Annex XVI (B)

NOTE:
The Code Commission encourages Member Countries to review all relevant reports when reviewing this document including the following:

- February 2015 report of the Scientific Commission for the rationale on the proposed amendments
- September–October 2014, November 2014 and January 2015 reports of the OIE ad hoc Group on the Evaluation of Foot and Mouth Disease Status of Member Countries attached to the February 2015 report of the Scientific Commission

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. Dromedaries (*Camelus dromedarius*) are not susceptible to FMDV *infection* ~~of dromedaries and~~ while South American camelids are ~~has~~ not ~~been shown~~ 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* 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 suspected or 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 suspected or confirmed ~~or suspected~~ *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.

5) For the purposes of the *Terrestrial Code*, the *incubation period* of FMD ~~is~~ shall be 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~~e~~is 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.

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

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~~ demonstrate no evidence of:

      i) FMDV *infection* in ~~non-~~unvaccinated animals;

      ii) FMDV transmission in previously vaccinated animals when ~~transition is made from~~ the FMD free country or *zone* where *vaccination* is practised is seeking to become one ~~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~~ 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 ~~a~~ the primary purpose ~~to~~ of exhibiting *animals* or preserv~~e~~ing 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 identifiedable 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~~ 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 8.7.3.

FMD free country or zone where vaccination is practised

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

Susceptible animals in the FMD free country or *zone* where *vaccination* is practised should be protected by the application of ~~animal health~~ 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*~~ 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~~ demonstrate no evidence of:

i) FMDV *infection* in ~~non-~~un 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~~ *vaccination* has been carried out following ~~e 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 of the cessation. 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~~ 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 8.7.4.

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~~ may 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).

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:

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1) on suspicion, a strict standstill ~~of animal movements~~ has been imposed on the suspected *establishments* and in the country or *zone* 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, 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* ~~may only be~~ have been established ~~once~~ after 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 identified~~able~~ 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 the OIE as 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 *infection* in unvaccinated animals or FMDV transmission in vaccinated animals in the *containment zone,* the approval of the *containment zone* is withdrawn~~.~~ and ~~T~~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 be achieved within 12 months of its approval and 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~~ animal killed 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~~ animal killed 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. are applied; or

c) six months after the disposal of the last ~~*case*~~ 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* ~~are applied~~ in accordance with Articles 8.7.40. to 8.7.42. are applied. However, this requires a serological survey based on the detection of antibodies to nonstructural proteins of FMDV to demonstrate ~~the absence~~ no evidence 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~~ six months after the disposal of the last ~~*case*~~ animal killed where a *stamping-out policy* has been applied and a continued *vaccination* policy has been adopted, provided that *surveillance* is applied in accordance with Articles 8.7.40. to 8.7.42., and a serological survey based on the detection of antibodies to nonstructural proteins of FMDV demonstrates ~~the absence~~ no evidence of FMDV transmission.

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

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

3) When a *case* of FMD ~~*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*~~ animal killed 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~~ no evidence 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~~ no evidence 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*.

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

Article 8.7.8.

Direct transfer of FMD susceptible animals from an infected zone for slaughter in a free zone (~~where~~ whether vaccination ~~either is or is not~~ 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 *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 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* with no evidence of FMD, 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 accordance with Articles 8.7.31. to 8.7.38 in order ~~such a way as~~ to destroy any ~~residual~~ FMDV potentially present ~~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~~ whether vaccination ~~either is or is not~~ 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 *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 *slaughterhouse/abattoir* without coming into contact with other susceptible animals;

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

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

The animals should have been subjected to ante- and post-mortem inspection ~~for FMD, with favourable results,~~ within 24 hours before and after *slaughter* with no evidence of FMD 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 accordance with Articles 8.7.31. to 8.7.38. in order ~~such a way as~~ to destroy any ~~residual~~ FMDV potentially present ~~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 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) prior to isolation, the animals were kept in the *establishment* of origin:

   a) ~~since birth, or~~

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

be) for the past three months, or since birth if younger than three months if a *stamping-out policy* is not applied to control FMD 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 10 kilometre radius of the *establishment* during that period, or the *establishment* is a *quarantine station*;

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 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*s 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* with FMDV ;

