CHAPTER 8.8.

INFECTION WITH FOOT AND MOUTH DISEASE VIRUS

Article 8.8.1.

General provisions

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

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

2bis) For the purposes of this chapter, 'cattle' means animals of the species *Bos taurus* or *Bos indicus*.

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

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

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

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

4) Transmission of FMDV in a vaccinated *population* is demonstrated by change in virological or serological evidence indicative of recent *infection*, even in the absence of clinical signs or any cause for suspicion of previous association or contact with FMDV.

5) For the purposes of the *Terrestrial Code*, the *incubation period* of FMD shall be 14 days.

6) *Infection* with FMDV can give rise to *disease* of variable severity and to ~~FMDV~~ transmission of FMDV. FMDV may persist in the pharynx and associated lymph nodes of ruminants for a variable but limited period of time beyond 28 days after *infection*. Such animals have been termed carriers. ~~However,~~ The only persistently infected species from which transmission of FMDV has been proven is the African buffalo *(Syncerus caffer)*. However, transmission from this species to domestic livestock is rare.

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

~~8~~7) Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 8.8.1bis.

Safe commodities

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

1) UHT *milk* and derivatives thereof;

2) *meat* in hermetically sealed container with a F_0 value of 3 or above;

3) ~~*meat* and bone meal and blood~~ *protein* meal;

4) gelatine;

5) *in vivo* derived bovine embryos collected, processed and stored in accordance with Chapter 4.8.

Other *commodities* of susceptible species can be traded safely if in accordance with the relevant articles in this chapter.

Article 8.8.2.

~~FMD free~~ Country or zone free from FMD where vaccination is not practised

In defining a *zone* where *vaccination* is not practised the principles of Chapter 4.~~3~~4. should be followed.

Susceptible animals in the ~~FMD free~~ country or *zone* free from FMD, where *vaccination* is not practised should be protected by the application of *biosecurity* ~~measures~~ that prevents the entry of FMDV into the free country or *zone*.

Taking into consideration physical or geographical barriers with any neighbouring infected country or *zone*, these measures may include a *protection zone*.

A country or *zone* may be considered free from FMD where *vaccination* is not practised when the relevant provisions in point 2 of Article 1.4.6. have been complied with, and when within the proposed free country or *zone* for at least the past 12 months:

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

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

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

1) ~~a)~~ there has been no *case* of *infection* with FMDV;

2) the *Veterinary Authority* has current knowledge of, and authority over, all *herds* of domestic and *captive wild* susceptible animals in the country or *zone*;

3) the *Veterinary Authority* has current knowledge of the distribution, habitat and indication of disease occurrence through passive *surveillance* of *wild* and *feral* susceptible animals in the country or *zone*;

4) appropriate *surveillance* has been implemented in accordance with:

   a) Article 1.4.6. where historical freedom can be demonstrated; or

   b) ~~no *vaccination* against FMD has been carried out;~~

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

   ~~a)~~ ~~*surveillance* in accordance with~~ Articles 8.8.40. to 8.8.42. where historical freedom cannot be demonstrated which includes the ~~has been implemented to~~ detection of clinical signs of FMD and demonstrate ~~no evidence of~~:

      i) no *infection* with FMDV in unvaccinated animals;

      ii) no ~~FMDV~~ transmission of FMDV in previously vaccinated animals ~~when the FMD free country or *zone* where *vaccination* is practised is seeking to become one where *vaccination* is not practised~~;

5) ~~d)~~ measures to prevent the introduction of the *infection* have been in place: in particular, the importations or movements of *commodities* into the country or *zone* have been carried out in accordance with this chapter and other relevant chapters of the *Terrestrial Code*.: ~~the control of the movement of susceptible animals, their *meat* and other products, and fomites into the proposed FMD free country or *zone*, in particular the measures described in Articles 8.8.8., 8.8.9. and to 8.8.12. has been effectively implemented and supervised;~~

~~measures to prevent the introduction of no vaccinated animals has been introduced, except in accordance with Articles 8.8.8. and 8.8.9., 8.8.9bis., 8.8.11. and 8.8.11bis. have been effectively implemented and supervised. Any vaccinated a~~Animals introduced for direct *slaughter* in accordance with Articles 8.8.8., 8.8.9. and 8.8.11bis. ~~were~~ should be subjected to ante- and post-mortem inspections in accordance with Chapter 6.3~~2~~. ~~with favourable results~~. For ruminants the head, including the pharynx, tongue and associated lymph nodes, was either destroyed or treated in accordance with Article 8.8.31.;

6) *vaccination* against FMD is prohibited and the prohibition has been effectively implemented and supervised.

The country ~~Member Country or the proposed free~~ or *zone* will be included in the list of ~~FMD free~~ countries or *zones* free from FMD, where *vaccination* is not practised in accordance with Chapter 1.6.~~only after the submitted evidence, based on the provisions of Article 1.6.6., has been accepted by the OIE.~~

Retention on the list requires annual reconfirmation of compliance with all points above and relevant provisions under point 4 of Article 1.4.6. Documented evidence should be resubmitted ~~that the information in points 2, 3 and 4 above be re-submitted~~ annually for all points above. ~~and~~ Any changes in the epidemiological situation or other significant events ~~including those relevant to points 3b) and 4~~ should be ~~reported~~ notified to the OIE in accordance with ~~the requirements in~~ Chapter 1.1.

~~A country or *zone* free from FMD may maintain its free status despite an incursion of potentially infected African buffaloes provided that the *surveillance* programme substantiates the absence of transmission of FMDV.~~

Provided the conditions of point~~s 1 to 4~~ ~~3~~ ~~4~~are ~~is~~ are fulfilled, the status of a country or *zone* will not be affected by applying official emergency *vaccination* to FMD susceptible animals in zoological collections in the face of a FMD threat identified by the *Veterinary Authorities*, provided that the following conditions are met:

– the zoological collection has the primary purpose of exhibiting animals or preserving rare species, has been identified, including the boundaries of the facility, and is included in the country's contingency plan for FMD;

– appropriate *biosecurity* measures are in place, including effective separation from other susceptible domestic *population*s or *wildlife*;

– the animals are identified as belonging to the collection and any movements can be traced;

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

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

– the zoological collection is placed under *surveillance* for at least 12 months after *vaccination*.

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

~~In the case of an incursion of stray African buffalo, a *protection zone* according to Article 4.4.6. should be established to manage the threat and maintain the free status of the rest of the country.~~

~~If A~~a ~~*protection zone* used is established, to preserve the *status* of a free country or *zone* from a newly identified likelihood of introduction of FMDV it should comply with Article 4.4~~3.6. ~~If *vaccination* is implemented in the *protection zone*, this will not affect the freedom of the rest of the country or *zone* the *animal health status* of the rest of the country or *zone* is not affected.~~

A country or *zone* free from FMD may maintain its free status despite an incursion of African buffalo from a neighbouring infected country or *zone* provided that the relevant conditions are met and documented evidence has been submitted to and accepted by the OIE.

Article 8.8.3.

~~FMD free~~ Country or zone free from FMD where vaccination is practised

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

~~Susceptible animals in the FMD free country or *zone* free from FMD where *vaccination* is practised should be protected by the application of *biosecurity* measures that prevent the entry of FMDV into the free country or *zone*. Taking into consideration physical or geographical barriers with any neighbouring infected country or *zone*, these measures may include a *protection zone*.~~

Based on the epidemiology of FMD in the country, it may be decided to vaccinate only a defined *subpopulation* comprised of certain species or other subsets of the total susceptible *population*.

