals is greater than the number of non-specific test system findings expected, susceptible animals that have been in contact or otherwise epidemiologically associated with the reactor animals should be investigated further.

~~In the case of a vaccinated *herd* in a country, or *zone* or *compartment* trying to establish or re-establish the status of an FMD free country, or *zone* or *compartment* where *vaccination* is practised, the follow-up investigations may be considered completed where the *herd* can be declared free of FMDV circulationtransmission. In the case of a number of FMD positive animals at a level above the expected number of non-specific test system findings, susceptible animals that have been in contact or otherwise epidemiologically associated with the reactor animal(s) should be investigated.~~

~~In all other cases, when a small number of FMD positive *animals* are found, at a level consistent with the expected number of non-specific test system findings, it is recommended that such reactor *animals* should be slaughtered, and then the *herd* declared free of FMDV *infection*. In the case of a number of FMD positive *animals* at a level above the expected number of non-specific test system findings, it is recommended that the *herd* should be slaughtered and susceptible *animals* that have been in contact or otherwise epidemiologically associated with the reactor *animal(s)* should be investigated.~~

~~2.~~ ~~The follow-up procedure in case of positive test results if vaccination is used in order to establish or re-establish FMD free country or zone where vaccination is practised status with vaccination~~

~~In case of vaccinated populations, one has to exclude that positive test results are indicative of virus circulation. To this end, the following procedure should be followed in the investigation of positive serological test results derived from *surveillance* conducted on FMD vaccinated populations.~~

~~The investigation should examine all evidence that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were not due to virus circulation. All the epidemiological information should be substantiated, and the results should be collated in the final report.~~

~~It is suggested that in the primary sampling units where at least one *animal* reacts positive to the NSP test, the following strategy(ies) should be applied:~~

~~a)~~ ~~Following clinical examination, a second serum sample should be taken from the *animals* tested in the initial survey after an adequate interval of time has lapsed, on the condition that they are individually identified, accessible and have not been vaccinated during this period. The number of *animals* with antibodies against NSP in the population at the time of retest should be statistically either equal to or less than that observed in the initial test if virus is not circulating.~~

~~The *animals* sampled should remain in the holding pending test results and should be clearly identifiable. If the three conditions for retesting mentioned above cannot be met, a new serological survey should be carried out in the holding after an adequate period of time, repeating the application of the primary survey design and ensuring that all *animals* tested are individually identified. These *animals* should remain in the holding and should not be vaccinated, so that they can be retested after an adequate period of time.~~

~~b)~~ ~~Following clinical examination, serum samples should be collected from representative numbers of susceptible *animals* that were in physical contact with the primary sampling unit. The magnitude and prevalence of antibody reactivity observed should not differ in a statistically significant manner from that of the primary sample if virus is not circulating.~~

~~c)~~ ~~Following clinical examination, epidemiologically linked *herds* should be serologically tested and satisfactory results should be achieved if virus is not circulating.~~

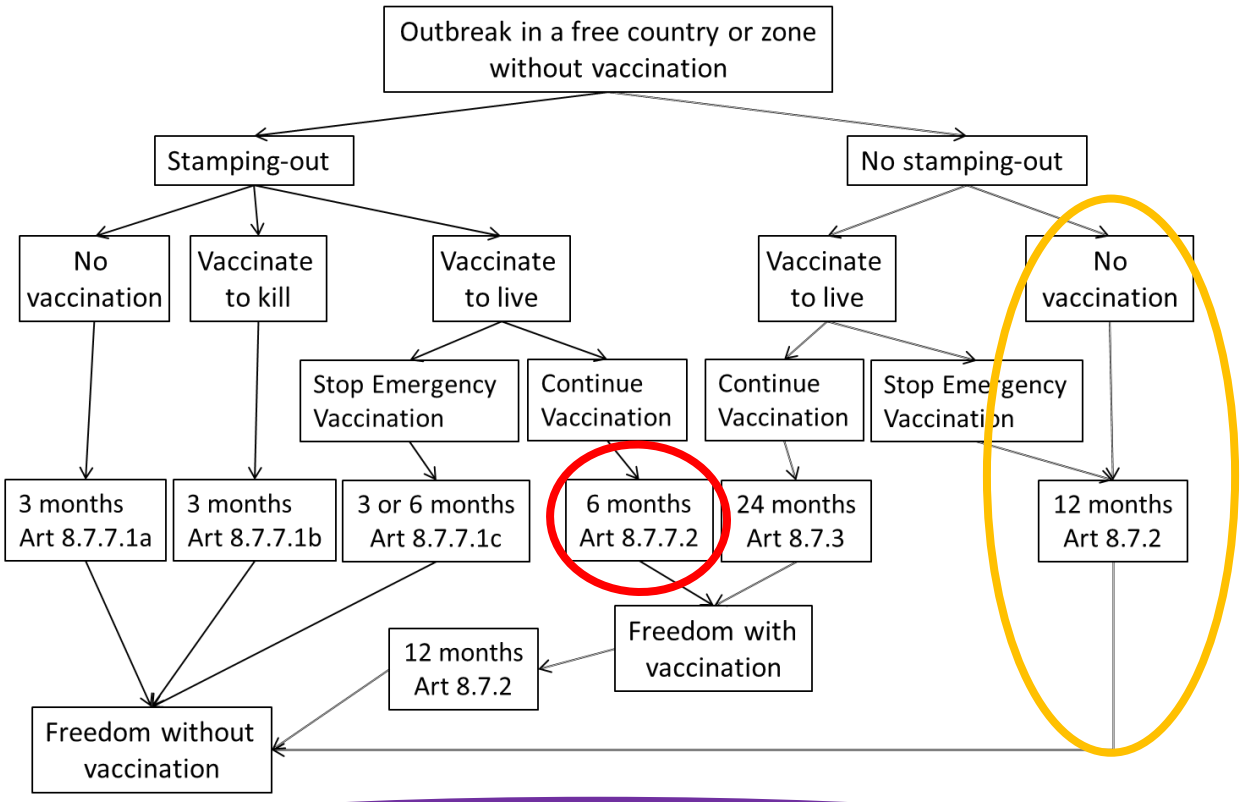
~~d)~~ ~~Sentinel *animals* can also be used. These can be young, unvaccinated *animals* or *animals* in which maternally conferred immunity has lapsed and belonging to the same species resident within the positive initial sampling units. They should be serologically negative if virus is not circulating. If other susceptible, unvaccinated *animals* are present, they could act as sentinels to provide additional serological evidence.~~

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

- ~~characterization of the existing production systems;~~
- ~~results of clinical *surveillance* of the suspects and their cohorts;~~
- ~~quantification of *vaccinations* performed on the affected sites;~~
- ~~sanitary protocol and history of the *establishments* with positive reactors;~~
- ~~control of *animal identification* and movements;~~
- ~~other parameters of regional significance in historic FMDV transmission.~~

~~The entire investigative process should be documented as standard operating procedure within the *surveillance* programme.~~

