

NOTE:

The Code Commission proposes the following amendments in this chapter, taking into consideration Member Countries' comments and the technical advices from Scientific Commission, *ad hoc* Groups and other OIE experts. The rationale for the amendments is given in the reports of Scientific Commission and *ad hoc* groups as well as in Part A of this report.

The Code Commission strongly encourages that Member Countries consult all relevant reports when reviewing and preparing comments on this revised chapter.

Relevant reports of Scientific Commission and *ad hoc* groups are:

- [September 2014 report of the Scientific Commission](#)
- [February 2014 report of the OIE *ad hoc* Group on the evaluation of foot and mouth disease status of Member Countries](#)

CHAPTER 8.7.

INFECTION WITH FOOT AND MOUTH DISEASE VIRUS

Article 8.7.1.

- 1) Many different species belonging to diverse taxonomic orders are known to be susceptible to *infection* with foot and mouth disease virus (FMDV). Their epidemiological significance depends upon the degree of susceptibility, the husbandry system, the density and extent of populations and the contacts between them. Amongst *Camelidae* only Bactrian camels (*Camelus bactrianus*) are sufficiently susceptible to have potential for epidemiological significance. Infection of dromedaries and South American camelids has not been shown to be of epidemiological significance.
- 2) For the purposes of the *Terrestrial Code*, foot and mouth disease (FMD) is defined as an *infection* of animals of the suborder *ruminantia* and of the family *suidae* of the order *Artiodactyla*, and *Camelus bactrianus* with any FMDV.
- 3) The following defines the occurrence of FMDV *infection*:
 - a) FMDV has been isolated from a sample from an animal listed in point 2; or
 - b) viral antigen or viral ribonucleic acid (RNA) specific to a serotype of FMDV has been identified in a sample from an animal listed in point 2, showing clinical signs consistent with FMD, or epidemiologically linked to a confirmed or suspected *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV; or
 - c) antibodies to structural or nonstructural proteins of FMDV that are not a consequence of *vaccination*, have been identified in a sample from an animal listed in point 2, showing clinical signs consistent with FMD, or epidemiologically linked to a confirmed or suspected *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV.

Annex XVI (A) (contd)

- 4) Transmission of FMDV in a vaccinated population is demonstrated by change in virological or serological evidence indicative of recent *infection*, even in the absence of clinical signs.
- 5) For the purposes of the *Terrestrial Code*, the *incubation period* of FMD is 14 days.
- 6) *Infection* with FMDV can give rise to *disease* of variable severity and to FMDV transmission. FMDV may persist in the pharynx and associated lymph nodes of ruminants for a variable but limited period of time beyond 28 days. Such animals have been termed carriers. However, the only persistently infected species from which transmission of FMDV has been proven is the African buffalo (*Syncerus caffer*).
- 7) The chapter deals not only with the occurrence of clinical signs caused by FMDV, but also with the presence of FMDV *infection* and transmission, in the absence of clinical signs.
- 8) Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 8.7.2.

FMD free country or zone where vaccination is not practised

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

Susceptible animals in the FMD free country or *zone* where *vaccination* is not practised should be protected by the application of animal health 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*.

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

- 1) have a record of regular and prompt animal *disease* reporting;
- 2) send a declaration to the OIE stating that during the past 12 months, within the proposed FMD free country or *zone*:
 - a) there has been no *case* of FMD;
 - b) no evidence of FMDV *infection* has been found;
 - c) no *vaccination* against FMD has been carried out;
- 3) supply documented evidence that for the past 12 months:
 - a) *surveillance* in accordance with Articles 8.7.40. to 8.7.42. has been implemented to detect clinical signs of FMD and show absence of:
 - i) FMDV *infection* in non-vaccinated animals;
 - ii) FMDV transmission in previously vaccinated animals when transition is made from FMD free country or *zone* where *vaccination* is practised to FMD free country or *zone* where *vaccination* is not practised;
 - b) regulatory measures for the prevention and early detection of FMD have been implemented;

- 4) describe in detail and supply documented evidence that for the past 12 months the following have been properly implemented and supervised:
- a) in the case of a FMD free *zone*, the boundaries of the proposed FMD free *zone*;
 - b) the boundaries and measures of a *protection zone*, if applicable;
 - c) the system for preventing the entry of FMDV into the proposed FMD free country or *zone*;
 - d) the control of the movement of susceptible animals, their *meat* and other products into the proposed FMD free country or *zone*, in particular the measures described in Articles 8.7.8., 8.7.9. and 8.7.12.;
 - e) no vaccinated animal has been introduced except in accordance with Articles 8.7.8. and 8.7.9.

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

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

Provided the conditions of points 1 to 4 are fulfilled, the status of a country or *zone* will not be affected by applying official emergency *vaccination* of the 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 a primary purpose to exhibit *animals* or preserve rare species, has been identified, including the boundaries of the facility, and is included in the country's contingency plan for FMD;
- appropriate biosecurity measures are in place, including effective separation from other susceptible domestic populations or *wildlife*;
- the *animals* are identifiable as belonging to the collection and any movements can be traced;
- the vaccine used complies with the standards described in the *Terrestrial Manual*;
- *vaccination* is conducted under the supervision of the *Veterinary Authority*;
- the zoological collection is placed under *surveillance* for at least 12 months after *vaccination*.