A country or *zone* may be considered free from FMD where *vaccination* is practised when the relevant provisions in point 2 of Article 1.4.6. have been complied with, and when within the proposed free country or *zone* ~~To qualify for inclusion in the list of FMD free countries or *zones* free from FMD where *vaccination* is practised, a Member Country should~~:

1) ~~have a record of regular and prompt animal *disease* reporting;~~ for at least the past 12 months:

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

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

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

b) there has been no *infection* of FMDV in the unvaccinated subpopulations ~~*case* with clinical sign of FMD during the past 12 months~~;

c) the *Veterinary Authority* has current knowledge of, and authority over, all *herds* of domestic and *captive wild* susceptible animals in the country or *zone*;

d) the *Veterinary Authority* has current knowledge of the distribution, habitat and indication of disease occurrence through passive *surveillance* of *wild* and *feral* susceptible animals in the country or *zone*;

~~e)~~ compulsory systematic *vaccination* in the target *population* has been carried out to achieve adequate *vaccination* coverage and population immunity;

f) *vaccination* has been carried out following appropriate vaccine strain selection;

g) measures to prevent the introduction of *infection* have been in place: in particular, the importations or movements of *commodities* into the country or *zone* have been carried out in accordance with this chapter and other relevant chapters of the *Terrestrial Code*;

2~~3~~) for the past 24 months ~~supply documented evidence that~~:

a) appropriate *surveillance* ~~to detect clinical signs of FMD~~ has been implemented in accordance with Articles 8.8.40. to 8.8.42. ~~has been implemented to detect clinical signs of FMD for the past two years~~ and demonstrates points 1(a) and 1(b) above. ~~no evidence of that there has been no:~~

~~i) *infection* with FMDV in unvaccinated animals for the past two years 12 months;~~

~~ii) FMDV transmission of FMDV in vaccinated animals for the past 12 months;~~

~~b) regulatory measures for the prevention and early detection of FMD have been implemented for the past 12 months two years;~~

~~c) compulsory systematic *vaccination* in the target *population* has been carried out to achieve adequate *vaccination* coverage and population immunity for the past 12 months two years;~~

d) *vaccination* has been carried out following appropriate vaccine strain selection for the past 12 months two years;

4) describe in detail and supply provide documented evidence that for the past 12 months the following have been properly implemented and supervised:

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

b) the boundaries and *biosecurity* measures of any *protection zone*, if applicable have been established and effectively supervised;

c) the system for preventing the entry of FMDV into the proposed FMD free country or *zone*, in particular the measures described in Articles 8.8.8., 8.8.9. and 8.8.12. has been established and effectively supervised;

d) the control of the movement of susceptible animals and their products into the proposed FMD free country or *zone* has been effectively implemented and supervised.

The country Member Country or the proposed free *zone* will be included in the list of FMD free countries or *zones* free from FMD where *vaccination* is practised in accordance with Chapter 1.6.only after the submitted evidence, based on the provisions of Article 1.6.6., has been accepted by the OIE.

Retention on the list requires annual reconfirmation of compliance with all points above and relevant provisions under point 4 of Article 1.4.6. Documented evidence should be resubmitted that the information in points 2, 3 and 4 above be re-submitted annually for all points above. and Any changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported notified to the OIE in accordance with the requirements in Chapter 1.1.

Article 8.8.3bis.

Transition of vaccination status in a country or zone free from FMD

If a Member Country that meets the requirements of a FMD free country or *zone* free from FMD where *vaccination* is practised and is recognised by the OIE as such, wishes to change its status to FMD free country or *zone* free from FMD where *vaccination* is not practised, it should notify the OIE in advance of the intended date of cessation of *vaccination* and apply for the new status within 24 months of the cessation. The status of this country or *zone* remains unchanged until compliance with Article 8.8.2. is approved by the OIE. If the dossier for the new status is not provided within 24 months then the status of the country or *zone* as being free with *vaccination* will be suspended. If the country does not comply with requirements of Article 8.8.2., evidence should be provided within three months that it complies with Article 8.8.3. Otherwise the status will be withdrawn.

If a Member Country that meets the requirements of a country or *zone* free from FMD where *vaccination* is not practised and is recognised by the OIE as such, wishes to change its status to country or *zone* free from FMD where *vaccination* is practised, it should provide the OIE with an application and a plan following the structure of the Questionnaire of Article 1.6.6., indicating the intended date of beginning of *vaccination*. The status as country or *zone* free from FMD where *vaccination* is not practised of this country or *zone* remains unchanged until the application and plan are approved by the OIE. As soon as recognised free with *vaccination* the country or *zone* will begin the *vaccination*. The Member Country should provide evidence within six months that it complies with Article 8.8.3. for this time period. Otherwise the status will be withdrawn.

If a country needs to define a *protection zone* in accordance with Article 4.34.6. in response to an increased risk, including by the application of *vaccination*, once a the *protection zone* has been approved by the OIE, the freedom of the rest of the country or *zone* remains unchanged.

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

Article 8.8.4.

~~FMD free~~ Compartment free from FMD where vaccination is not practised

A ~~FMD free~~ *compartment* free from FMD where *vaccination* is not practised can be established in ~~either a FMD free~~ any country or *zone* ~~or in an infected country or *zone*~~. In defining such a *compartment* the principles of Chapters 4.~~3~~4. and 4.4~~5~~. should be followed. Susceptible animals in the ~~FMD~~ free *compartment* should be separated from any other susceptible animals by the effective application of an ~~effective~~ *biosecurity plan* ~~management system~~.

A Member Country wishing to establish a ~~FMD free~~ *compartment* free from FMD where *vaccination* is not practised should:

1) have a record of regular and prompt animal *disease* reporting and, if not ~~FMD~~ free, have an *official control programme* and a *surveillance* system for FMD in place in accordance with Articles 8.8.40. to 8.8.42. that allows knowledge of the prevalence, distribution and characteristics of FMD in the country or *zone*;

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

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

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

   ~~cb~~) *vaccination* against FMD is prohibited;

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

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

   ~~fe~~) documented evidence shows that *surveillance* in accordance with Articles 8.8.40. to 8.8.42. is in operation;

   ~~gf~~) an *animal identification* and *traceability* system in accordance with Chapters 4.2~~1~~. and 4.3~~2~~. is in place;

3) describe in detail:

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

   b) the *biosecurity plan* to mitigate the risks identified by the *surveillance* carried out in accordance with point 1.

The *compartment* should be approved by the *Veterinary Authority*. The ~~first~~ approval should only be granted when no *infection* ~~case~~ or transmission of FMDV has occurred within a 10 ~~ten~~ kilometre radius of the *compartment* during the ~~past~~ three months prior to the effective establishment of the *biosecurity plan*.

Article 8.8.4bis.

Compartment free from FMD where vaccination is practised

A *compartment* free from FMD where *vaccination* is practised can be established in either a free country or *zone* where *vaccination* is practised or in an infected country or *zone*. In defining such a *compartment* the principles of Chapters 4.34. and 4.45. should be followed. Susceptible animals in the free *compartment* should be separated from any other susceptible animals by the application of an effective *biosecurity plan*.

A Member Country wishing to establish a *compartment* free from FMD where *vaccination* is practised should:

1) have a record of regular and prompt animal *disease* reporting and, if not free, have an *official control programme* and a *surveillance* system for FMD in place in accordance with Articles 8.8.40. to 8.8.42. that allows knowledge of the prevalence, distribution and characteristics of FMD in the country or *zone*;

2) declare for the free *compartment* where *vaccination* is practised that:

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

~~a~~b) no ~~evidence of *infection* with~~ *infection* or transmission of FMDV has ~~been found~~ occurred during the past 12 months;

c) compulsory systematic *vaccination* is carried out using a vaccine that complies with the standards described in the *Terrestrial Manual*, including appropriate vaccine strain selection. The *vaccination* coverage and population immunity are closely monitored;

d) animals, semen, embryos and animal products may only enter the *compartment* in accordance with relevant articles in this chapter;

e) documented evidence shows that regular clinical, serological and virological *surveillance* in accordance with Articles 8.8.40. to 8.8.42. is in operation, so as to detect *infection* at an early stage with a high level of confidence;

f) an *animal identification* and *traceability* system in accordance with Chapters 4.~~1~~2. and 4.~~2~~3. is in place;

3) describe in detail:

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

b) the *biosecurity plan* to mitigate the risks identified by the *surveillance* carried out according to point 1 and the *vaccination* plan;

c) implementation of points 2(c), 2(e) and 2(f).

The *compartment* should be approved by the *Veterinary Authority*. The approval should only be granted when no *infection* ~~case~~ or transmission of FMDV has occurred within a 10-kilometre radius of the *compartment* during the three months prior to the effective establishment of the *biosecurity plan*.

Article 8.8.5.

~~FMD infected~~ Country or zone infected with FMDV

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

Article 8.8.5bis.

Establishment of a protection zone within a country or zone free from FMD

Susceptible animals in the country or *zone* free from FMD should be protected by the application of *biosecurity* that prevents the entry of FMDV into the free country or *zone*. Taking into consideration physical or geographical barriers with any neighbouring infected country or *zone*, these measures may include a *protection zone*.