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

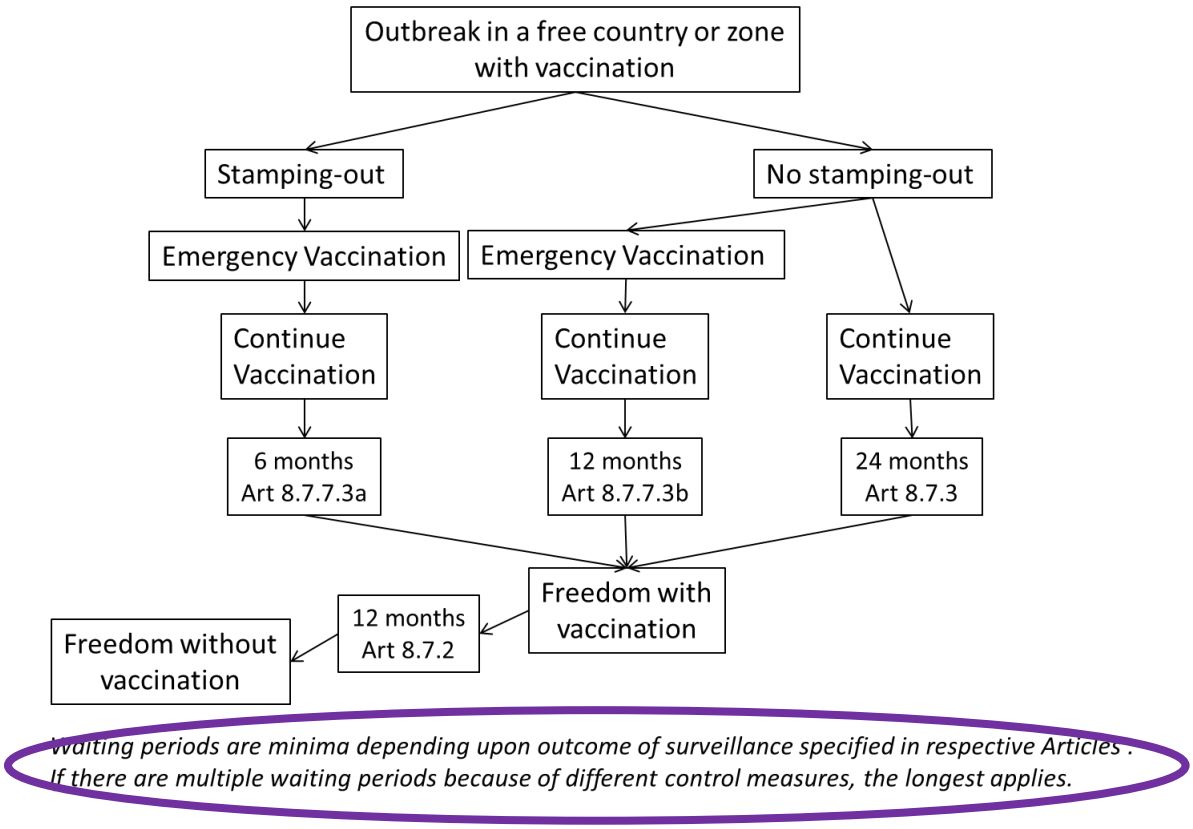


Waiting periods are minima depending upon outcome of surveillance specified in respective Articles. If there are multiple waiting periods because of different control measures, the longest applies.

Comment/Rationale:

- Purple oval: waiting times are minimal because of many factors, not just because of surveillance requirements
- Orange oval: This flow, as shown, is inaccurate. For a country with an outbreak, "free without vaccination" – if no stamping-out is done and no vaccination is conducted, how can the country return to freedom in 12 months? How was the disease eliminated (i.e. after doing nothing at all?)
- Red oval: In the *Code* text, this is now three months, not six months.

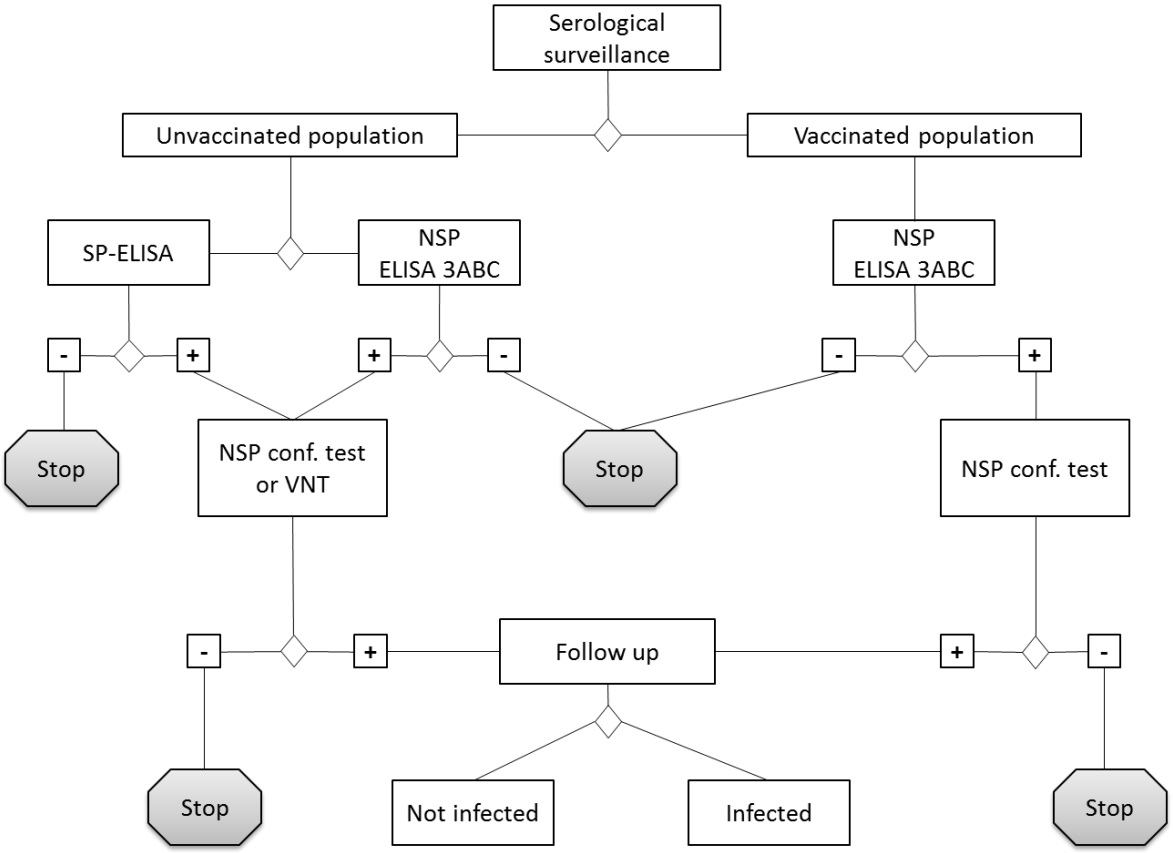
Figure 2: Schematic representation of the minimum waiting periods and pathways for recovery of FMD free status after an outbreak in a free country or zone where vaccination is practised



Comment/Rationale

Purple oval: waiting times are minimal because of many factors, not just because of surveillance requirements

Figure ~~1~~23: Schematic representation of laboratory tests for determining evidence of FMDV infection ~~through or following~~ by means of serological surveys



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

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Text deleted.

CHAPTER 1.6.

PROCEDURES FOR SELF DECLARATION AND FOR OFFICIAL RECOGNITION BY THE OIE

Article 1.6.1.

General principles

Member Countries may wish to make a self declaration as to the freedom of a country, *zone* or *compartment* from an OIE *listed disease*. The Member Country may inform the OIE of its claimed status and the OIE may publish the claim. Publication does not imply endorsement of the claim. The OIE does not publish self declaration for bovine spongiform encephalopathy (BSE), foot and mouth disease (FMD), contagious bovine pleuropneumonia (CBPP), African horse sickness (AHS), peste des petits ruminants (PPR) and classical swine fever (CSF).

Member Countries may request official recognition by the OIE as to:

1) the risk status of a country or *zone* with regard to BSE;

2) the freedom of a country or *zone* from FMD, with or without *vaccination*;

3) the freedom of a country or *zone* from CBPP;

4) the freedom of a country or *zone* from AHS;

5) the freedom of a country or *zone* from PPR;

6) the freedom of a country or *zone* from CSF.

The OIE does not grant official recognition for other *diseases*.

In these cases, Member Countries should present documentation setting out the compliance of the *Veterinary Services* of the applicant country or *zone* with the provisions of Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code* and with the provisions of the relevant *disease* chapters in the *Terrestrial Code* and the *Terrestrial Manual*.