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

Article 8.7.3.

FMD free country or zone where vaccination is practised

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

Annex XVI (A) (contd)

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

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

- 1) have a record of regular and prompt animal *disease* reporting;
- 2) send a declaration to the OIE stating that, based on the *surveillance* described in point 3, within the proposed FMD free country or *zone*:
 - a) there has been no case of FMD during the past two years;
 - b) there has been no evidence of FMDV transmission during the past 12 months;
- 3) supply documented evidence that:
 - a) *surveillance* in accordance with Articles 8.7.40. to 8.7.42. has been implemented to detect clinical signs of FMD and show absence of:
 - i) FMDV *infection* in non-vaccinated animals;
 - ii) FMDV transmission in vaccinated animals;
 - b) regulatory measures for the prevention and early detection of FMD have been implemented;
 - c) compulsory systematic *vaccination* in the target population has been carried out to achieve adequate vaccination coverage and population immunity;
 - d) the vaccine used complies with the standards described in the *Terrestrial Manual*, including appropriate vaccine strain selection;
- 4) describe in detail and supply documented evidence that the following have been properly implemented and supervised:
 - a) in case of FMD free *zone*, the boundaries of the proposed FMD free *zone*;
 - b) the boundaries and measures of a *protection zone*, if applicable;
 - c) the system for preventing the entry of FMDV into the proposed FMD free country or *zone*, in particular the measures described in Articles 8.7.8., 8.7.9. and 8.7.12.;
 - d) the control of the movement of susceptible animals and their products into the proposed FMD free country or *zone*.

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

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

If a Member Country that meets the requirements of a FMD free country or *zone* where *vaccination* is practised wishes to change its status to FMD free country or *zone* where *vaccination* is not practised, it should notify the OIE in advance of the intended date of cessation of *vaccination* and apply for the new status within 24 months. The status of this country or *zone* remains unchanged until compliance with Article 8.7.2. is approved by the OIE. If the dossier for the new status is not provided within 24 months then the status of the country or *zone* as being free with *vaccination* will be suspended. If the country does not comply with requirements of Article 8.7.2., evidence should be provided within three months that it complies with Article 8.7.3. Otherwise the status will be withdrawn.

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

Article 8.7.4.

FMD free compartment

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

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

- 1) have a record of regular and prompt animal *disease* reporting and if not FMD free, have an *official control programme* and a *surveillance* system for FMD in place according to Articles 8.7.40. to 8.7.42. that allows knowledge of the prevalence, distribution and characteristics of FMD in the country or *zone*;
- 2) declare for the FMD free *compartment* that:
 - a) there has been no case of FMD during the past 12 months;
 - b) no evidence of FMDV *infection* has been found during the past 12 months;
 - c) *vaccination* against FMD is prohibited;
 - d) no animal vaccinated against FMD within the past 12 months is in the *compartment*;
 - e) animals, semen, embryos and animal products should only enter the *compartment* in accordance with relevant articles in this chapter;
 - f) documented evidence shows that *surveillance* in accordance with Articles 8.7.40. to 8.7.42. is in operation;
 - g) an *animal identification* and traceability system in accordance with Chapters 4.1. and 4.2. is in place;
- 3) describe in detail:
 - a) the animal *subpopulation* in the *compartment*;
 - b) the *biosecurity plan* to mitigate the risks identified by the *surveillance* carried out according to point 1.

Annex XVI (A) (contd)

The *compartment* should be approved by the *Veterinary Authority*. The first approval should only be granted when no case of FMD has occurred within a ten-kilometre radius of the *compartment* during the past three months.

Article 8.7.5.

FMD infected country or zone

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

Article 8.7.6.

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

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

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

- 1) on suspicion, standstill of animal movements has been imposed on the suspected *establishments* and animal movement control has been imposed in the country or *zone*, and effective controls on the movement of other *commodities* mentioned in this chapter are in place;
- 2) on confirmation, standstill of susceptible animals has been imposed in the *containment zone* and movement controls have been reinforced;
- 3) the boundaries of the *containment zone* may only be established once an epidemiological investigation (trace-back, trace-forward) has demonstrated that the *outbreaks* are epidemiologically related and limited in number and geographic distribution;
- 4) investigations into the likely source of the *outbreak* 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 8.7.1. 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 identifiable as belonging to the *containment zone*;
- 8) *surveillance* in accordance with Articles 8.7.40.to 8.7.42. is in place in the *containment zone* and in the rest of the country or *zone*;
- 9) animal health measures that prevent the spread of FMDV to the rest of the country or *zone*, taking into consideration physical and geographical barriers, are in place.

The free status of the areas outside the *containment zone* is suspended while the *containment zone* is being established. The free status of these areas may be reinstated irrespective of the provisions of Article 8.7.7., once the *containment zone* has been approved, by complying with points 1 to 9 above. *Commodities* from susceptible animals for *international trade* should be identified as to their origin, either from inside or outside the *containment zone*.