A *protection zone* may be established, in response to an increased risk of FMD, in accordance with Article 4.4.6. The *Veterinary Authority* should submit as soon as possible to the OIE, in addition to the requirements of Article 4.4.6. in support of the application, documented evidence that:

1) the susceptible animal populations within the *protection zone* are clearly identified as belonging to the *protection zone;*

2) strict movement control of susceptible animals and their products is in place in line with the relevant provisions of this chapter;

3) enhanced *surveillance* in accordance with Articles 8.8.40. to 8.8.42. is in place in the *protection zone* and in the rest of the country or *zone*;

4) intensified *biosecurity* in the rest of the country is in place;

5) awareness campaigns aimed at the general public, breeders, traders, *veterinarians* and other relevant stakeholders;

6) *biosecurity plan* including the implementation of emergency *vaccination* is in place, in particular when the *protection zone* is established in a country or *zone* free from FMD where *vaccination* is not practised.

The *protection zone* is considered as effectively established when the conditions described in this article and in Article 4.4.6. have been applied and documented evidence is submitted to and has been accepted by the OIE.

If *vaccination* is implemented in the *protection zone* established within a country or *zone* free from FMD where *vaccination* is not practised, the free status of the *protection zone* is suspended while the free status of the rest of the country or *zone* is not affected. The status of the *protection zone* can be recovered following point 1 of Article 8.8.7. Should the Member Country wish to maintain *vaccination* in the *protection zone,* Article 8.8.3bis applies.

In the event of an *outbreak* within a previously free *protection zone*, the free status of the *protection zone* is suspended while the free status of the rest of the country or *zone* is not affected. For the establishment of a *containment zone* after an *outbreak* in the *protection zone*, the *Veterinary Authority* should submit as soon as possible an application in accordance with Articles 4.4.7. and 8.8.6. In particular, when applying for a *containment zone*, it should be stated whether the boundaries would be the same as the boundaries of the *protection zone* or within the boundaries of the *protection zone*.

A *protection zone*, in which the free status has remained unchanged, should be limited to less than 24 months from the date of its approval by the OIE. The Member Country should either apply for the removal of the *protection zone* or official recognition of the *protection zone* as a separate zone within 24 months from the date of its approval by the OIE.

Article 8.8.6.

Establishment of a containment zone within a ~~FMD free~~ country or zone previously free from FMD

In the event of ~~limited~~ *outbreaks* within a ~~FMD free~~ country or *zone* previously free from FMD, including within a *protection zone*, with or without *vaccination*, a ~~single~~*containment zone*, which includes all epidemiologically linked *outbreaks*, may be established, in accordance with Article 4.4.7., ~~for the purpose of minimising~~ to minimise the impact on the ~~entire~~ ~~rest of the~~ country or *zone* ~~in accordance with Article 4.4.7~~.

For this to be achieved and for the Member Country to take full advantage of this process, the *Veterinary Authority* should submit as soon as possible to the OIE, in addition to the requirements of Article 4.4.7. in support of the application, documented evidence that:

1) on suspicion, a strict standstill has been imposed on the suspected *establishments* and in the country or *zone* animal movement control has been imposed and effective controls on the movement of other *commodities* mentioned in this chapter are in place;

2) on confirmation, an additional standstill of susceptible animals has been imposed in the entire *containment zone* and the movement controls described in point 1 have been reinforced;

~~3) the definitive boundaries of the *containment zone* have been established after an epidemiological investigation (trace-back, trace-forward) has demonstrated that the *outbreaks* are epidemiologically related and limited in number and geographic distribution;~~

34) investigations into the likely source of the *outbreaks* have been carried out;

~~5 a *stamping-out policy*, with or without the use of emergency *vaccination*, has been applied;~~

~~6) no new *cases* have been found in the *containment zone* within a minimum of two *incubation periods* as defined in Article 8.8.1. after the application of a *stamping-out policy* to the last detected *case*;~~

~~7) the susceptible domestic and *captive wild* animal populations within the *containment zone* are clearly identified as belonging to the *containment zone*;~~

48) *surveillance* in accordance with Articles 8.8.40. to 8.8.42. is in place in the *containment zone* and in the rest of the country or *zone*;

5~~9~~) measures that prevent the spread of FMDV to the rest of the country or *zone*, taking into consideration physical and geographical barriers, are in place.

~~The free status of the areas outside the *containment zone* is suspended while the *containment zone* is being established.~~ The free status of the ~~these~~ areas outside the *containment zone* may be reinstated irrespective of the provisions of Article 8.8.7., once the *containment zone* has been approved by the OIE as complying with points 1 to 5~~9~~ above. ~~*Commodities* from susceptible animals for *international trade* should be identified as to their origin, either from inside or outside the *containment zone*.~~

In the event of recurrence of *infection* with FMDV in unvaccinated animals or ~~FMDV~~ transmission of FMDV in vaccinated animals in the *containment zone*, established in accordance with point 4~~(~~a) of Article 4.4.7., the approval of the *containment zone* is withdrawn and the FMD status of the whole country or *zone* is suspended until the relevant requirements of Article 8.8.7. are fulfilled.

In the event of occurrence of *infection* with FMDV in unvaccinated animals or transmission of FMDV in vaccinated animals in the outer zone of a *containment zone* established in accordance with point 4(~~a~~b) of Article 4.4.7., the approval of the *containment zone* is withdrawn and the status of the whole country or *zone* is suspended until the relevant requirements of Article 8.8.7. are fulfilled.

The recovery of the ~~FMD~~ free status of the *containment zone* should be achieved within ~~12~~18 months of its approval and follow the provisions of Article 8.8.7.

Article 8.8.7.

Recovery of free status ~~(see Figures 1 and 2)~~

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

   a) three months after the disposal of the last animal killed where a *stamping-out policy*, without emergency *vaccination*, and *surveillance* are applied in accordance with Articles 8.8.40. to 8.8.42.; or

   b) three months after the disposal of the last animal killed or the *slaughter* of all vaccinated animals, whichever occurred last, where a *stamping-out policy*, emergency *vaccination* and *surveillance* in accordance with Articles 8.8.40. to 8.8.42. are applied; or

   c) six months after the disposal of the last animal killed or the last *vaccination*, whichever occurred last, where a *stamping-out policy*, emergency *vaccination* not followed by the slaughtering of all vaccinated animals, and *surveillance* in accordance with Articles 8.8.40. to 8.8.42. are applied. However, this requires a serological survey based on the detection of antibodies to ~~non-structural proteins~~ NSP of FMDV to demonstrate no ~~evidence of *infection*~~ transmission of FMDV in the ~~remaining~~ vaccinated *population*. This period can be reduced to a minimum of three months if a country can submit sufficient evidence demonstrating absence of *infection* in the non-vaccinated *population*, and absence of transmission in the emergency vaccinated *population* based on the provisions of point 7 of Article 8.8.40. ~~effectiveness of *vaccination* is demonstrated by a serological survey and serological *surveillance* for antibodies to nonstructural proteins is carried out in all vaccinated *herds* by sampling all vaccinated ruminants and their unvaccinated offspring, and a representative number of FMD susceptible animals of other species.~~

   The country or *zone* will regain ~~the~~ its free status ~~of FMD free country or *zone* where *vaccination* is not practised~~ only after the submitted evidence, based on the provisions of Article 1.6.6., has been accepted by the OIE.

   The time periods in points 1(a) to 1(c) are not affected if official emergency *vaccination* of zoological collections has been carried out following the relevant provisions of Article 8.8.2.

   Where a *stamping-out policy* is not practised, the above waiting periods do not apply, and Article 8.8.2. applies.

2) When ~~a~~ ~~FMD~~ ~~case of *infection* with~~ FMDV occurs in a ~~FMD free~~ country or *zone* previously free from FMD where *vaccination* is not practised, the following waiting period is required to gain the status of ~~FMD free~~ country or *zone* free from FMD where *vaccination* is practised: six months after the disposal of the last animal killed where a *stamping-out policy* has been applied and a continued *vaccination* policy has been adopted, provided that *surveillance* is applied in accordance with Articles 8.8.40. to 8.8.42., and a serological survey based on the detection of antibodies to ~~nonstructural proteins~~ NSP of FMDV demonstrates no ~~evidence of FMDV~~ transmission of FMDV.

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

Where a *stamping-out policy* is not practised, the above waiting periods do not apply, and Article 8.8.3. applies.