When requesting official recognition of disease status, the Member Country should submit to the OIE Scientific and Technical Department a dossier providing the information requested (as appropriate) in Articles 1.6.4. (for BSE), 1.6.5. (for FMD), 1.6.6. (for CBPP), 1.6.7. (for AHS), 1.6.8. (for PPR) or 1.6.9. (for CSF).

The OIE framework for the official recognition and maintenance of disease status is described in Resolution N° XXX (administrative procedures) and Resolution N° XXXI (financial obligations) adopted during the 81st General Session in May 2013.

Article 1.6.2.

Endorsement by the OIE of an official control programme for FMD

Member Countries may wish to request an endorsement by the OIE of their *official control programme* for FMD.

When requesting endorsement by the OIE of an *official control programme* for FMD, the Member Country should submit to the OIE Scientific and Technical Department a dossier providing the information requested in Article 1.6.10.

[Article 1.6.3.]

[Article 1.6.4.]

Article 1.6.5.

Questionnaires on FMD

FMD FREE COUNTRY WHERE VACCINATION IS NOT PRACTISED

Report of a Member Country which applies for recognition of status,

under Chapter 8.7. of the *Terrestrial Code*,

as a~~n~~ FMD free country not practising vaccination

Please address concisely the following topics. National regulations and laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction

   a) Geographical factors. Provide a general description of the country including physical, geographical and other factors that are relevant to FMD dissemination, countries sharing common borders and other countries that although may not be adjacent share a link for the potential introduction of *disease*. Provide a map identifying the factors above.

   b) Livestock industry. Provide a general description of the livestock industry in the country.

2. Veterinary system

   a) Legislation. Provide a list and summary of all relevant veterinary legislations in relation to FMD.

   b) *Veterinary Services*. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and Article 1.1.3. of the *Terrestrial Code* ~~*Manual*~~ and describe how the *Veterinary Services* supervise, ~~and~~ control and maintain all FMD related activities. Provide maps and tables wherever possible.

   c) Role of farmers, industry and other relevant groups in FMD *surveillance* and control (include a description of training and awareness programmes on FMD).

   d) Role of private veterinary profession in FMD *surveillance* and control.

3. FMD eradication

   a) History. Provide a description of the FMD history in the country, date of first detection, origin of *infection*, date of eradication (date of last *case*), types and subtypes present.

   b) Strategy. Describe how FMD was controlled and eradicated (e.g. *stamping-out policy*, *modified stamping-out policy*, zoning)~~, provide time frame for eradication~~.

   c) Vaccines and *vaccination*. Was FMD vaccine ever used? If so, when was the last *vaccination* carried out? What species were vaccinated? What was the ~~fate~~ disposition of these animals?

Rationale on 1.6.5.3.c: Suggest using the word "disposition" for consistency, as it is used below.

   d) Legislation, organisation and implementation of the FMD eradication campaign. Provide a description of the organisational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.

e) *Animal identification* and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the methods of *animal identification*, *herd* registration and traceability. How are animal movements controlled in the country? Provide evidence on the effectiveness of *animal identification* and movement controls. Please provide information on pastoralism, transhumance and related paths of movement. Describe the action taken when an illegal movement is detected. Provide information on detected illegal movements

4. FMD diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.1.5. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

a) Is FMD laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name~~(s)~~ of and the arrangements with the laboratory(ies) samples are sent to, the follow-up procedures and the time frame for obtaining results.

b) Provide an overview of the FMD approved laboratories, in particular to address the following points:

i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or planned for, the laboratory system.

ii) Give details of ~~participation~~ performance in inter-laboratory ~~validation tests (ring tests)~~ proficiency tests.

iii) ~~Is~~Provide details on the handling of live virus ~~handled?~~

iv) Biosecurity measures applied.

v) Details of the type of tests undertaken and their performance for their applied use (specificity~~/~~ and sensitivity).

vi) Laboratory capacity in processing tests and samples.

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the country complies with the provisions of Articles 8.7.4~~0~~2. to 8.7.4~~2~~7. ~~and Article 8.6.49.~~ of the *Terrestrial Code* and Chapter 2.1.5. of the *Terrestrial Manual*. In particular, the following points should be addressed:

a) Clinical suspicion. What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past two years, the number of suspected cases, the number of samples tested for FMDV, species, type of sample, testing method~~(s)~~ and results (including differential diagnosis).

b) Serological *surveillance*. ~~Are~~ Have serological surveys been conducted to demonstrate freedom from *infection*? If so, provide detailed information on the survey design (target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used). How frequently are they conducted? Are *wildlife* susceptible species included in serological surveys? Provide a summary table indicating, for the past two years, the number of samples tested for FMDV, species, type of sample, testing method~~(s)~~ and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted *surveillance* based on the risk and numbers of animals examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.

c) Livestock demographics and economics. What is the susceptible animal population by species and production systems? How many *herds*, *flocks*, etc. of each susceptible species are in the country? How are they distributed (e.g. *herd* density, etc.)? Provide tables and maps as appropriate.

d) *Wildlife* demographics. What susceptible species are present in the country? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and *wildlife* susceptible species?

e) *Slaughterhouses* and markets or events associated with the congregation of FMD-susceptible livestock (e.g. fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country? How are the animals transported and handled during these transactions?

6. FMD prevention

a) Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries or *zones* that should be taken into account (e.g. size, distance from adjacent border to affected *herds* or animals)? Describe coordination, collaboration and information sharing activities with neighbouring countries.

b) Are there controls in place for the feeding of swill containing animal products to pigs? If so provide information on the extent of the practice, and describe controls and *surveillance* measures.

c) Import control procedures

From what countries or *zones* does the country authorise the import of susceptible animals or their products? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such *animals* and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported animals of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible animals and their products for the past two years, specifying country or *zone* of origin, species and volume and quantity.

i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.

ii) Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past two years, of the quantity disposed of and the disposal location~~(s)~~.

iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country ~~and/~~or their final destination, concerning the import and follow-up of the following:

– *animals*,

– genetic material (semen and embryos),

– animal products,

– *veterinary medicinal products* (i.e. biologics),

– other FMD risk materials (e.g. stock feed and animal bedding).

iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

d) Describe and justify the corrective actions that have been implemented to prevent future FMD outbreaks in response to any past disease incursions.

7. ~~Control measures and c~~Contingency planning and outbreak response programmes

a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed *outbreaks* of FMD.

b) Is quarantine imposed on premises with suspicious cases, pending final diagnosis? What other procedures are followed regarding suspicious cases (e.g. livestock standstills)?

c) In the event of a~~n~~ FMD *outbreak*:

i) indicate the sampling and testing procedures to be used to identify and confirm presence of the causative agent;

ii) describe the actions to be taken to report and control the disease situation in and around any ~~holdings~~ *establishments* found to be infected with FMD;

iii) indicate the control ~~and/~~or eradication procedures (e.g. *vaccination*, *stamping-out policy*, partial *slaughter~~/~~* or *vaccination*, methods of disposal of carcasses and other contaminated products and ~~/~~materials, decontamination, etc.) that would be taken. Include ~~details on~~ information on access to antigen and vaccine banks;

iv) describe the procedures to be used to confirm ~~that an outbreak has been~~ successful~~ly controlled/eradicated~~ control ~~/~~ or eradication, including any ~~restrictions on~~ restocking provisions, sentinel animal and serological surveillance programmes;

v) give details of any compensation payments made available to farmers, etc. when animals are slaughtered for *disease* control~~/~~ or eradication purposes and their prescribed timetable.