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

The recovery of the FMD free status of the *containment zone* should follow the provisions of Article 8.7.7.

Article 8.7.7.

Recovery of free status (see Figures 1 and 2)

- 1) When a FMD case occurs in a FMD free country or *zone* where *vaccination* is not practised, one of the following waiting periods is required to regain this free status:
 - a) three months after the disposal of the last case where a *stamping-out policy*, without emergency *vaccination*, and *surveillance* are applied in accordance with Articles 8.7.40. to 8.7.42.; or
 - b) three months after the disposal of the last case or the *slaughter* of all vaccinated animals whichever occurred last, where a *stamping-out policy*, emergency *vaccination* and *surveillance* in the remaining animals are applied in accordance with Articles 8.7. 40. to 8.7.42.; or
 - c) six months after the disposal of the last case or the last *vaccination* whichever occurred last, where a *stamping-out policy*, emergency *vaccination* not followed by the slaughtering of all vaccinated animals, and *surveillance* are applied in accordance with Articles 8.7.40. to 8.7.42. However, this requires a serological survey based on the detection of antibodies to nonstructural proteins of FMDV to demonstrate the absence of *infection* in the remaining vaccinated population. This period can be reduced to three months if effectiveness of *vaccination* using vaccine compliant with the *Terrestrial Manual* is demonstrated and additional serological *surveillance* for antibodies to nonstructural proteins is carried out in all vaccinated *herds*. This includes sampling all vaccinated ruminants and their non-vaccinated offspring, and a representative number of animals of other species, based on an acceptable level of confidence.

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

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

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

- 2) When a FMD case occurs in a FMD free country or *zone* where *vaccination* is not practised, the following waiting period is required to gain the status of FMD free country or *zone* where *vaccination* is practised: three months after the disposal of the last case where a *stamping-out policy* has been applied and a continued *vaccination* policy has been adopted, provided that *surveillance* is applied in accordance with Articles 8.7.40. to 8.7.42., and a serological survey based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of FMDV.

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

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

Annex XVI (A) (contd)

- 3) When a FMD *outbreak* or FMDV transmission occurs in a FMD free country or *zone* where *vaccination* is practised, one of the following waiting periods is required to regain this free status:
- a) six months after the disposal of the last *case* where a *stamping-out policy*, with emergency *vaccination*, and *surveillance* in accordance with Articles 8.7.40. to 8.7.42. are applied, provided that serological *surveillance* based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of virus transmission; or
 - b) 12 months after the detection of the last *case* where a *stamping-out policy* is not applied, but where emergency *vaccination* and *surveillance* in accordance with Articles 8.7.40. to 8.7.42. are applied, provided that serological *surveillance* based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of virus transmission.

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

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

- 4) When a FMD *case* occurs in a FMD free *compartment*, Article 8.7.4. 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* has been successfully eradicated within the *containment zone*.

Article 8.7.8.

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

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

- 1) no FMD susceptible animal has been introduced into the *establishment* of origin and no animal in the *establishment* of origin has shown clinical signs of FMD for at least 30 days prior to movement;
- 2) the animals were kept in the *establishment* of origin for at least three months prior to movement;
- 3) FMD has not occurred within a ten-kilometre radius of the *establishment* of origin for at least four weeks prior to movement;
- 4) the animals should be transported under the supervision of the *Veterinary Authority* in a *vehicle*, which was cleansed and disinfected before *loading*, directly from the *establishment* of origin to the *slaughterhouse/abattoir* without coming into contact with other susceptible animals;
- 5) such 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 subjected to thorough cleansing and *disinfection* immediately after use.

The animals should have been subjected to ante- and post-mortem inspection for FMD, with favourable results, within 24 hours before and after *slaughter* and the *meat* derived from them treated according to point 2 of Article 8.7.22. or Article 8.7.23. Other products obtained from the animals and any products coming into contact with them should be treated in such a way as to destroy any residual FMDV in accordance with Articles 8.7. 31. to 8.7. 38.

Article 8.7.9.

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

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

- 1) the *containment zone* has been officially established according to the requirements in Article 8.7.6.;
- 2) the animals should be transported under the supervision of the *Veterinary Authority* in a *vehicle*, which was cleansed and disinfected before *loading*, directly from the *establishment* of origin to the *abattoir* without coming into contact with other susceptible animals;
- 3) such an *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 *abattoir* should be subjected to thorough cleansing and *disinfection* immediately after use.

The animals should have been subjected to ante- and post-mortem inspection for FMD, with favourable results, within 24 hours before and after *slaughter* and the *meat* derived from them treated according to point 2 of Article 8.7.22. or Article 8.7.23. Other products obtained from the animals and any products coming into contact with them should be treated in such a way as to destroy any residual FMDV in accordance with Articles 8.7.31. to 8.7.38.

Article 8.7.10.