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

   a) six months after the disposal of the last animal killed where a *stamping-out policy*, with emergency *vaccination*, and *surveillance* in accordance with Articles 8.8.40. to 8.8.42. are applied, provided that serological *surveillance* based on the detection of antibodies to ~~nonstructural proteins~~ NSP of FMDV demonstrates no ~~evidence of~~ ~~virus~~ transmission of FMDV. This period can be reduced to a minimum of three months if a country can submit sufficient evidence demonstrating absence of *infection* in the non-vaccinated *population* and absence of transmission of FMDV in the vaccinated *population* based on the provisions of points 7 and 8 of Articles 8.8.40. as appropriate; or

   b) 12 months after the detection of the last *case* where a *stamping-out policy* is not applied, but where emergency *vaccination* and *surveillance* in accordance with Articles 8.8.40. to 8.8.42. are applied, provided that serological *surveillance* based on the detection of antibodies to ~~nonstructural proteins~~ NSP of FMDV demonstrates no evidence of ~~virus~~ transmission of FMDV.

   The country or *zone* will regain its free status only after the submitted evidence, based on the provisions of ~~Article 1.6.6~~ Chapter 1.11., has been accepted by the OIE.

   When~~re~~ emergency *vaccination* is not applied, the above waiting periods do not apply, and Article 8.8.3. applies.

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

4) When ~~a~~ ~~FMD *case of*~~ *infection* with FMDV occurs in a ~~FMD free~~ *compartment* free from FMD, Article 8.8.4. or Article 8.8.4bis. applies.

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

   For Member Countries not applying for recovery within 24 months after suspension, the provisions of Article 8.8.2., Article 8.8.3. or Article 8.8.4. apply.

Article 8.8.8.

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

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

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

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

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

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

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

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

The animals should have been subjected to ante- and post-mortem inspection within 24 hours before and after *slaughter* with no evidence of FMD, and the *meat* derived from them treated in accordance with point 2 of Article 8.8.22. or Article 8.8.23. Other products obtained from the animals and any products coming into contact with them should be treated in accordance with Articles 8.8.31. to 8.8.38. in order to destroy any FMDV potentially present.

~~Article 8.8.9.~~

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

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

~~1) the *containment zone* has been officially established in accordance with the requirements in Article 8.8.6.;~~

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

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

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

~~The animals should have been subjected to ante- and post-mortem inspection within 24 hours before and after *slaughter* with no evidence of FMD and the *meat* derived from them treated in accordance with point 2 of Article 8.8.22. or Article 8.8.23. Other products obtained from the animals and any products coming into contact with them should be treated in accordance with Articles 8.8.31. to 8.8.38. in order to destroy any FMDV potentially present.~~

Article 8.8.9bis.

Direct transfer of FMD vaccinated animals from a ~~free~~ zone free from FMD where vaccination is practised or not for slaughter in a free zone where vaccination is not practised

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

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

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

3) the animals are transported under the supervision of the *Veterinary Authority* in a *vehicle*, directly from the *establishment* of origin to the *slaughterhouse/abattoir*;

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

Article 8.8.10.

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

For FMD susceptible animals

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

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

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

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

4) if previously vaccinated, comply with point 4 of Article 8.8.11.

Article 8.8.11.

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

For domestic ruminants and pigs

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

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

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

3) if not vaccinated were subjected to ~~a~~ virological and serological tests for FMD with negative results on samples collected not earlier than 14 days before the shipment;

4) if vaccinated were subjected to virological and NSP serological tests for FMD with negative results on samples collected not earlier than 14 days before the shipment;

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

6) if transiting a free *zone* where *vaccination* is not practised, were not in contact with any FMD susceptible animal during transportation to the place of shipment.

Article 8.8.11bis.

Recommendations for the importation from a ~~free~~ country, zone or compartment free from FMD where vaccination is practised

For vaccinated animals destined for slaughter

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

1) no animal in the *establishment* of origin has shown clinical signs of FMD for at least 30 days prior to shipment;

2) the animals were kept in the country, *zone* or *compartment* of origin since birth or for at least three months prior to shipment;

3) the animals were transported under the supervision of the *Veterinary Authority* directly from the *establishment* of origin in sealed *vehicles/vessels*;

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

Article 8.8.12.

Recommendations for importation from ~~FMD infected~~ countries or zones infected with FMDV, where an official control programme exists

For domestic ruminants and pigs

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

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

2) pigs have not been fed swill not complying with Article 8.8.31bis.;

3~~2~~) prior to isolation, the animals were kept in the *establishment* of origin:

a) for 30 days, or since birth if younger than 30 days, if a *stamping-out policy* is applied to control FMD in the *exporting country* or *zone*, or

b) for three months, or since birth if younger than three months if a *stamping-out policy* is not applied to control FMD in the *exporting country* or *zone*;

4~~3~~) the *establishment* of origin is covered by the *official control programme* and FMD has not occurred within it ~~the *establishment* of origin~~ for the relevant period as defined in points 2~~3~~(a) and 2~~3~~(b) above;

5~~4~~a) 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 for evidence of FMDV with negative results on samples collected at least 28 days after the start of isolation period, and

b) if the animals were isolated in an establishment that is not a *quarantine station,* ~~that~~ FMD did not occur within a 10-kilometre radius of the *establishment* during that period~~, or the *establishment* is a *quarantine station*~~;

6~~5~~) the animals were not exposed to any source of FMDV during their transportation from the *establishment* to the *place of shipment*.

~~Article 8.8.13.~~

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

~~For fresh semen of domestic ruminants and pigs~~

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

~~1) the donor males:~~

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

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

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

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

Article 8.8.14.

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

For fresh and frozen semen of domestic ruminants and pigs

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

1) the donor males:

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

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

   c) were kept in an *artificial insemination centre*;

2) the semen was collected, processed and stored in accordance with Chapters 4.~~5~~6. and 4.~~6~~7.

Article 8.8.15.

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

For frozen semen of domestic ruminants and pigs

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

1) the donor males:

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

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

   c) either

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

      or

      ii) have not been vaccinated and were subjected, not less than 21 days and not more than 60 days after collection of the semen, to tests for antibodies against FMDV, with negative results;

2) the semen:

   a) was collected, processed and stored in accordance with Chapters 4.~~5~~6. and 4.~~6~~7.;

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

Article 8.8.16.

Recommendations for importation from ~~FMD infected~~ countries or zones infected with FMDV

For frozen semen of domestic ruminants and pigs

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

1) the donor males:

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

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

c) either

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

or

ii) have not been vaccinated and were subjected, not less than 21 days and not more than 60 days after collection of the semen, to tests for antibodies against FMDV, with negative results;

2) the semen:

a) was collected, processed and stored in accordance with Chapters 4.~~5~~6. and 4.~~6~~7.;

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

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

~~Article 8.8.17.~~

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

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

Article 8.8.18.

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

For *in vitro* produced embryos of ~~bovines~~ ~~cattle~~cattle

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

1) the donor females:

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

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

2) fertilisation was achieved with semen meeting the conditions referred to in Articles ~~8.8.13.,~~ 8.8.14., 8.8.15. or 8.8.16., as relevant;

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

Article 8.8.19.

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

For *in vitro* produced embryos of ~~bovines~~ ~~cattle~~cattle

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

1) the donor females:

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

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

   c) either

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

      or

      ii) were subjected, not less than 21 days after collection, to tests for antibodies against FMDV, with negative results;

2) fertilisation was achieved with semen meeting the conditions referred to in Articles ~~8.8.13.,~~ 8.8.14., 8.8.15. or 8.8.16., as relevant;

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

Article 8.8.20.

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

For fresh meat or meat products of FMD susceptible animals

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

1) have been kept in a ~~FMD free~~ country or *zone* or *compartment* free from FMD where *vaccination* is not practised ~~or FMD free *compartment*~~ free from FMD~~,~~ or ~~which~~ have been imported in accordance with Article 8.8.10., Article 8.8.11. or Article 8.8.12.;

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

Article 8.8.21.

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

For fresh meat and meat products of ruminants and pigs

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

1) have been kept in the ~~FMD free~~ country or *zone* or *compartment* free from FMD where *vaccination* is practised, or which have been imported in accordance with Article 8.8.10., Article 8.8.11. or Article 8.8.12.;

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

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

Article 8.8.22.