8. Compliance with the *Terrestrial Code*

a) In addition to the documentary evidence that the provisions of Article 8.7.2. are properly implemented and supervised, the Delegate of the Member Country must submit a declaration indicating:

i) there has been no *outbreak* of FMD during the past 12 months;

ii) no evidence of FMDV *infection* has been found during the past 12 months;

iii) no *vaccination* against FMD has been carried out during the past 12 months,

b) and should confirm that since the cessation of *vaccination* no animals vaccinated against FMD have been imported.

9. Recovery of status

Member Countries applying for recovery of status should comply with the provisions of Articles 8.7.~~9~~7., 8.7.2.1, 8.7.2.3 and 8.7.2.4. of the *Terrestrial Code* and provide ~~detailed~~ information as specified in sections 1 – 7 (inclusive) of this questionnaire. Particular emphasis should be given to FMD eradication (section 3.), FMD diagnosis (section 4.), FMD serological surveillance (section 5.b.), FMD prevention (section 6.) and contingency planning and outbreak response programmes (section 7.). ~~3.a), 3.b), 3.c) and 5.b) of this questionnaire. Information in relation to other sections need only be supplied if relevant.~~

FMD FREE COUNTRY WHERE VACCINATION IS PRACTISED

Report of a Member Country which applies for recognition of status,

under Chapter 8.7. of the *Terrestrial Code*,

as a~~n~~ FMD free country practising vaccination

Please address concisely the following topics. National regulations and laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction

   a) Geographical factors. Provide a general description of the country including physical, geographical and other factors that are relevant to FMD dissemination, countries sharing common borders and other countries that although may not be adjacent share a link for the potential introduction of *disease*. Provide a map identifying the factors above.

   b) Livestock industry. Provide a general description of the livestock industry in the country.

2. Veterinary system

   a) Legislation. Provide a list and summary of all relevant veterinary legislations in relation to FMD.

   b) *Veterinary Services*. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and Article 1.1.3. of the *Terrestrial Code* ~~*Manual*~~ and describe how the *Veterinary Services* supervise , ~~and~~ control and maintain all FMD related activities. Provide maps and tables wherever possible.

   c) Role of farmers, industry and other relevant groups in FMD *surveillance* and control (include a description of training and awareness programmes on FMD).

   d) Role of private veterinary profession in FMD *surveillance* and control.

3. FMD eradication

   a) History. Provide a description of the FMD history in the country, date of first detection, origin of *infection*, date of eradication (date of last *case*), types and subtypes present.

   b) Strategy. Describe how FMD was controlled and eradicated (e.g. *stamping-out policy*, *modified stamping-out policy*, zoning)~~, provide time frame for eradication~~.

   c) Vaccines and *vaccination*. ~~What type of vaccine is used? What species are vaccinated? Provide evidence that the vaccine used complies with Chapter 2.1.5. of the *Terrestrial Manual*. Describe the *vaccination* programme, including records kept, and provide evidence to show its effectiveness (e.g. *vaccination* coverage, serosurveillance, etc.).~~ Provide a description and justification of the *vaccination* strategy, including, the selection of vaccine strain, potency and type, purity, details of any vaccine matching performed, the animal species vaccinated, identification of vaccinated animals, the way in which the *vaccination* of animals was certified~~/~~ or reported and the records maintained, the date on which the last *vaccination* was performed, and the disposition of vaccinated animals (e.g. removed from or retained in the population). Provide evidence to show its effectiveness (e.g. *vaccination* coverage, serological surveillance, etc). Also provide evidence that the vaccine used complies with Chapter 2.1.5. of the *Terrestrial Manual*.

   d) Legislation, organisation and implementation of the FMD eradication campaign. Provide a description of the organisational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.

   e) *Animal identification* and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the methods of *animal identification*, *herd* registration and traceability, including *vaccination* data. How are animal movements controlled in the country? Provide evidence on the effectiveness of *animal identification* and movement controls. Please

provide information on pastoralism, transhumance and related paths of movement. Describe the action taken when an illegal movement is detected. Provide information on detected illegal movements

4. FMD diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.1.5. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

a) Is FMD laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name~~(s)~~ of and the arrangements with the laboratory(ies) samples are sent to and the follow-up procedures and the time frame for obtaining results.

b) Provide an overview of the FMD approved laboratories, in particular to address the following points:

i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or planned for, the laboratory system.

ii) Give details of ~~participation~~ performance in inter-laboratory ~~validation tests (ring tests).~~proficiency tests.

iii) ~~Is~~Provide details on the handling of live virus ~~handled?~~

iv) Biosecurity measures applied.

v) Details of the type of tests undertaken and their performance for their applied use (specificity and ~~/~~sensitivity).

vi) Laboratory capacity in processing tests and~~/~~samples.

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the country complies with the provisions of Articles 8.7.4~~0~~2. to 8.7.4~~2~~7. ~~and Article 8.6.49.~~ of the *Terrestrial Code* and Chapter 2.1.5. of the *Terrestrial Manual*. In particular, the following points should be addressed:

a) Clinical suspicion. What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past two years, the number of suspected cases, the number of samples tested for FMDV, species, type of sample, testing method~~(s)~~ and results (including differential diagnosis).

b) *Surveillance*. Are serological and virological surveys conducted to demonstrate freedom from *infection*?, in particular applying the provisions of Article 8.7.4~~6~~.2 If so, provide detailed information on the survey design (target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used). How frequently are they conducted? Are susceptible *wildlife* species included in serological surveys? Provide a summary table indicating, for the past two years, the number of samples tested for FMD and FMDV, species, type of sample, testing method~~(s)~~ and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted *surveillance* based on the risk and numbers of animals examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.

c) Livestock demographics and economics. What is the susceptible animal population by species and production systems? How many *herds*, *flocks*, etc. of each susceptible species are in the country? How are they distributed (e.g. *herd* density, etc.)? Provide tables and maps as appropriate.

d) *Wildlife* demographics. What susceptible species are present in the country? Provide estimates of

population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and *wildlife* susceptible species?

e) *Slaughterhouses*, ~~and~~ markets~~/~~ and events associated with the congregation of FMD-susceptible livestock (e.g. fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country? How are the animals transported and handled during these transactions?

6. FMD prevention

a) Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries or *zones* that should be taken into account (e.g. size, distance from adjacent border to affected *herds* or animals)? Describe coordination, collaboration and information sharing activities with neighbouring countries.

b) Are there controls in place for the feeding of swill containing animal products to pigs? If so provide information on the extent of the practice, and describe controls and *surveillance* measures.

c) Import control procedures

From what countries or *zones* does the country authorise the import of susceptible animals or their products? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such animals and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported animals of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible animals and their products for the past two years, specifying country or *zone* of origin, species and volume~~/~~ and quantity

i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.

ii) Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past two years, of the quantity disposed of and the disposal location~~(s)~~.

iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country ~~and/~~or their final destination, concerning the import and follow-up of the following:

- *animals*,
- genetic material (semen and embryos),
- animal products,
- *veterinary medicinal products* (i.e. biologics)~~.~~,
- other FMD risk materials (e.g. stock feed and animal bedding).

iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

d) Describe and justify the corrective actions that have been implemented to prevent future FMD outbreaks in response to any past disease incursions.

7. ~~Control measures and c~~Contingency planning and outbreak response programmes

a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed *outbreaks* of FMD.

b) Is quarantine imposed on premises with suspicious cases, pending final diagnosis? What other procedures are followed regarding suspicious cases (e.g. stock standstills)?

c) In the event of a~~n~~ FMD *outbreak*:

i) indicate the sampling and testing procedures to be used to identify and confirm presence of the causative agent;

ii) describe the actions to be taken to report and control the disease situation in and around any ~~holdings~~ *establishments* found to be infected with FMD;

iii) indicate the control ~~and/~~or eradication procedures (e.g. *vaccination*, *stamping-out policy*, partial *slaughter~~/~~* or *vaccination*, methods of disposal of carcasses and other contaminated products~~/~~ or materials, decontamination, etc.) that would be taken. Include ~~details on~~ information on access to antigen and vaccine banks;

iv) describe the procedures to be used to confirm ~~that an outbreak has been~~ successful~~ly controlled/eradicated~~ control or ~~/~~eradication, including any ~~restrictions on~~ restocking provisions, sentinel animal and serological surveillance programmes;

v) give details of any compensation payments made available to farmers, etc. when animals are slaughtered for *disease* control or ~~/~~eradication purposes and their prescribed timetable.