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

   c) either

      i) have been vaccinated at least twice, with the last *vaccination* not less than one month and not more than six months prior to collection, unless protective immunity has been ~~proven~~ demonstrated 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~~ male has been vaccinated within the 12 months prior to collection;

Annex XVI (B) (contd)

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~~ males 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 *zone~~s~~* 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 *zone~~s~~* 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~~ demonstrated 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 *zone*~~s~~ where *vaccination* is not practised or FMD free *compartment*~~s~~, 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;

Annex XVI (B) (contd)

b) have been vaccinated at least twice with the last *vaccination* not more than six months, unless protective immunity has been ~~proven~~ demonstrated 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 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 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 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* 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 ~~above~~ greater than + 2°C for a minimum period of 24 hours following *slaughter* and in which the pH value was ~~below~~ less than 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.

Annex XVI (B) (contd)

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.

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 identifiedable 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:

Annex XVI (B) (contd)

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% 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 at least 70°C ~~or more~~ 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 ~~between water and protein~~ that is not greater than 2.25:1 or a water activity (Aw) that is not greater than 0.85.

Annex XVI (B) (contd)

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; or

2) immersion for at least 24 hours in a % 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 (Na_2CO_3).

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.

Annex XVI (B) (contd)

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; 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 8.7.37

Procedures for the inactivation of FMDV in skins and trophies from ~~wild animals~~ wildlife 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; 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 ~~below~~ 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 8.7.38.

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* only.

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;

    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*.

Annex XVI (B) (contd)

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. 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, where appropriate, *wildlife* species as indicated in point 2) of Article 8.7.1. ~~within the country, *zone* or *compartment*.~~

1. Early detection

A *surveillance* system in accordance with Chapter 1.4. should be the responsibility of the *Veterinary Authority* and should provide~~s~~ 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~~ seek assistance from a team with expertise in FMD diagnosis and control.

2. Demonstration of freedom

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~~ demonstrating freedom from FMD following an *outbreak* caused by a pig-adapted strain of FMDV should differ significantly from an ~~application~~ approach designed to ~~prove~~ demonstrate freedom from FMD ~~for~~ 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 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 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 substantiate ~~demonstrate~~ FMD freedom where *vaccination* is not practised should ~~show absence~~ demonstrate no evidence of FMDV *infection*.

A Member Country wishing to substantiate ~~demonstrate~~ FMD freedom where *vaccination* is practised should ~~show~~ demonstrate that FMDV has not been transmitted in any susceptible populations. Within vaccinated populations, serological surveys to demonstrate ~~the absence~~ no evidence 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. In any unvaccinated *subpopulation, surveillance* should demonstrate no evidence ~~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*.

3. OIE endorsed official control programme

Surveillance strategies employed in support of an OIE endorsed *official control programme* should ~~show~~ demonstrate 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~~ T~~t~~he Member Country ~~to~~ 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.

~~*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.~~

4. Surveillance strategies

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.

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. 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;~~

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

– other parameters of regional significance in historic FMDV transmission.

6. Demonstration of population immunity

Following ~~the use of~~ routine ~~and emergency~~ *vaccination,* evidence should be provided to ~~show~~ demonstrate 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~~ 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* ~~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 for the presence and transmission of the virus.

3. Serological surveillance

Serological *surveillance* aims ~~at~~ to detect~~ing~~ 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.

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*.

Annex XVI (B) (contd)

Nonstructural protein tests may be used to screen sera for evidence of *infection* or transmission of all serotypes of FMDV regardless of the *vaccination* status of the animals provided the vaccines comply with the standards of the *Terrestrial Manual* with respect to purity. However, although animals vaccinated and subsequently infected with FMDV develop antibodies to nonstructural proteins, the levels may be lower than those found in infected 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 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~~ results. 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~~ which may include the results of virological tests and of any further serological tests that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were due to FMDV transmission. ~~and~~ This investigation should document the status for each positive *herd*. Epidemiological investigation should be continued concurrently.

Clustering of seropositive ~~reactions~~ 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 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 identifiedable, 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 lapsed, 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, unvaccinated sentinel animals may also be used. These can be young~~, unvaccinated~~ 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 should remain serologically negative if FMDV is not circulating.