Recommendations for importation from ~~FMD infected~~ countries or zones infected with FMDV, where an official control programme exists

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

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

1) comes from animals which:

   a) have remained, for at least three months prior to *slaughter*, in a *zone* of the *exporting country* where ~~bovines~~ ~~cattle~~cattle and water buffaloes are regularly vaccinated against FMD and where an *official control programme* is in operation;

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

   c) were kept for the past 30 days in:

      – a *quarantine station*; or ~~in~~

      – an *establishment*, within a ~~ten~~ 10-kilometre radius of which ~~and that~~ FMD has not occurred ~~within a 10-kilometre radius of the *establishment*~~ during that period~~, or the *establishment* is a *quarantine station*~~;

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

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

      i) which is officially designated for export;

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

   f) were subjected to ante- and post-mortem inspections in accordance with Chapter 6.~~2~~3., with favourable results ~~have been subjected, with favourable results, to ante-mortem inspection within 24 hours of *slaughter* and to post-mortem inspections within 24 hours before and after *slaughter* with no evidence of FMD~~;

2) comes from deboned carcasses:

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

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

Article 8.8.22bis.

Recommendations for importation from countries or zones infected with FMDV, where an official control programme exists

For fresh meat of domestic pigs

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

1) the *meat* comes from animals complying with ~~points 1 to 6 of~~ Article 8.8.12.;

2) the animals were transported, in a *vehicle* which was cleaned and disinfected before the pigs were loaded, directly from the *establishment* of origin or *quarantine station* to the approved *slaughterhouse/abattoir* without coming into contact with other FMD susceptible animals that do not fulfil the conditions required for export, either during transport or at the *slaughterhouse/abattoir*;

3) the animals were slaughtered in an approved *slaughterhouse/abattoir*:

   a) which is officially designated for export;

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

4) the animals were subjected to ante- and post-mortem inspections in accordance with Chapter 6. ~~23~~., with favourable results;

5) the carcasses were not released earlier than 24 hours after *slaughter* and not before *Veterinary Authorities* have confirmed that FMD has not occurred in the *establishment* of origin.

Article 8.8.23.

Recommendations for importation from ~~FMD infected~~ countries or zones infected with FMDV

For meat products of FMD susceptible animals

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

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

2) the *meat products* have been processed to ensure the destruction of FMDV in accordance with one of the procedures in Article 8.8.31.;

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

Article 8.8.24.

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

For milk and milk products (other than those defined in Article 8.8.1bis.) intended for human consumption and for products of animal origin (from FMD susceptible animals) intended for use in animal feeding or for agricultural or industrial use

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products come from animals which have been kept in a ~~FMD free~~ country, *zone* or *compartment* free from FMD, or which have been imported in accordance with Article 8.8.10., Article 8.8.11. or Article 8.8.12.

Article 8.8.25.

Recommendations for importation from ~~FMD infected~~ countries or zones infected with FMDV, where an official control programme exists

For milk and milk products (other than those defined in Article 8.8.1bis.)

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

1) these products:

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

b) have been processed to ensure the destruction of FMDV in accordance with one of the procedures in Article 8.8.35. and in Article 8.8.36.;

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

~~Article 8.8.26.~~

~~**Recommendations for importation from FMD infected countries or zones infected with FMDV**~~

~~For blood-meal and meat-meals from FMD susceptible animals~~

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

~~1) the manufacturing method for these products included heating to a minimum core temperature of 70°C for at least 30 minutes.;~~

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

Article 8.8.27.

Recommendations for importation from ~~FMD infected~~ countries or zones infected with FMDV

For wool, hair, bristles, raw hides and skins from FMD susceptible animals

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

1) these products have been processed to ensure the destruction of FMDV in accordance with one of the procedures in Articles 8.8.32., 8.8.33. and 8.8.34.;

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

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

Article 8.8.28.

Recommendations for importation from ~~FMD infected~~ countries or zones infected with FMDV

For straw and forage

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

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

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

   a) either to the action of steam in a closed chamber such that the centre of the bales has reached a minimum temperature of 80°C for at least ~~ten~~ 10 minutes,

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

OR

3) have been kept in bond for at least four months before being released for export.

Article 8.8.29.

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

For skins and trophies derived from FMD susceptible wildlife

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

Article 8.8.30.

Recommendations for importation from ~~FMD infected~~ countries or zones infected with FMDV

For skins and trophies derived from FMD susceptible wildlife

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products have been processed to ensure the destruction of FMDV in accordance with the procedures in Article 8.8.37.

Article 8.8.31.

Procedures for the inactivation of FMDV in meat and meat products

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

1. Canning

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

2. Thorough cooking

   Meat, previously deboned and defatted, and *meat products* are subjected to a heat treatment that results in a core temperature of at least 70°C for a minimum of 30 minutes.

   After cooking, they should be packed and handled in such a way they are not exposed to a source of FMDV.

3. Drying after salting

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

   'Completely dried' is defined as a moisture protein ratio that is not greater than 2.25:1 or a water activity (Aw) that is not greater than 0.85.

Article 8.8.31bis.

Procedures for the inactivation of FMDV in swill

For the inactivation of FMDV in swill, one of the following procedures should be used:

1) the swill is maintained at a temperature of at least 90°C for at least 60 minutes, with continuous stirring; or

2) the swill is maintained at a temperature of at least 121°C for at least ten minutes at an absolute pressure of 3 bar; or

3) the swill is subjected to an equivalent treatment that has been demonstrated to inactivate FMDV.

Article 8.8.32.

Procedures for the inactivation of FMDV in wool and hair

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

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

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

3) fumigation with formaldehyde in a hermetically sealed chamber for at least 24 hours;

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

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

Article 8.8.33.

Procedures for the inactivation of FMDV in bristles

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

1) boiling for at least one hour; or

2) immersion for at least 24 hours in a 1% aqueous solution of formaldehyde.

Article 8.8.34.

Procedures for the inactivation of FMDV in raw hides and skins

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

Article 8.8.35.

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

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

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

~~2~~1) if the *milk* has a pH less than 7.0, a process applying a minimum temperature of 72°C for at least 15 seconds (high temperature - short time pasteurisation [HTST]),; or

~~3~~2) if the *milk* has a pH of 7.0 or greater, the HTST process applied twice.

~~Article 8.8.36.~~

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

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

~~1)~~ ~~the HTST process applied twice; or~~

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

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

Article 8.8.37.

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

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

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

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

3) soaking, with agitation, in a 4% (weight/volume) solution of sodium carbonate (Na_2CO_3) maintained at pH 11.5 or greater for at least 48 hours; or

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

5) in the case of raw hides, treating for at least 28 days with salt (NaCl) containing 2% sodium carbonate (Na_2CO_3).

Article 8.8.38.

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

For the inactivation of FMDV present in casings of ruminants and pigs, the following procedures should be used: treating for at least 30 days either with dry salt (NaCl) or with saturated brine (NaCl, $a_w < 0.80$), or with phosphate supplemented salt containing 86.5% NaCl, 10.7% Na_2HPO_4 and 2.8% Na_3PO_4 (weight/weight/weight), either dry or as a saturated brine ($a_w < 0.80$), and kept at a temperature of greater than 12°C during this entire period.

Article 8.8.39.

OIE endorsed official control programme for FMD

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

A Member ~~Countries~~ Country may, on a voluntary basis, apply for endorsement of ~~their~~ its *official control programme* for FMD in accordance with Chapter 1.6., when ~~they have~~ it has 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 provide an *official control programme* for the control and eventual eradication of FMD in the country or *zone*. This document should address and provide documented evidence on the following:

1) epidemiology:

   a) the detailed epidemiological situation of FMD in the country, highlighting the current knowledge and gaps;

   b) the main production systems and movement patterns of susceptible animals and their products within and into the country and, where applicable, the specific *zone*;

2) surveillance and diagnostic capabilities:

   a) FMD *surveillance* in place, in accordance with Chapter 1.4. and Articles 8.8.40. to 8.8.42.;

   b) diagnostic capability and procedures, including regular submission of samples to a *laboratory* that performs diagnostic testing and further characterisation of strains;

   c) serosurveillance conducted in susceptible species, including *wildlife*, to serve as sentinels for FMDV circulation in the country;

3) *vaccination*:

a) *vaccination* is compulsory in the target *population* and is practised in accordance with Chapter 4.18.;

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

i) the strategy that is adopted for the *vaccination* campaign;

ii) target *populations* for *vaccination*;

iii) target geographical area for *vaccination*;

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

v) the strategy to identify vaccinated animals;

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

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

viii) the proposed strategy and work plan including the timeline for transition to the cessation of *vaccination*;

4) the measures implemented to prevent the introduction of the pathogenic agent and to ensure the rapid detection of all FMD *outbreaks*;

5) an emergency preparedness plan and an emergency response plan to be implemented in case of FMD *outbreaks*;

6) work plan and timelines of the *official control programme*;

7) performance indicators for assessing the effectiveness of the control measures to be implemented;

8) monitoring, evaluation and review of the *official control programme* to demonstrate the effectiveness of the strategies.