8. Compliance with the *Terrestrial Code*

In addition to the documentary evidence that the provisions of Article 8.7.3. are properly implemented and supervised, the Delegate of the Member Country must submit a declaration indicating that there has been no *outbreak* of FMD for the past two years and no evidence of FMDV ~~circulation~~transmission for the past 12 months, with documented evidence that:

a) *surveillance* for FMD and FMDV ~~circulation~~transmission in accordance with Articles 8.7.40 ~~42~~. to 8.7.42 ~~47~~. ~~and Article 8.7.49.~~ is in operation, and that regulatory measures for the prevention and control of FMD have been implemented;

b) routine *vaccination* is carried out for the purpose of the prevention of FMD;

c) the vaccine used complies with the standards described in the *Terrestrial Manual*.

9. Recovery of status

Member Countries applying for recovery of status should comply with the provisions of Articles 8.7.~~9~~7., 8.7.3.1, 8.7.3.3 and 8.~~5~~7.3.4. of the *Terrestrial Code* and provide ~~detailed~~ information as specified in sections 1 – 7 (inclusive) of this questionnaire. Particular emphasis should be given to FMD eradication (section 3.), FMD diagnosis (section 4.), FMD serological surveillance (section 5.b.), FMD prevention (section 6.) and contingency planning and outbreak response programmes (section 7.). ~~3.a), 3.b), 3.c) and 5.b) of this questionnaire. Information in relation to other sections need only be supplied if relevant.~~

FMD FREE ZONE WHERE VACCINATION IS NOT PRACTISED

Report of a Member Country which applies for recognition of status,

under Chapter 8.7. of the *Terrestrial Code*,

as a~~n~~ FMD free zone not practising vaccination

Please address concisely the following topics. National regulations and laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction

   a) Geographical factors. Provide a general description of the country and the *zone* including physical, geographical and other factors that are relevant to FMD dissemination, countries or *zones* sharing common borders and other countries or *zones* that although may not be adjacent share a link for the potential introduction of *disease*. The boundaries of the *zone* must be clearly defined, including a *protection zone* if applied. Provide a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the *zone*.

   b) Livestock industry. Provide a general description of the livestock industry in the country and the *zone*.

2. Veterinary system

   a) Legislation. Provide a list and summary of all relevant veterinary legislations in relation to FMD.

   b) *Veterinary Services*. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and Article 1.1.3. of the *Terrestrial Code* ~~*Manual*~~ and describe how the *Veterinary Services* supervise, ~~and~~ control and maintain all FMD related activities. Provide maps and tables wherever possible.

   c) Role of farmers, industry and other relevant groups in FMD *surveillance* and control (include a description of training and awareness programmes on FMD).

   d) Role of private veterinary profession in FMD *surveillance* and control.

3. FMD eradication

   a) History. Provide a description of the FMD history in the country and *zone*, provide date of first detection, origin of *infection*, date of eradication in the *zone* (date of last *case*), types and subtypes present.

   b) Strategy. Describe how FMD was controlled and eradicated in the *zone* (e.g. *stamping-out policy*, *modified stamping-out policy*)~~, provide time frame for eradication~~.

   c) Vaccines and *vaccination*. If *vaccination* is used in the rest of the country, ~~What type of vaccine is used? What species are vaccinated? Provide evidence that the vaccine used complies with Chapter 2.1.5. of the *Terrestrial Manual*. Describe the *vaccination* programme, including records kept, and provide evidence to show its effectiveness (e.g. *vaccination* coverage, serosurveillance, etc.).~~ provide a description and justification of the *vaccination* strategy, including, the selection of vaccine strain, potency and type, purity, details of any vaccine matching performed, the animal species vaccinated, identification of vaccinated animals, the way in which the *vaccination* of animals was certified or reported and the records maintained, the date on which the last *vaccination* was performed, and the disposition of vaccinated animals (e.g. removed from or retained in the population). Provide evidence to show its effectiveness (e.g. *vaccination* coverage, serological surveillance, etc). Also provide evidence that the vaccine used complies with Chapter 2.1.5. of the *Terrestrial Manual*.

   d) Legislation, organisation and implementation of the FMD eradication campaign. Provide a description of the organisational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.

   e) *Animal identification* and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the methods of *animal identification*, *herd* registration and traceability. How are animal movements controlled in and between *zones* of the same or different status, in particular if the provisions of the *Terrestrial Code* in Article 8.7.10. are applied? Provide evidence on the effectiveness of *animal identification* and movement controls. Please provide information on pastoralism, transhumance and related paths of movement. Describe the action taken when an illegal movement is detected. Provide information on detected illegal movements.

4. FMD diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.1.5. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

a) Is FMD laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name~~(s)~~ of and the arrangements with the laboratory(ies) samples are sent to. Indicate the laboratory(ies) where samples originating from the *zone* are diagnosed, the follow-up procedures and the time frame for obtaining results.

b) Provide an overview of the FMD approved laboratories, in particular to address the following points:

i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or planned for, the laboratory system.

ii) Give details of ~~participation~~ performance in inter-laboratory ~~validation tests (ring tests)~~ proficiency tests.

iii) ~~Is~~Provide details on the handling of live virus ~~handled?~~

iv) Biosecurity measures applied.

v) Details of the type of tests undertaken and their performance for their applied use (specificity and sensitivity).

vi) Laboratory capacity in processing tests and ~~/~~samples.

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the country complies with the provisions of Articles 8.7.402. to 8.7.427. ~~and Article 8.6.49.~~ of the *Terrestrial Code* and Chapter 2.1.5. of the *Terrestrial Manual*. In particular, the following points should be addressed:

a) Clinical suspicion. What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past two years, the number of suspected cases, the number of samples tested for FMDV, species, type of sample, testing method~~(s)~~ and results (including differential diagnosis).

b) Serological *surveillance*. ~~Are~~ Have serological surveys been conducted to demonstrate freedom from *infection*? If so, provide detailed information on the survey design (target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used). How frequently are they conducted? Are *wildlife* susceptible species included in serological surveys? Provide a summary table indicating, for the past two years, the number of samples tested for FMDV, species, type of sample, testing method~~(s)~~ and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted *surveillance* based on the risk and numbers of animals examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.

c) Livestock demographics and economics. What is the susceptible animal population by species and production systems in the country and the *zone*? How many *herds*, *flocks*, etc. of each susceptible species are in the country? How are they distributed (e.g. *herd* density, etc.)? Provide tables and maps as appropriate.

d) *Wildlife* demographics. What susceptible species are present in the country and the *zone*? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and *wildlife* susceptible species?

e) *Slaughterhouses*, ~~and~~ markets and ~~/~~events associated with the congregation of FMD-susceptible livestock (e.g. fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country? How are the animals transported and handled during these transactions?

6. FMD prevention

a) Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries and *zones* that should be taken into account (e.g. size, distance from adjacent border to affected *herds* or animals)? Describe coordination, collaboration and information sharing activities with neighbouring countries and *zones*.