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

For FMD susceptible animals

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

- 1) showed no clinical sign of FMD on the day of shipment;
- 2) were kept since birth or for at least the past three months in a FMD free country or *zone* where *vaccination* is not practised or a FMD free *compartment*;
- 3) if transiting an *infected zone*, were not exposed to any source of FMDV during transportation to the *place of shipment*.

Article 8.7.11.

Recommendations for importation from FMD free countries or zones 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* where *vaccination* is practised;
- 3) were subjected to a test for FMD with negative results;
- 4) if transiting an *infected zone*, were not exposed to any source of FMDV during transportation to the *place of shipment*.

Article 8.7.12.

Recommendations for importation from FMD infected countries or zones

For domestic ruminants and pigs

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

- 1) the animals showed no clinical sign of FMD on the day of shipment;
- 2) prior to isolation, the animals were kept in the *establishment* of origin:
 - a) since birth, or
 - b) for the past 30 days, if a *stamping-out policy* is in force in the *exporting country or zone*, or
 - c) for the past 3 months, if a *stamping-out policy* is not in force in the *exporting country or zone*,
- 3) and that FMD has not occurred within the *establishment* of origin for the relevant period as defined in points 2 a) and 2 b) above;
- 4) the animals were isolated in an *establishment* for the 30 days prior to shipment, and all animals in isolation were subjected to diagnostic virological and serological tests for evidence of FMDV with negative results on samples collected at least 28 days after the start of isolation period, and that FMD did not occur within a ten-kilometre radius of the *establishment* during that period;
- 5) the animals were not exposed to any source of FMDV during their transportation from the *establishment* to the *place of shipment*.

Article 8.7.13.

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

For fresh semen of domestic ruminants and pigs

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

- 1) the donor animals:
 - a) showed no clinical sign of FMD on the day of collection of the semen;
 - b) were kept for at least three months prior to collection in a FMD free country or *zones* where *vaccination* is not practised or FMD free *compartments*;
 - c) were kept in an *artificial insemination centre* where none of the animals had a history of *infection*;
- 2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 8.7.14.

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

For frozen semen of domestic ruminants and pigs

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

- 1) the donor animals:
 - a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;
 - b) were kept for at least three months prior to collection in a FMD free country or *zone* where *vaccination* is not practised or FMD free *compartments*;
- 2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 8.7.15.

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

For frozen semen of domestic ruminants and pigs

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

- 1) the donor animals:
 - a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;
 - b) were kept for at least three months prior to collection in a FMD free country or *zone* where *vaccination* is practised;
 - c) either
 - i) have been vaccinated at least twice, with the last *vaccination* not less than one month and not more than six months prior to collection, unless protective immunity has been proven for more than six months;or
 - ii) were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMDV, with negative results;
- 2) the semen:
 - a) was collected, processed and stored in accordance with the provisions of Chapters 4.5. and 4.6.;
 - b) was stored in the country of origin for a period of at least one month following collection, and during this period no animal on the *establishment* where the donor animals were kept showed any sign of FMD.

Article 8.7.16.

Recommendations for importation from FMD infected countries or zones

For frozen semen of domestic ruminants and pigs

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

- 1) the donor animals:
 - a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;
 - b) were kept in an *artificial insemination centre* where no animal had been added in the 30 days before collection, and that FMD has not occurred within a ten-kilometre radius of the *artificial insemination centre* for the 30 days before and after collection;

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- c) either
 - i) have been vaccinated at least twice, with the last *vaccination* not less than one month and not more than six month prior to collection, unless protective immunity has been proven for more than six months;
 - or
 - ii) were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMDV, with negative results;
- 2) the semen:
 - a) was collected, processed and stored in accordance with the provisions of Chapters 4.5. and 4.6.;
 - b) was subjected, with negative results, to a test for evidence of FMDV if the donor animal has been vaccinated within the 12 months prior to collection;
 - c) was stored in the country of origin for a period of at least one month following collection, and that during this period no animal on the *establishment* where the donor animals were kept showed any sign of FMD.

Article 8.7.17.

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

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

Article 8.7.18.

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

For *in vitro* produced embryos of cattle

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

- 1) the donor females:
 - a) showed no clinical sign of FMD at the time of collection of the oocytes;
 - b) were kept for at least three months prior to collection in a FMD free country or *zones* where *vaccination* is not practised or FMD free *compartments*;
- 2) fertilisation was achieved with semen meeting the conditions referred to in Articles 8.7.13., 8.7.14., 8.7.15. or 8.7.16., as relevant;
- 3) the oocytes were collected, and the embryos were processed and stored in accordance with the provisions of Chapters 4.8. and 4.9., as relevant.

Article 8.7.19.

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

For *in vitro* produced embryos of cattle

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

- 1) the donor females:
 - a) showed no clinical sign of FMD at the time of collection of the oocytes;
 - b) were kept for at least three months prior to collection in a FMD free country or *zones* where *vaccination* is practised;
 - c) either
 - i) have been vaccinated at least twice, with the last *vaccination* not less than one month and not more than six months prior to collection, unless protective immunity has been proven for more than six months;
 - 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 8.7.13., 8.7.14., 8.7.15. or 8.7.16., as relevant;
- 3) the oocytes were collected, and the embryos were processed and stored in accordance with the provisions of Chapters 4.8. and 4.9., as relevant.