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

~~2) submit documented evidence of the capacity of the *Veterinary Services* to control FMD; one way of providing this evidence is through the OIE PVS Pathway;~~

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

~~a) the timeline;~~

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

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

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

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

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

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

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

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

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

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

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

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

i) target populations for *vaccination*;

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

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

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

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

The Member Country's *official control programme* for FMD will be included in the list of programmes endorsed by the OIE only after the submitted evidence, based on the provisions of Article 1.6.11., has been accepted by the OIE.

The country will be included in the list of countries having an OIE endorsed *official control programme* for FMD in accordance with Chapter 1.6.

Retention on the list requires an annual update on the progress of the *official control programme* and information on significant changes concerning the points above. Changes in the epidemiological situation and other significant events should be reported to the OIE in accordance with the requirements in Chapter 1.1.

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

– non-compliance with the timelines or performance indicators of the programme; or

– significant problems with the performance of the *Veterinary Services*; or

– an increase in the incidence or an extension of the distribution of FMD that cannot be addressed by the programme.

Article 8.8.40.

General principles of surveillance

Articles 8.8.40. to 8.8.42. define the principles and provide a guide for the *surveillance* of FMD in accordance with Chapter 1.4. applicable to Member Countries seeking establishment, maintenance or recovery of freedom from FMD at the country, *zone* or *compartment* level or seeking endorsement by the OIE of their *official control programme* for FMD, in accordance with Article 8.8.39. *Surveillance* aimed at identifying *disease* and ~~FMDV~~ *infection* with, or transmission of, FMDV should cover domestic and, where appropriate, *wildlife* species as indicated in point 2 of Article 8.8.1.

1. Early detection

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

2. Demonstration of freedom

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

Surveillance for FMD should be in the form of a continuing programme. Programmes to demonstrate no evidence of *infection* with, ~~FMDV~~ and transmission of, FMDV should be carefully designed and implemented to avoid producing results that are insufficient to be accepted by the OIE or trading partners, or being excessively costly and logistically complicated.

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

A Member Country wishing to substantiate FMD freedom where *vaccination* is not practised should demonstrate no evidence of *infection* with FMDV in unvaccinated animals. Previously or newly introduced vaccinated animals should be considered in the strategy and design of the *surveillance* programme.

A Member Country wishing to substantiate FMD freedom where *vaccination* is practised should demonstrate that FMDV has not been transmitted in any susceptible *population*s. Within vaccinated *population*s, serological surveys to demonstrate no evidence of ~~FMDV~~ transmission of FMDV should target animals that are less likely to show vaccine-derived antibodies to ~~non-structural proteins~~ NSP, such as young animals vaccinated a limited number of times, or unvaccinated animals. In any unvaccinated *subpopulation*, *surveillance* should demonstrate no evidence of *infection* with FMDV.

Surveillance strategies employed for establishing and maintaining a *compartment* should identify the prevalence, distribution and characteristics of FMD outside the *compartment*.

3. OIE endorsed official control programme

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

Therefore considerable latitude is available to Member Countries to design and implement *surveillance* to establish that the whole territory or part of it is free from ~~FMDV~~ *infection* with, and transmission of, FMDV and to understand the epidemiology of FMD as part of the *official control programme*.

The Member Country should submit a dossier to the OIE in support of its application that not only explains the epidemiology of FMD in the region concerned but also demonstrates how all the risk factors, including the role of *wildlife*, if appropriate, are identified and managed. This should include provision of scientifically based supporting data.

4. Surveillance strategies

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

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

5. Follow-up of suspected cases and interpretation of results

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

The sensitivity and specificity of the diagnostic tests employed, including the performance of confirmatory tests, are key factors in the design, sample size determination and interpretation of the results obtained. Selection of diagnostic tests and interpretation of results should take into account ~~The sensitivity and specificity of the tests used should be validated for~~ the *vaccination* or *infection* history and production class of animals in the target population.

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

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

– characterisation of the existing production systems;

– results of clinical *surveillance* of the suspects and their cohorts;

– description of number of, and protocol for, *vaccinations* performed in the area under assessment;

– *biosecurity* and history of the *establishments* with reactors;

– identification and traceability of animals and control of their movements;

– other parameters of regional significance in historic ~~FMDV~~ transmission of FMDV.

6. Demonstration of population immunity

Following routine *vaccination*, evidence should be provided to demonstrate the effectiveness of the *vaccination* programme such as adequate *vaccination* coverage and population immunity. This can support the interpretation of ~~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.

7. Additional measures for early recovery of free status without vaccination or early recovery of free status with vaccination in the area(s) where emergency vaccination has been applied but not followed by the slaughtering of all vaccinated animals

In addition to the general conditions described in this chapter, a Member Country seeking either recovery of status of a country or *zone* previously free from FMD where *vaccination* is not practised, including a *containment zone*, or recovery of status of a country or *zone* previously free from FMD where *vaccination* is practiced, earlier than the six months as specified respectively under point 1c) of Article 8.8.7. or under point 3a) of Article 8.8.7. should justify the circumstances and measures that demonstrate sufficient confidence to substantiate a claim for freedom. This may be achieved when answering the relevant questionnaire in Chapter 1.11. by demonstrating compliance with either a) or b) and c) below, in the area(s) where emergency *vaccination* has been applied. It is advisable that countries should consider the different options for the recovery of a free status when control measures are first implemented at the onset of the *outbreak* in order to plan for the applicable requirements to be met.

a) The following serological surveys have been conducted in the area where emergency *vaccination* has been applied and have demonstrated the absence of *infection* in unvaccinated *animals* and the absence of transmission in emergency vaccinated *animals*:

i) for vaccinated ruminants, serological surveys using ~~nonstructural protein~~ NSP tests to detect antibodies in all vaccinated ruminants and their non-vaccinated offspring in all *epidemiological units* (census serosurveillance);

ii) for vaccinated pigs and their non-vaccinated offspring, serological surveys using ~~nonstructural protein~~ NSP tests to detect antibodies in all vaccinated *epidemiological units* with maximum 5% within *herd* design prevalence (95% confidence level);

iii) for non-vaccinated susceptible species that do not show reliable clinical signs or husbandry systems that do not allow sufficient observation, serological surveys with maximum design prevalence of 1% at *herd* level and 5% within *herds* (95% confidence level).

b) The following *surveillance* components have been implemented in the area where emergency *vaccination* has been applied and have demonstrated the absence of *infection* in unvaccinated *animals* and the absence of transmission in vaccinated *animals*:

i) risk-based serological *surveillance* in vaccinated *herds* with stratification according to relevant factors such as proximity to known infected *herds*, region/*establishment* with numerous movement of animals, epidemiological links to infected *herds*, species, production management systems and *herd* size;

ii) random serological *surveillance* in vaccinated *herds* with maximum design prevalence of 1% at *herd* level and 5% within *herds* (95% confidence level) in each emergency *vaccination* area;

iii) intensified clinical and *slaughterhouse/abattoir surveillance*;

iv) for non-vaccinated susceptible species that do not show reliable clinical signs or husbandry systems that do not allow sufficient observation, serological surveys with maximum design prevalence of 1% at *herd* level and 5% within *herds* (95% confidence level);

v) virological *surveillance* to investigate the status of vaccinated *herds* may also be conducted to contribute to additional confidence in demonstrating freedom.

c) Vaccine efficacy and *vaccination* effectiveness of the emergency *vaccination* deployed have been demonstrated by documenting the following:

i) Vaccine efficacy

– vaccine that provides high ~~potency of at least 6PD50 or equivalent~~ probability of protection which may be achieved by a vaccine with high potency of at least 6PD50 or equivalent and evidence of a good match between the vaccine strain and the field virus; or

- evidence that the vaccine used can protect against the field strain that has caused the *outbreak*, demonstrated through the results of a heterologous challenge test or indirect serological assay (i.e., sera from vaccinated *animals* tested against the field virus). This should also establish the cut-off titre for protection to be used in the test for population immunity studies.

ii) Vaccination effectiveness

- objective and strategy of the emergency *vaccination* deployed;
- evidence of the timeliness of the emergency *vaccination* (start and completion dates);
- evidence of *vaccination* delivery including preservation of vaccine (e.g., cold chain) and at least 95% *vaccination* coverage achieved in the targeted and eligible *population*;
- evidence of high population immunity at *herd* and individual level through serological *surveillance*.