If the FMD free *zone* without *vaccination* is situated in a~~n~~ FMD infected country or borders an infected country or *zone*, describe the animal health measures implemented to effectively prevent the introduction of the agent, taking into consideration physical or geographical barriers.

b) Are there controls in place for the feeding of swill containing animal products to pigs? If so, provide information on the extent of the practice, and describe controls and *surveillance* measures.

c) Import control procedures

From what countries or *zones* does the country authorise the import of susceptible animals or their products into a free *zone*? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such animals and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported animals of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible animals and their products for the past two years, specifying country or *zone* of origin, species and volume~~/~~ and quantity.

i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.

ii) Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past two years, of the quantity disposed of of and the disposal location~~(s)~~.

iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country ~~and/~~or their final destination, concerning the import and follow-up of the following:

- *animals*,

- genetic material (semen and embryos),

- animal products,

- *veterinary medicinal products* (i.e. biologics),

- other FMD risk materials (e.g. stock feed and animal bedding).

iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

d) Describe and justify the corrective actions that have been implemented to prevent future FMD outbreaks in response to any past disease incursions.

7. ~~Control measures and c~~Contingency planning and outbreak response programmes

a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed *outbreaks* of FMD.

b) Is quarantine imposed on premises with suspicious cases, pending final diagnosis? What other procedures are followed regarding suspicious cases (e.g. livestock standstills)?

c) In the event of a~~n~~ FMD *outbreak*:

i) indicate the sampling and testing procedures to be used to identify and confirm presence of the causative agent;

ii) describe the actions to be taken to report and control the disease situation in and around any ~~holdings~~ *establishments* found to be infected with FMD;

iii) indicate the control ~~and/~~or eradication procedures (e.g. *vaccination*, *stamping-out policy*, partial *slaughter~~/~~* or *vaccination*, methods of disposal of carcasses and other contaminated products~~/~~ or materials, decontamination, etc.) that would be taken. Include ~~details on~~ information on access to antigen and vaccine banks;

iv) describe the procedures to be used to confirm ~~that an outbreak has been~~ successful~~ly controlled/eradicated~~ control~~/~~ or eradication, including any ~~restrictions on~~ restocking provisions, sentinel animal and serological surveillance programmes;

v) give details of any compensation payments made available to farmers, etc. when animals are slaughtered for *disease* control~~/~~ or eradication purposes and their prescribed timetable.

8. Compliance with the *Terrestrial Code*

In addition to the documentary evidence that the provisions of Article 8.7.4. are properly implemented and supervised, the Delegate of the Member Country must submit a declaration indicating:

a) there has been no *outbreak* of FMD during the past 12 months;

b) no evidence of FMDV *infection* has been found during the past 12 months;

c) no *vaccination* against FMD has been carried out during the past 12 months;

d) no vaccinated animal has been introduced into the *zone* since the cessation of *vaccination*, except in accordance with Article 8.7.10.

9. Recovery of status

Member Countries applying for recovery of status should comply with the provisions of Articles 8.7.~~9~~7., 8.7.2.1, 8.7.2.3 and 8.7.2.4. of the *Terrestrial Code* and provide ~~detailed~~ information as specified in sections 1 – 7 (inclusive) of this questionnaire. Particular emphasis should be given to FMD eradication (section 3.), FMD diagnosis (section 4.), FMD serological surveillance (section 5.b.), FMD prevention (section 6.) and contingency planning and outbreak response programmes (section 7.). ~~3.a), 3.b), 3.c) and 5.b) of this questionnaire. Information in relation to other sections need only be supplied if relevant.~~

FMD FREE ZONE WHERE VACCINATION IS PRACTISED

Report of a Member Country which applies for recognition of status,

under Chapter 8.7. of the *Terrestrial Code*,

as a~~n~~ FMD free zone practising vaccination

Please address concisely the following topics. National regulations and laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction

a) Geographical factors. Provide a general description of the country and the *zone* including physical, geographical and other factors that are relevant to FMD dissemination, countries or *zones* sharing common borders and other countries or *zones* that although may not be adjacent share a link for the potential introduction of *disease*. The boundaries of the *zone* must be clearly defined, including a *protection zone* if applied. Provide a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the *zone*.

b) Livestock industry. Provide a general description of the livestock industry in the country and the *zone*.

2. Veterinary system

a) Legislation. Provide a list and summary of all relevant veterinary legislations in relation to FMD.

b) *Veterinary Services*. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and Article 1.1.3. of the *Terrestrial Code* ~~*Manual*~~ and describe how the *Veterinary Services* supervise, ~~and~~ control and maintain all FMD related activities. Provide maps and tables wherever possible.

c) Role of farmers, industry and other relevant groups in FMD *surveillance* and control (include a description of training and awareness programmes on FMD).

d) Role of private veterinary profession in FMD *surveillance* and control.

3. FMD eradication

a) History. Provide a description of the FMD history in the country and *zone*, provide date of first detection, origin of *infection*, date of eradication in the *zone* (date of last *case*), types and subtypes present.

b) Strategy. Describe how FMD was controlled and eradicated in the *zone* (e.g. *stamping-out policy*, *modified stamping-out policy*)~~, provide time frame for eradication~~.

c) Vaccines and *vaccination*. ~~What type of vaccine is used? What species are vaccinated? Provide evidence that the vaccine used complies with Chapter 2.1.5. of the *Terrestrial Manual*. Describe the *vaccination* programme in the country and in the *zone*, including records kept, and provide evidence to show its effectiveness (e.g. *vaccination* coverage, serosurveillance, etc.).~~ provide a description and justification of the *vaccination* strategy, including, the selection of vaccine strain, potency and type, purity, details of any vaccine matching performed, the animal species vaccinated, identification of vaccinated animals, the way in which the *vaccination* of animals was certified~~/~~ or reported and the records maintained, the date on which the last *vaccination* was performed, and the disposition of vaccinated animals (e.g. removed from or retained in the population). Provide evidence to show its effectiveness (e.g. *vaccination* coverage, serological surveillance, etc). Also provide evidence that the vaccine used complies with Chapter 2.1.5. of the *Terrestrial Manual*.

d) Legislation, organisation and implementation of the FMD eradication campaign. Provide a description of the organisational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.

e) *Animal identification* and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the methods of *animal identification*, *herd* registration and traceability, including *vaccination* data. How are animal movements controlled in and between *zones* of the same or different status, in particular if the provisions of the *Terrestrial Code* in Article 8.7.10. are applied? Provide evidence on the effectiveness of *animal identification* and movement controls. Please provide information on pastoralism, transhumance and related paths of movement. Describe the action taken when an illegal movement is detected. Provide information on detected illegal movements.

4. FMD diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.1.5. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

a) Is FMD laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name~~(s)~~ of and the arrangements with the laboratory(ies) samples are sent to, the follow-up procedures and the time frame for obtaining results. Indicate the laboratory(ies) where samples originating from the *zone* are diagnosed.

b) Provide an overview of the FMD approved laboratories, in particular to address the following points.

i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or planned for, the laboratory system.

ii) Give details of ~~participation~~ performance in inter-laboratory ~~validation tests (ring tests).~~proficiency tests.

iii) ~~Is~~Provide details on the handling of live virus ~~handled?~~

iv) Biosecurity measures applied.

v) Details of the type of tests undertaken and their performance for their applied use (specificity~~/~~ and sensitivity).

vi) Laboratory capacity in processing tests~~/~~ and samples.

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the country complies with the provisions of Articles 8.7.40~~2~~. to 8.7.42~~7~~. ~~and Article 8.6.49.~~ of the *Terrestrial Code* and Chapter 2.1.5. of the *Terrestrial Manual*. In particular, the following points should be addressed:

a) Clinical suspicion. What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past two years, the number of suspected cases, the number of samples tested for FMDV, species, type of sample, testing method~~(s)~~ and results (including differential diagnosis).

b) *Surveillance*. Are serological and virological surveys conducted to demonstrate freedom from *infection*?, in particular applying the provisions of Article 8.7.4~~6~~.2 If so, provide detailed information on the survey design (target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used). How frequently are they conducted? Are *wildlife* susceptible species included in serological surveys? Provide a summary table indicating, for the past two years, the number of samples tested for FMD and FMDV, species, type of sample, testing method~~(s)~~ and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted *surveillance* based on the risk and numbers of animals examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators

c) Livestock demographics and economics. What is the susceptible animal population by species and production systems in the country and the *zone*? How many *herds*, *flocks*, etc. of each susceptible species are in the country? How are they distributed (e.g. *herd* density, etc.)? Provide tables and maps as appropriate.

d) *Wildlife* demographics. What susceptible species are present in the country and in the *zone*? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and *wildlife* susceptible species?

e) *Slaughterhouses*, ~~and~~ markets~~/~~ and events associated with the congregation of FMD-susceptible livestock (e.g. fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country? How are the animals transported and handled during these transactions?