Article 8.7.20.

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

For fresh meat or meat products of FMD susceptible animals

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

- 1) have been kept in a FMD free country or *zones* where *vaccination* is not practised or FMD free *compartments*, or which have been imported in accordance with Article 8.7.10., Article 8.7.11. or Article 8.7.12.;
- 2) have been slaughtered in an approved *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections with favourable results.

Article 8.7.21.

Recommendations for importation from FMD free countries, or zones 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* where *vaccination* is practised, or which have been imported in accordance with Article 8.7. 10., Article 8.7. 11. or Article 8.7. 12.;
- 2) have been slaughtered in an approved *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections for FMD with favourable results;
- 3) for ruminants the head, including the pharynx, tongue and associated lymph nodes, has been excluded from the shipment.

Article 8.7.22.

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

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

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

- 1) comes from animals which:
 - a) have remained, for at least three months prior to *slaughter*, in a *zone* of the *exporting country* where 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 proven for more than six months, and not less than one month prior to *slaughter*;
 - c) were kept for the past 30 days in an *establishment*, and that FMD has not occurred within a ten-kilometre radius of the *establishment* during that period;
 - d) have been transported, in a *vehicle* which was cleansed and disinfected before the cattle and water buffaloes were loaded, directly from the *establishment* of origin to the approved *slaughterhouse/abattoir* without coming into contact with other *animals* which do not fulfil the required conditions for export;
 - e) 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) have been subjected to ante- and post-mortem inspections for FMD with favourable results within 24 hours before and after *slaughter*;
- 2) comes from deboned carcasses:
 - a) from which the major lymphatic nodes have been removed;
 - b) which, prior to deboning, have been submitted to maturation at a temperature above + 2°C for a minimum period of 24 hours following *slaughter* and in which the pH value was below 6.0 when tested in the middle of both the longissimus dorsi muscle.

Article 8.7.23.

Recommendations for importation from FMD infected countries or zones

For meat products of FMD susceptible animals

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

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

- 2) the *meat products* have been processed to ensure the destruction of FMDV in accordance with one of the procedures in Article 8.7.31.;
- 3) the necessary precautions were taken after processing to avoid contact of the *meat products* with any potential source of FMDV.

Article 8.7.24.

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

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

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products come from animals which have been kept in a FMD free country, *zone* or *compartment*, or which have been imported in accordance with Article 8.7.10., Article 8.7.11. or Article 8.7.12.

Article 8.7.25.

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

For milk and milk products

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

- 1) these products:
 - a) originate from *establishments* which were not infected or suspected of being infected with FMD at the time of *milk* collection;
 - b) have been processed to ensure the destruction of FMDV in accordance with one of the procedures in Article 8.7.35. and in Article 8.7.36.;
- 2) the necessary precautions were taken after processing to avoid contact of the products with any potential source of FMDV.

Article 8.7.26.

Recommendations for importation from FMD infected countries

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

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

Article 8.7.27.

Recommendations for importation from FMD infected countries

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 8.7.32., 8.7.33. and 8.7.34.;
- 2) the necessary precautions were taken after collection or processing to avoid contact of the products with any potential source of FMDV.

Annex XVI (A) (contd)

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 8.7.28.

Recommendations for importation from FMD infected countries or zones

For straw and forage

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

- 1) are free of grossly identifiable contamination with material of animal origin;
- 2) have been subjected to one of the following treatments, which, in the case of material sent in bales, has been shown to penetrate to the centre of the bale:
 - a) either to the action of steam in a closed chamber such that the centre of the bales has reached a minimum temperature of 80°C for at least ten minutes,
 - b) or to the action of formalin fumes (formaldehyde gas) produced by its commercial solution at 35–40 percent in a chamber kept closed for at least eight hours and at a minimum temperature of 19°C;

OR

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

Article 8.7.29.

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

For skins and trophies derived from FMD susceptible wildlife

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

Article 8.7.30.

Recommendations for importation from FMD infected countries or zones

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 8.7.37.

Article 8.7.31.

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 70°C or more.

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 ratio between water and protein that is not greater than 2.25:1.

Article 8.7.32.

Procedures for the inactivation of FMDV in wool and hair

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

- 1) industrial washing, which consists of the immersion of the wool in a series of baths of water, soap and sodium hydroxide (soda) or potassium hydroxide (potash);
- 2) chemical depilation by means of slaked lime or sodium sulphide;
- 3) fumigation with formaldehyde in a hermetically sealed chamber for at least 24 hours;
- 4) industrial scouring which consists of the immersion of wool in a water-soluble detergent held at 60–70°C;
- 5) storage of wool at 4°C for four months, 18°C for four weeks or 37°C for eight days.

Article 8.7.33.

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

Article 8.7.34.

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 (Na₂CO₃).

Article 8.7.35.