8. Additional measures for early recovery of free status with *vaccination* in the area outside of the area(s) where emergency *vaccination* has been applied.

In addition to the general conditions described in this chapter, a Member Country seeking recovery of status of a country or *zone* previously free from FMD where *vaccination* is practised in the area outside of the area(s) where emergency *vaccination* has been applied, earlier than six months as specified under point 3a) of Article 8.8.7. should justify the circumstances and measures that demonstrate sufficient confidence to substantiate a claim for freedom. This may be achieved either by meeting the requirements listed in a) below or by demonstrating compliance with the requirements listed in b) and c) below, when answering the questionnaire in Article 1.11.2. or Article 1.11.4.

With regard to the *surveillance* requirements listed in b), it should be noted that clinical signs may not be apparent in the routinely vaccinated *population*. The expression of clinical signs would depend on the relationship between the virus strain used in the routine *vaccination* to the virus that caused the *outbreak*. For example, following an incursion of a new serotype it would be expected that the routinely vaccinated animals would show clinical signs if infected. In contrast, following an incursion of a serotype or strain covered by the vaccine it would be expected that most of the routinely vaccinated animals would be protected and therefore less likely to be infected and to show clinical signs if infected. Other factors such as *vaccination* coverage and timing of *vaccination* could influence the likelihood of *infection* and expression of clinical signs.

It is advisable that countries should consider the different options for the recovery of a free status when control measures are first implemented at the onset of the *outbreak* in order to plan for the applicable requirements to be met.

a) Establishment of a containment zone

A *containment zone* that includes all emergency *vaccination* area(s) has been established based on the provisions of Article 8.8.6. to provide assurance that FMD has not occurred in the area outside the emergency *vaccination* area(s).

b) The following *surveillance* components have been implemented in the area outside of the area(s) where emergency *vaccination* has been applied and have demonstrated the absence of *infection* in unvaccinated *animals* and the absence of transmission in vaccinated *animals*:

i) risk-based serological *surveillance* in vaccinated *herds* with stratification according to relevant factors such as proximity to the emergency *vaccination* area, region/*establishment* with numerous movement of *animals*, epidemiological links to infected *herds*, species and age, production management systems, *herd* size;

ii) random serological *surveillance* in vaccinated *herds* with maximum design prevalence of 1% at *herd* level and 5% within *herds* (95% confidence level);

iii) intensified clinical and *slaughterhouse/abattoir surveillance*;

iv) serological survey in non-vaccinated susceptible species that do not show reliable clinical signs or husbandry systems that do not allow sufficient observation with risk-based stratification according to factors such as proximity to the emergency *vaccination* area, region/*establishment* with numerous movement of *animals*, epidemiological links to infected *herds*, species, production management systems, *herd* size;

v) virological *surveillance* to investigate the status of vaccinated *herds* may also be conducted to contribute to additional confidence in demonstrating freedom.

The efficacy of the routine vaccine against the virus that caused the *outbreak(s)* has been documented.

The entire investigative process should be documented within the *surveillance* programme.

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

Article 8.8.41.

Methods of surveillance

1. Clinical surveillance

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

Clinical *surveillance* requires the physical examination of susceptible *animals*. Although significant emphasis is placed on the diagnostic value of mass serological screening, *surveillance* based on clinical inspection may provide a high level of confidence of detection of *disease* if a sufficient number of clinically susceptible *animals* is examined at an appropriate frequency and investigations are recorded and quantified.

Clinical examination and diagnostic testing should be applied to clarify the status of suspected *cases*. Diagnostic testing may confirm clinical suspicion, while clinical *surveillance* may contribute to confirmation of positive laboratory test results. Clinical *surveillance* may be insufficient in *wildlife* and domestic species that usually do not show clinical signs or husbandry systems that do not permit sufficient observations. In such situations, serological *surveillance* should be used. Hunting, capture and non-invasive sampling and observation methods can be used to obtain information and diagnostic samples from *wildlife* species.

2. Virological surveillance

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

Virological *surveillance* aims to:

a) confirm clinically suspected *cases*;

b) follow up positive serological results;

c) characterise isolates for epidemiological studies and vaccine matching;

d) monitor *populations* at risk for the presence and transmission of the virus.

3. Serological surveillance

Serological *surveillance* aims to detect antibodies resulting from *infection* or *vaccination* using ~~nonstructural protein~~ NSP tests or ~~structural protein~~ SP tests.

Serological *surveillance* may be used to:

a) estimate the prevalence or substantiate freedom from ~~FMDV~~ *infection* with, or transmission of, FMDV;

b) monitor population immunity.

Serum collected for other purposes can be used for FMD *surveillance*, provided the principles of survey design described in this chapter are met.

The results of random or targeted serological surveys are important in providing reliable evidence of the FMD situation in a country, *zone* or *compartment*. It is therefore essential that the survey be thoroughly documented.

Article 8.8.42.

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

The selection and interpretation of serological tests should be considered in the context of the epidemiological situation. Test protocols, reagents, performance characteristics and validation of all tests used should be known. Where combinations of tests are used, the overall test system performance characteristics should also be known.

Animals infected with FMDV produce antibodies to both the ~~structural proteins~~ SP and the ~~nonstructural proteins~~ NSP of the virus. Vaccinated *animals* produce antibodies mainly or entirely to the ~~structural proteins~~ SP of the virus depending upon vaccine purity. The ~~structural protein~~ SP tests are serotype specific and for optimal sensitivity one should select an antigen or virus closely related to the field strain expected. In unvaccinated *population*s, ~~structural protein~~ SP tests may be used to screen sera for evidence of ~~FMDV~~ *infection* with, ~~or transmission of,~~ FMDV or to detect the introduction of vaccinated *animals*. In vaccinated *population*s, ~~structural protein~~ SP tests may be used to monitor the serological response to the *vaccination*.

~~Nonstructural protein~~ NSP tests may be used to screen sera for evidence of *infection* or transmission of all serotypes of FMDV regardless of the *vaccination* status of the *animals* provided the vaccines comply with the standards of the *Terrestrial Manual* with respect to purity. However, although *animals* vaccinated and subsequently infected with FMDV develop antibodies to ~~nonstructural proteins~~ NSP, the levels may be lower than those found in infected *animals* that have not been vaccinated. To ensure that all *animals* that had contact with FMDV have seroconverted, it is recommended that for each *vaccination* area samples for ~~nonstructural protein~~ 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*.

Positive FMDV antibody test results can have four possible causes:

– *infection* with FMDV;

– *vaccination* against FMD;

– maternal antibodies (maternal antibodies in ~~bovines cattle~~ cattle are usually found only up to six months of age but in some individuals and in some other species, maternal antibodies can be detected for longer periods);

– non-specific reactivity of the serum in the tests used.

1. Procedure in case of positive test results

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

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

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

Clustering of seropositive results within *herds* or within a region should be investigated as it may reflect any of a series of events, including the demographics of the *population* sampled, vaccinal exposure or the presence of *infection* or transmission. As clustering may signal *infection* or transmission, the investigation of all instances should be incorporated in the survey design.

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

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

In some circumstances, unvaccinated sentinel *animals* may also be used. These can be young *animals* from unvaccinated dams or *animals* in which maternally conferred immunity has lapsed and preferably of the same species as in the positive sampling units. If other susceptible, unvaccinated *animals* are present, they could act as sentinels to provide additional serological evidence. The sentinels should be kept in close contact with the *animals* of the *epidemiological unit* under investigation for at least two *incubation periods*. ~~and~~ If there is no transmission of FMDV, they ~~should~~ will remain serologically negative ~~if FMDV is not circulating~~.