6. FMD prevention

a) Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries and *zones* that should be taken into account (e.g. size, distance from adjacent border to affected *herds* or animals)? Describe coordination, collaboration and information sharing activities with neighbouring countries and *zones*.

If the FMD free *zone* with *vaccination* is situated in a~~n~~ FMD infected country or borders an infected country or *zone*, describe the animal health measures implemented to effectively prevent the introduction of the agent, taking into consideration physical or geographical barriers.

b) Are there controls in place for the feeding of swill containing animal products to pigs? If so, provide information on the extent of the practice, and describe controls and *surveillance* measures.

c) Import control procedures

From what countries or *zones* does the country authorise the import of susceptible animals or their products into a free *zone*? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such animals and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported animals of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible animals and their products for the past two years, specifying the country or *zone* of origin, the species and the volume~~/~~ and quantity.

i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.

ii) Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past two years, of the quantity disposed of and the disposal location~~(s)~~.

iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country ~~and/~~or their final destination, concerning the import and follow-up of the following:

- *animals*,
- genetic material (semen and embryos),
- animal products,
- *veterinary medicinal products* (i.e. biologics),
- other FMD risk materials (e.g. stock feed and animal bedding).

iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

d) Describe and justify the corrective actions that have been implemented to prevent future FMD outbreaks in response to any past disease incursions.

7. ~~Control measures and c~~Contingency planning and outbreak response programmes

a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed *outbreaks* of FMD.

b) Is quarantine imposed on premises with suspicious cases, pending final diagnosis? What other procedures are followed regarding suspicious cases (e.g. livestock standstills)?

c) In the event of a~~n~~ FMD *outbreak*:

i) indicate the sampling and testing procedures to be used to identify and confirm presence of the causative agent;

ii) describe the actions to be taken to report and control the disease situation in and around any ~~holdings~~ *establishments* found to be infected with FMD;

iii) indicate the control ~~and/~~or eradication procedures (e.g. *vaccination*, *stamping-out policy*, partial *slaughter*~~/~~ or *vaccination*, methods of disposal of carcasses and other contaminated products~~/~~ or materials, decontamination, etc.) that would be taken. Include ~~details on~~ information on access to antigen and vaccine banks;

iv) describe the procedures to be used to confirm ~~that an outbreak has been~~ successful~~ly controlled/eradicated~~ control~~/~~ or eradication, including any ~~restrictions on~~ restocking provisions, sentinel animal and serological surveillance programmes;

v) give details of any compensation payments made available to farmers, etc. when animals are slaughtered for *disease* control~~/~~ or eradication purposes and their prescribed timetable.

8. Compliance with the *Terrestrial Code*

In addition to the documentary evidence that the provisions of Article 8.7.5. are properly implemented and supervised, the Delegate of the Member Country must submit a declaration indicating:

a) that there has been no *outbreak* of FMD for the past two years,

b) no evidence of FMDV ~~circulation~~transmission for the past 12 months,

c) *surveillance* for FMD and FMDV ~~circulation~~transmission in accordance with Articles 8.7.40 to 8.7.42. ~~to 8.6.47. and Article 8.6.49.~~ is in operation.

9. Recovery of status

Member Countries applying for recovery of status should comply with the provisions of Articles 8.7.~~9~~7., 8.7.3.1, 8.7.3.3 and 8.7.3.4. of the *Terrestrial Code* and provide ~~detailed~~ information as specified in sections 1 – 7 (inclusive) of this questionnaire. Particular emphasis should be given to FMD eradication (section 3.), FMD diagnosis (section 4.), FMD serological *surveillance* (section 5.b.), FMD prevention (section 6.) and contingency planning and outbreak response programmes (section 7.). ~~3.a), 3.b), 3.c) and 5.b) of this questionnaire. Information in relation to other sections need only be supplied if relevant.~~

[Article 1.6.6.]

[Article 1.6.7.]

[Article 1.6.8.]

[Article 1.6.9.]

Article 1.6.10.

Questionnaire on FMD

COUNTRY WITH AN OIE ENDORSED OFFICIAL CONTROL PROGRAMME FOR FMD
Report of a Member Country which applies for the OIE endorsement
of its official control programme for FMD
under Chapter 8.7. of the *Terrestrial Code*

Please address concisely the following topics. National laws, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction

   a) Provide a general description of geographical factors in the country and *zones*, including physical, geographical and other factors that are relevant to FMD dissemination, countries or *zones* sharing common borders and other countries or *zones* that, although not adjacent, present a *risk* for the introduction of *disease*.

   b) If the endorsed plan is gradually implemented to specific parts of the country, the boundaries of the *zone*~~(s)~~ should be clearly defined, including the *protection zone*, if applied. Provide a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the *zone*~~(s)~~ .

   c) Provide a general description of the livestock industry in the country and any *zones*.

2. Veterinary system

   a) Legislation. Provide a list and summary of all relevant veterinary legislations in relation to the FMD control programme.

   b) *Veterinary Services*. Provide documentation on the compliance of the *Veterinary Services* of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and Article 1.1.3. of the *Terrestrial* ~~*Manual*~~*Code* and describe how the *Veterinary Services* supervise, ~~and~~ control and maintain all FMD related activities in the country and any *zones*. Provide maps and tables wherever possible.

   c) Provide a description on the involvement and the participation of industry, producers, farmers, including subsistence and small scale producers, community animal health workers and the role of the private veterinary profession in FMD *surveillance* and control. Include a description of training and awareness programmes on FMD.

   d) Provide information on any OIE PVS evaluation of the country and follow-up steps within the PVS Pathway.

   e) Provide evidence that the legal framework and budget ensure that control and *surveillance* activities are implemented in an effective and sustainable way.

3. FMD control

   a) Provide a description of the FMD history in the country and any *zones*, including date of first detection, origin of *infection*, date of implementation of the control programme in the country and any *zones*, and types and subtypes of the FMDV ~~virus~~ present.

b) Describe the general epidemiology of FMD in the country and the surrounding countries or *zones* highlighting the current knowledge and gaps.

c) Describe how FMD is controlled in the country or any *zones*.

d) Provide a description of the legislation, organisation and implementation of the FMD control programme. Indicate if detailed operational guidelines exist and give a brief summary.

e) Provide information on what types of vaccines are used and which species are vaccinated. Provide information on the licensing process of the vaccines used. Describe the *vaccination* programme in the country and in any *zones*, including records kept, and provide evidence to show its effectiveness, such as *vaccination* coverage, population immunity, etc. Provide details on the studies carried out to determine the population immunity, including the study design.

f) Provide a description of the methods of *animal identification* (at the individual or group level), *herd* registration and traceability; and how the movements of animals and products are assessed and controlled, including movement of infected animals to *slaughter*. Describe the effectiveness of *animal identification* and movement controls. Please provide information on pastoralism, transhumance and related paths of movement. Describe measures to prevent introduction of the virus from neighbouring countries or *zones* and through trade.

g) Provide evidence of the impact of the control measures already implemented in the event of outbreaks on the reduction of distribution and numbers of outbreaks. If possible, provide information on primary and secondary outbreaks.