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

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

- 1) a process applying a minimum temperature of 132°C for at least one second (ultra-high temperature [UHT]), or
- 2) if the *milk* has a pH less than 7.0, a process applying a minimum temperature of 72°C for at least 15 seconds (high temperature – short time pasteurisation [HTST]), or
- 3) if the *milk* has a pH of 7.0 or greater, the HTST process applied twice.

Article 8.7.36.

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

Article 8.7.37

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

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

- 1) boiling in water for an appropriate time so as to ensure that any matter other than bone, horns, hooves, claws, antlers or teeth is removed;
- 2) gamma irradiation at a dose of at least 20 kiloGray at room temperature (20°C or higher);
- 3) soaking, with agitation, in a 4 % (weight/volume) solution of sodium carbonate (Na_2CO_3) maintained at pH 11.5 or greater for at least 48 hours;
- 4) soaking, with agitation, in a formic acid solution (100 kg salt [NaCl] and 12 kg formic acid per 1,000 litres water) maintained at below pH 3.0 for at least 48 hours; wetting and dressing agents may be added;
- 5) in the case of raw hides, treating for at least 28 days with salt (NaCl) containing 2 % sodium carbonate (Na_2CO_3).

Article 8.7.38.

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 8.7.39.

OIE endorsed official control programme for FMD

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

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

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

- 1) have a record of regular and prompt animal *disease* reporting according to the requirements in Chapter 1.1.;
- 2) submit documented evidence of 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 in at least one *zone* in the country;
 - c) the main livestock production systems and movement patterns of FMD susceptible animals and their products within and into the country;
- 5) submit evidence that FMD *surveillance* is in place:
 - a) taking into account provisions in Chapter 1.4. and the provisions on *surveillance* of this chapter;
 - b) have diagnostic capability and procedures, including regular submission of samples to a *laboratory* that carries out diagnosis and further characterisation of strains;
- 6) where *vaccination* is practised as a part of the *official control programme* for FMD, provide:
 - a) evidence (such as copies of legislation) that *vaccination* of selected populations is compulsory;

Annex XVI (A) (contd)

- b) detailed information on *vaccination* campaigns, in particular on:
 - i) target populations for *vaccination*;
 - ii) monitoring of *vaccination* coverage, including serological monitoring of population immunity;
 - iii) technical specification of the vaccines used, including matching with the circulating FMDV strains, and description of the licensing procedures in place;
 - iv) the proposed timeline for the transition to the use of vaccines fully compliant with the standards and methods described in the *Terrestrial Manual*;
- 7) provide an emergency preparedness and response plan to be implemented in case of *outbreaks*.

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

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

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

Article 8.7.40.

General principles of surveillance

Articles 8.7.40. to 8.7.42. 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 Member Countries seeking endorsement by the OIE of their *official control programme* for FMD, in accordance with Article 8.7.39. *Surveillance* aimed at identifying *disease* and FMDV *infection* or transmission should cover domestic and *wildlife* species indicated in Article 8.7.1. point 2 within the country, *zone* or *compartment*.

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

The impact and epidemiology of FMD differ widely in different regions of the world and therefore it is 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 proving freedom from FMD following an *outbreak* caused by a pig-adapted strain of FMDV should differ significantly from an application designed to prove freedom from FMD for a country or *zone* where African buffaloes (*Syncerus caffer*) provide a potential reservoir of *infection*.

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

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

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

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

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

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* and transmission and to understand the epidemiology of FMD as part of the *official control programme*.

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

Surveillance for FMD should be in the form of a continuing programme. *Surveillance* programmes to prove the absence of FMDV *infection* and transmission 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 employed to establish the prevalence of FMDV *infection* or to substantiate freedom from FMDV *infection* or transmission may be based on randomised or targeted clinical investigation or sampling at an acceptable level of statistical confidence, as described in Articles 1.4.4. and 1.4.5. If an increased likelihood of *infection* in particular localities or species can be identified, targeted sampling may be appropriate. Clinical inspection may be targeted at particular species likely to exhibit clear clinical signs (e.g. cattle and pigs). The Member Country should justify the *surveillance* strategy chosen and the frequency of sampling as adequate to detect the presence of FMDV *infection* or transmission 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.

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.

Annex XVI (A) (contd)

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

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

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

- characterisation of the existing production systems;
- results of clinical *surveillance* of the suspects and their cohorts;
- description of number of, and protocol for, *vaccinations* performed in the area under assessment;
- biosecurity and history of the *establishments* with positive reactors;
- control of *animal identification* and movements;
- other parameters of regional significance in historic FMDV transmission.

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

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

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

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

Article 8.7.41.

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 Authority* should implement programmes to raise awareness among them.

Clinical *surveillance* requires close 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 detected by either of these complementary diagnostic approaches. 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.

3. Serological surveillance

Serological *surveillance* aims at detecting antibodies resulting from *infection* or *vaccination* using nonstructural protein tests or structural protein tests.

Serological *surveillance* may be used to:

- a) estimate the prevalence or substantiate freedom from FMDV *infection* or transmission;
- 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 8.7.42.

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.