2. Follow-up of field and laboratory findings

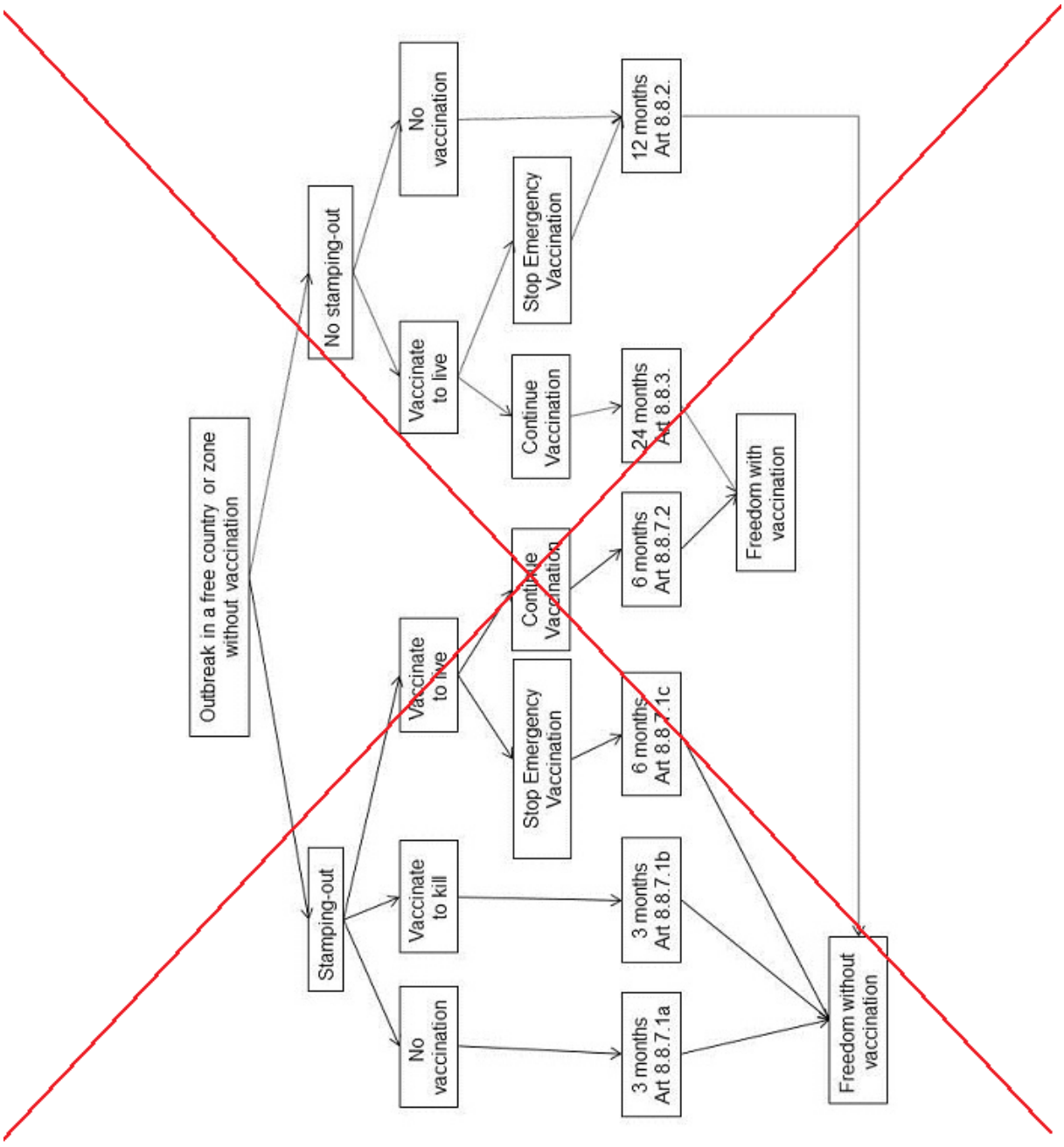
If transmission is demonstrated, an *outbreak* is declared.

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

However, if the number of seropositive *animals* is greater than the number of false positive results expected from the specificity of the diagnostic tests used, susceptible *animals* that have been in contact or otherwise epidemiologically associated with the reactor *animals* should be investigated further.

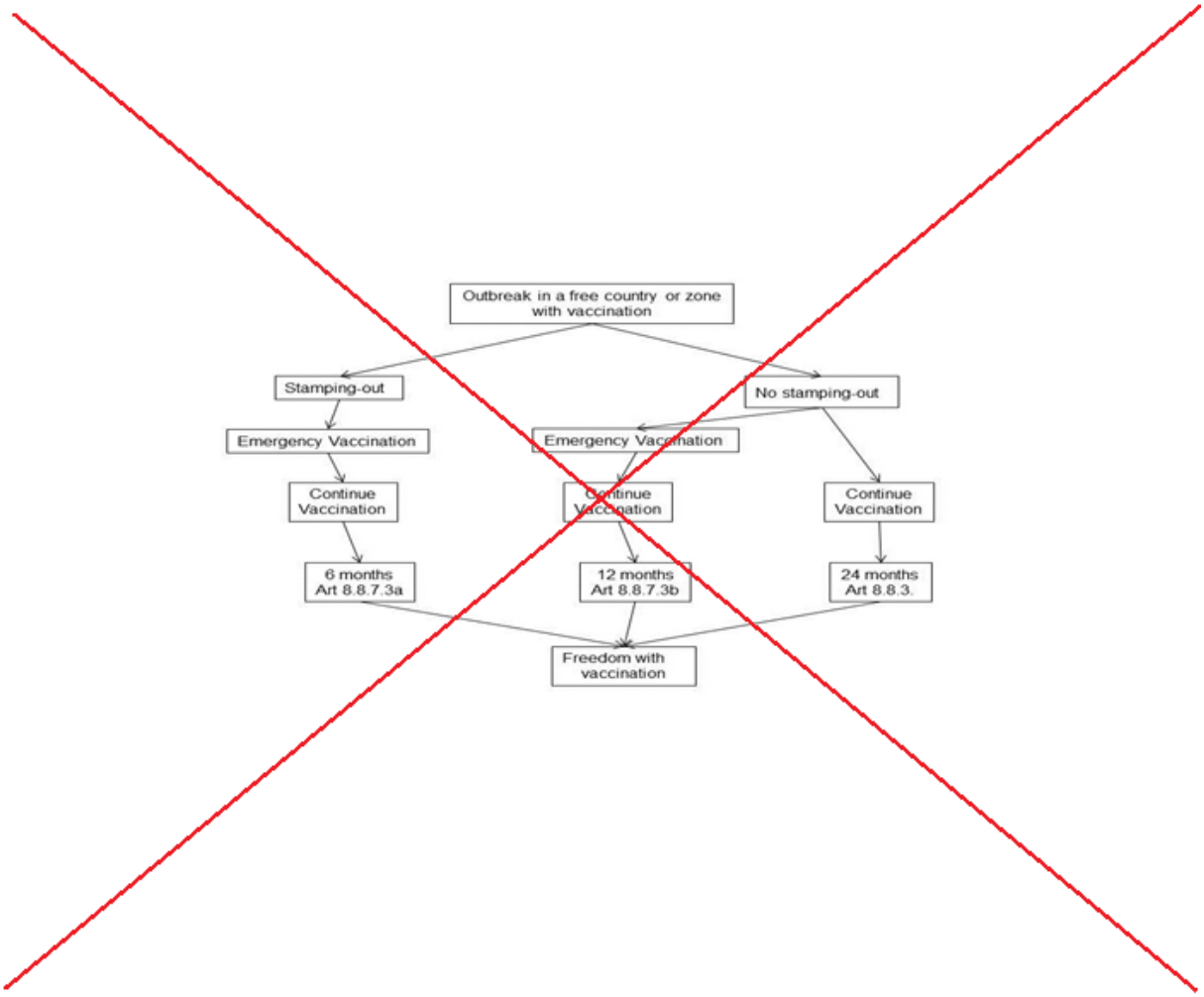
~~Abbreviations and acronyms:~~	
~~ELISA~~	~~Enzyme-linked immunosorbent assay~~
~~VNT~~	~~Virus neutralisation test~~
~~NSP~~	~~Nonstructural protein(s) of foot and mouth disease virus (FMDV)~~
~~3ABC~~	~~NSP antibody test~~
~~SP~~	~~Structural protein of foot and mouth disease virus~~

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



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

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



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

Fig. 3. Schematic representation of laboratory tests for determining evidence of infection with FMDV by means of serological surveys