4. FMD surveillance

Provide documentary evidence on whether *surveillance* for FMD in the country complies with the provisions of Articles 8.7.40 to 8.7.42. ~~to 8.6.47. and Article 8.6.49.~~ of the *Terrestrial Code* and Chapter 2.1.5. of the *Terrestrial Manual*. In particular, the following points should be addressed:

a) Describe the criteria for raising a suspicion of FMD and the procedure to notify (by whom and to whom) and what penalties are involved for failure to report.

b) Describe how clinical *surveillance* is conducted, including which levels of the livestock production system are included in clinical *surveillance*, such as farms, markets, fairs, *slaughterhouse*, check points, etc. Provide criteria for selection of populations for targeted *surveillance* and numbers of animals examined and samples tested in diagnostic laboratories. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators. Explain whether serological and virological surveys are conducted and, if so, how frequently and for what purpose.

c) Provide a summary table indicating, for at least the past two years, the number of samples tested for FMD and FMDV, species, type of sample, testing method~~(s)~~ and results (including differential diagnosis). Provide procedural details on follow-up actions taken on suspicious and positive results.

d) Provide information on livestock demographics and economics, including the susceptible animal population by species and production systems in the country and the *zone*. Identify how many *herds*, *flocks*, etc. of each susceptible species are in the country and how they are distributed, such as *herd* density, etc. Provide tables and maps as appropriate.

e) Provide information on the demographics and migration patterns of FMD susceptible *wildlife* species, including which susceptible species are present in the country and any *zones*. Provide estimates of population sizes and geographic distribution. Identify whether susceptible *wildlife* are included in *surveillance*. Identify the measures in place to prevent contact between domestic and susceptible *wildlife*.

f) Identify the livestock slaughter, marketing and collection centres. Provide information on the patterns of livestock movement within the country, including how animals are transported and handled during these transactions.

g) Provide information on circulating strains and risk in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (e.g. targeted serological surveys, active surveillance, participatory epidemiology studies, risk assessments, etc.) and that the acquired knowledge assists in more effective implementation of control measures.

h) Provide evidence that surveys are carried out to assess *vaccination* coverage and population immunity of the target population~~(s)~~, show laboratory evidence that the vaccine used is appropriate for circulating strains of virus, show analysis of surveillance data to assess the change in FMD prevalence over time in the target population~~(s)~~, assess the control measures (cost effectiveness, degree of implementation, impact), provide information on outcomes of outbreak investigations including outbreaks that have occurred despite control measures, documented inspections showing compliance with biosecurity and hygiene requirements.

5. FMD laboratory diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.1.5. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

a) Is FMD laboratory diagnosis carried out in the country? If so, provide a list of laboratories approved by the competent authority to diagnose FMD. If not, provide the name~~(s)~~ of and the arrangements with the laboratory(ies) samples are sent to, the follow-up procedures and the time frame for obtaining results. If applicable, indicate the laboratory(ies) where samples originating from any *zone* are diagnosed. Is there regular submission of samples from the country or *zone* to a laboratory that carries out diagnosis and further characterisation of strains in accordance with the standards and methods described in the *Terrestrial Manual*?

b) Provide an overview of the FMD approved laboratories, in particular to address the following points:

i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the laboratory system.

ii) Give details on participation in inter-laboratory validation tests (ring tests).

iii) Is live virus handled?

iv) Biosecurity measures applied.

v) Details of the type of tests undertaken.

6. FMD prevention

Describe the procedures in place to prevent the introduction of FMD into the country. In particular provide details on:

a) Coordination with neighbouring countries, trading partners and other countries within the same region. Identify relevant factors about the adjacent countries and *zones* that should be taken into account such as size, distance from adjacent borders to affected *herds* or animals, *surveillance* carried in adjacent countries. Describe coordination, collaboration and information sharing activities with neighbouring countries and *zones*. Describe the measures implemented to effectively prevent the introduction of the agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the propagation of the agent within the country or *zone* and through trade. Provide evidence that measures are in place at markets to reduce transmission of FMD such as enhancing awareness of FMD transmission mechanisms and behaviours that can interrupt transmission, implementation of good biosecurity practices, hygiene, cleaning and disinfection routines at critical points all along the production and marketing networks (typically where animals are being moved, and marketed through the country or region).

b) What measures are taken to limit access of susceptible domestic, *feral* and *wild* animals to waste

products of animal origin? Are there controls in place for the feeding of swill containing animal products to pigs? If so provide information on the extent of the practice, and describe controls and *surveillance* measures.

c) Provide information on countries or *zones* from which the country authorises the import of susceptible animals or their products into the country or *zone*. Describe the criteria applied to approve such countries or *zones*, the controls applied on entry of such animals and products, and subsequent internal movement. Describe the import conditions and test procedures required. Advise whether imported animals of susceptible species are required to undergo a quarantine or isolation period and, if so, the duration and location of quarantine. Advise whether import permits and health certificates are required. Describe any other procedures used. Provide summary statistics on imports of susceptible animals and their products for at least the past two years, specifying country or *zone* of origin, the species and the number or volume. Provide evidence that the import policy and the improved border controls have contributed to reducing the number of outbreaks.

i) Provide a map with the number and location of ports, airports and land crossings. Advise whether the service responsible for import controls is part of the official services, or if it is an independent body. If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.

ii) Provide a description on the methods used for the safe disposal of waste food from international traffic, who is responsible to supervise this and provide a summary, for the past two years, of the quantity disposed of.

iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and their final destination, concerning the import and follow up of the following:

- *animals*,
- genetic material (semen and embryos),
- animal products,
- *veterinary medicinal products*, i.e. biologics,
- other livestock related goods potentially contaminated with FMDV including bedding, litter and feeds.

iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports, if available.

7. Control measures and emergency response

a) Give details of any written guidelines, including emergency response plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of FMD.

b) Advise whether quarantine is imposed on premises with suspicious cases, pending final diagnosis and any other procedures followed in respect of suspicious cases.

c) In the event of a~~n~~ FMD *outbreak*:

i) provide a detailed description of procedures that are followed in case of an *outbreak* including forward and backward tracing;

ii) indicate the sampling and testing procedures used to identify and confirm presence of the causative agent;

iii) describe the actions taken to control the disease situation in and around any ~~holdings~~ *establishments* found to be infected with FMD;

iv) indicate the control or eradication procedures, such as *vaccination*, *stamping-out policy*, partial *slaughter* or *vaccination*, including *vaccination* delivery and cold chain, movement control, control of *wildlife*, pastured livestock and livestock as pets, control of the livestock waste, campaign to promote awareness of farmers, etc. that would be taken;

v) describe the procedures used to confirm that an *outbreak* has been successfully controlled or eradicated, including any restrictions on restocking;

vi) give details of any compensation payments made available to farmers, etc. when animals are slaughtered for *disease* control or eradication purposes and their prescribed timetable;

vii) describe how control efforts, including *vaccination* and biosecurity measures, have been targeted at critical risk control points.

8. Official control programme for FMD submitted for OIE endorsement

Submit a detailed plan on the measures, in addition to those described in point 3, for the control and eventual eradication of FMD in the Member Country, including:

a) objectives,

b) expected status to be achieved,

c) timelines of the control programme,

d) performance indicators and ~~including~~ methods for their measurement and verification, including the progressive reduction in *outbreak* incidence towards elimination of FMDV transmission in all susceptible livestock in at least one *zone* of the country,

e) description of the funding for the control programme and annual budgets for its duration,

f) details, if applicable, on a proposed timeline for the transition to the use of vaccines, which are fully compliant with in the *Terrestrial Manual* in order to enable demonstration of absence of virus ~~circulation~~transmission.

9. Recovery of official endorsement of the national FMD control programme

Member Countries applying for recovery of the official endorsement of the national FMD control programme should provide updated information in compliance with the provisions of Article 8.7.~~48~~39. of the *Terrestrial Code*.

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Text deleted.