Annex XVI (A) (contd)

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

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

- a) *infection* with FMDV;
- b) *vaccination* against FMD;
- c) maternal antibodies (maternal antibodies in cattle are usually found only up to six months of age but in some individuals and in some other species, maternal antibodies can be detected for longer periods);
- d) non-specific reactivity of the serum in the tests used.

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 reactors. The diagnostic sensitivity of the confirmatory test should approach that of the screening test.

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

Clustering of seropositive reactions 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 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 remain in the *establishment* pending test results, should be clearly identifiable, accessible and should not be vaccinated during the investigations, so that they can be retested after an appropriate period of time. Following clinical examination, a second sample should be taken from the animals tested in the initial survey with emphasis on animals in direct contact with the reactors after an appropriate time has lapsed. 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, sentinel animals may also be used. These can be young, unvaccinated animals 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 should remain serologically negative if FMDV is not circulating.

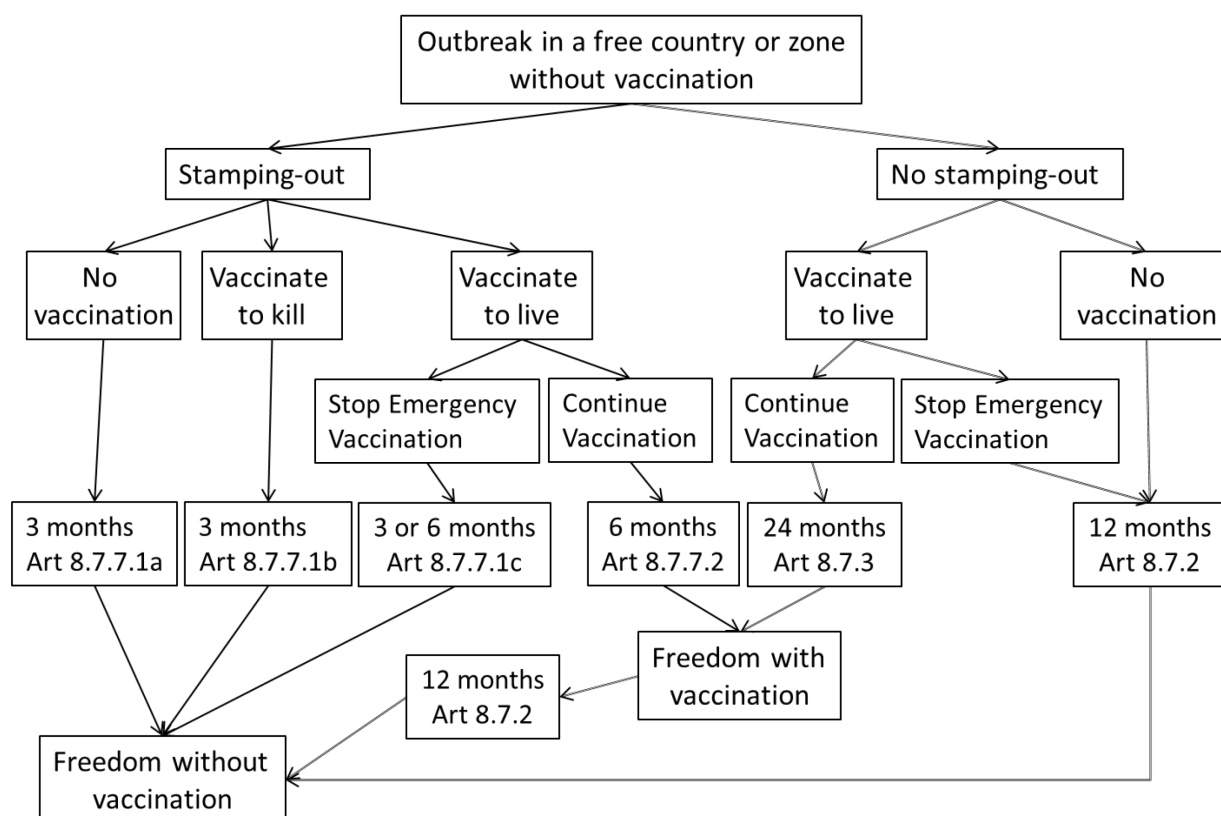
Follow-up of field and laboratory findings:

If transmission is proven then an *outbreak* is declared.

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

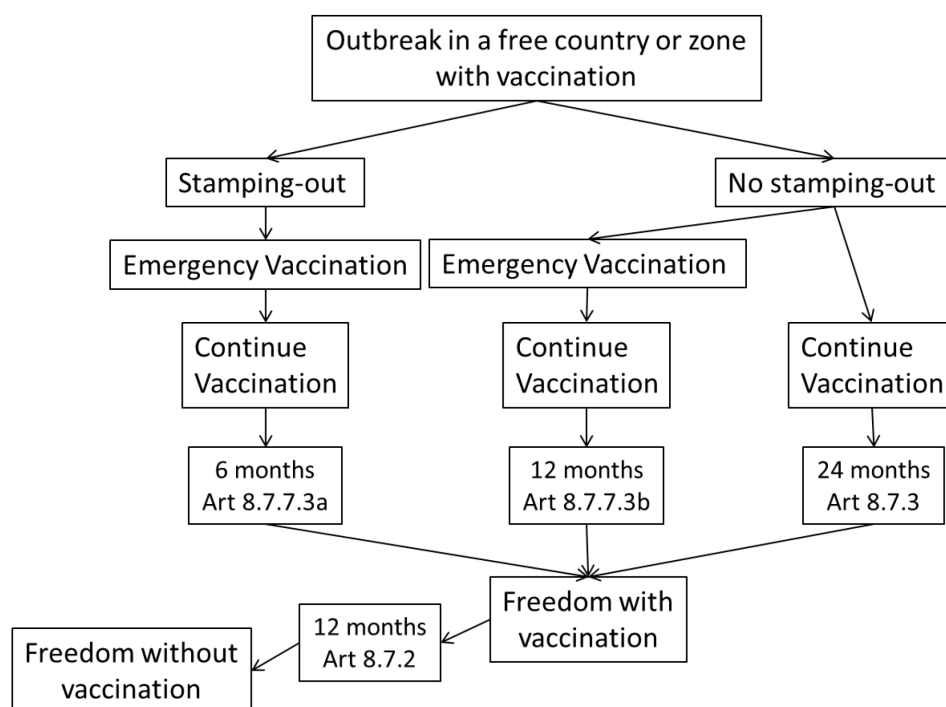
However, if the number of seropositive animals is greater than the number of non-specific test system findings expected, susceptible animals that have been in contact or otherwise epidemiologically associated with the reactor animals should be investigated further.

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



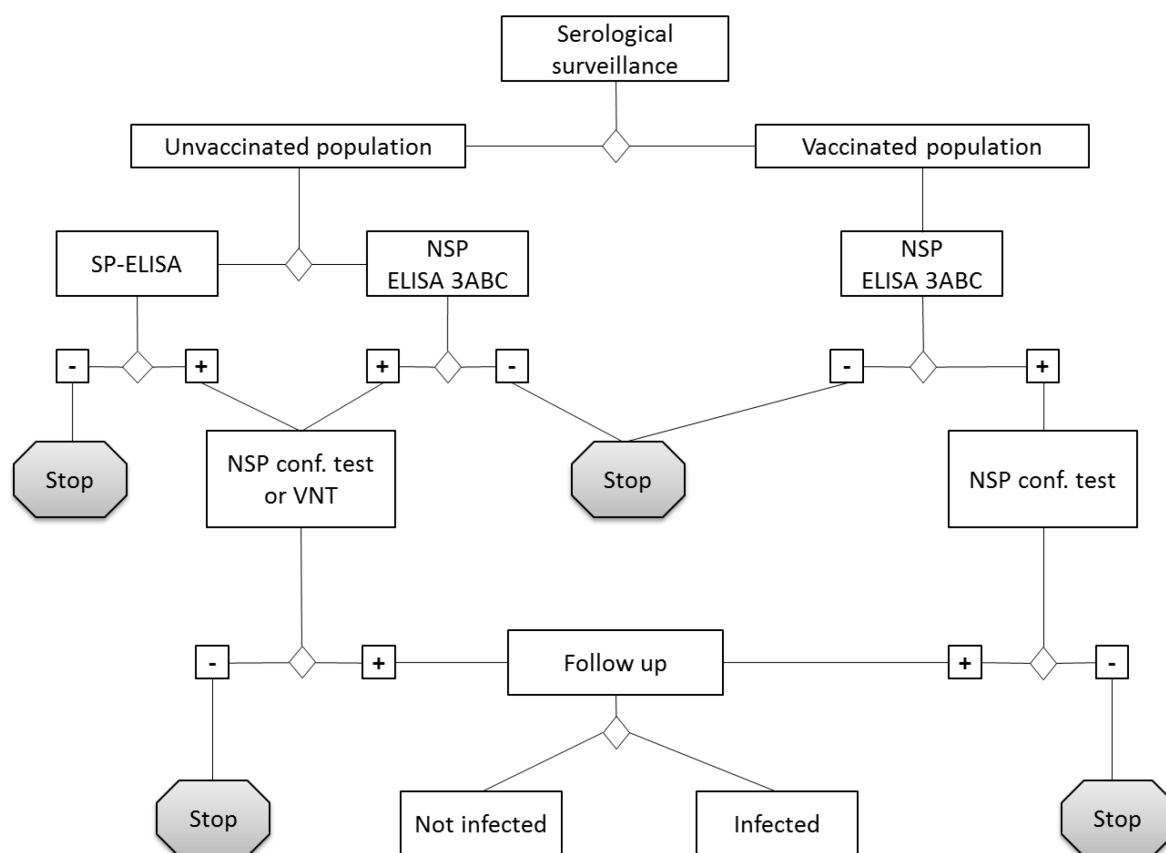
Waiting periods are minima depending upon outcome of surveillance specified in respective Articles. If there are multiple waiting periods because of different control measures, the longest applies.

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



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.

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



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