Follow-up of field and laboratory findings:

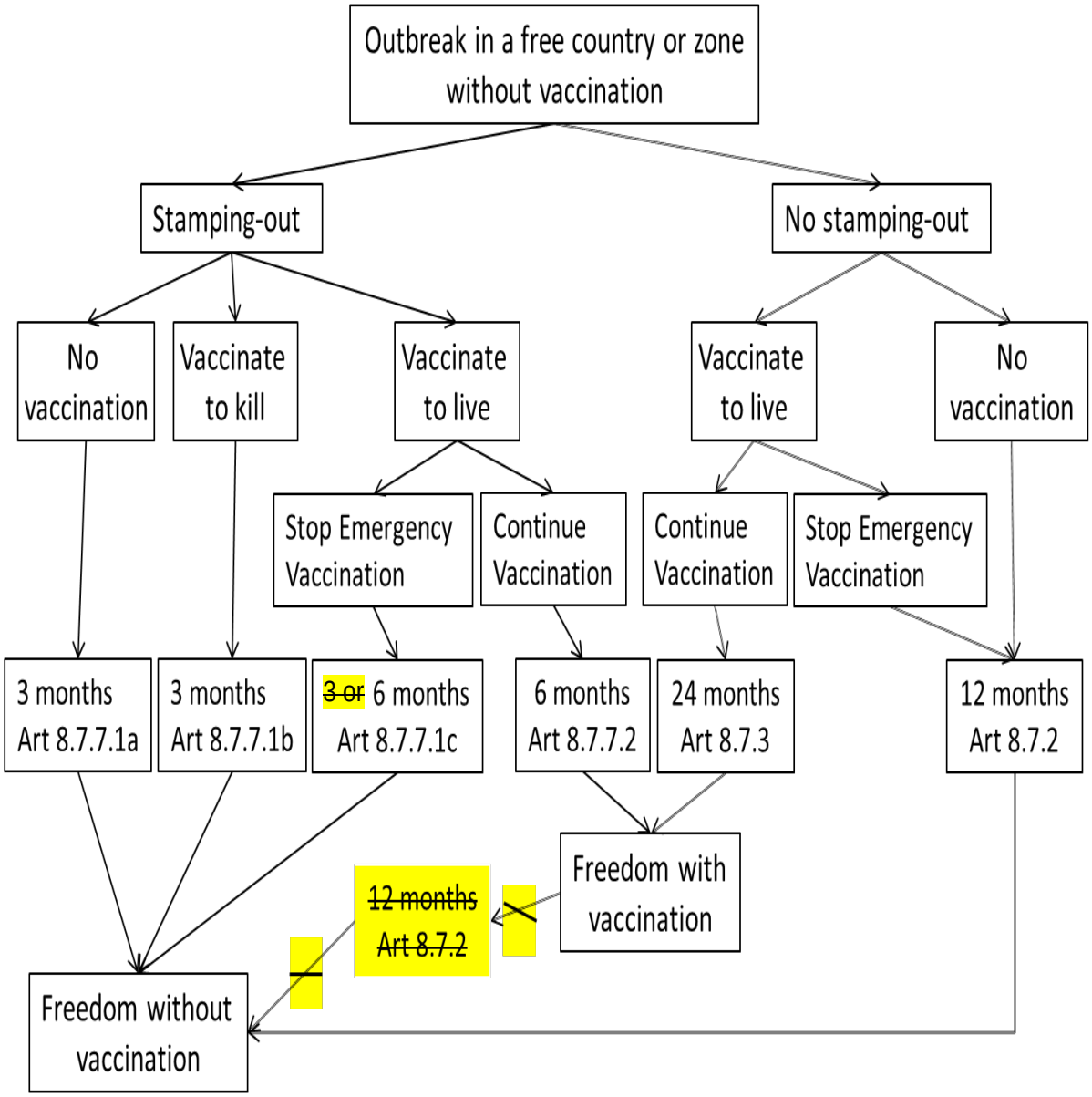
If transmission is ~~proven~~ demonstrated, ~~then~~ an *outbreak* is declared.

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 false positive results expected from the specificity of the diagnostic tests used ~~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.

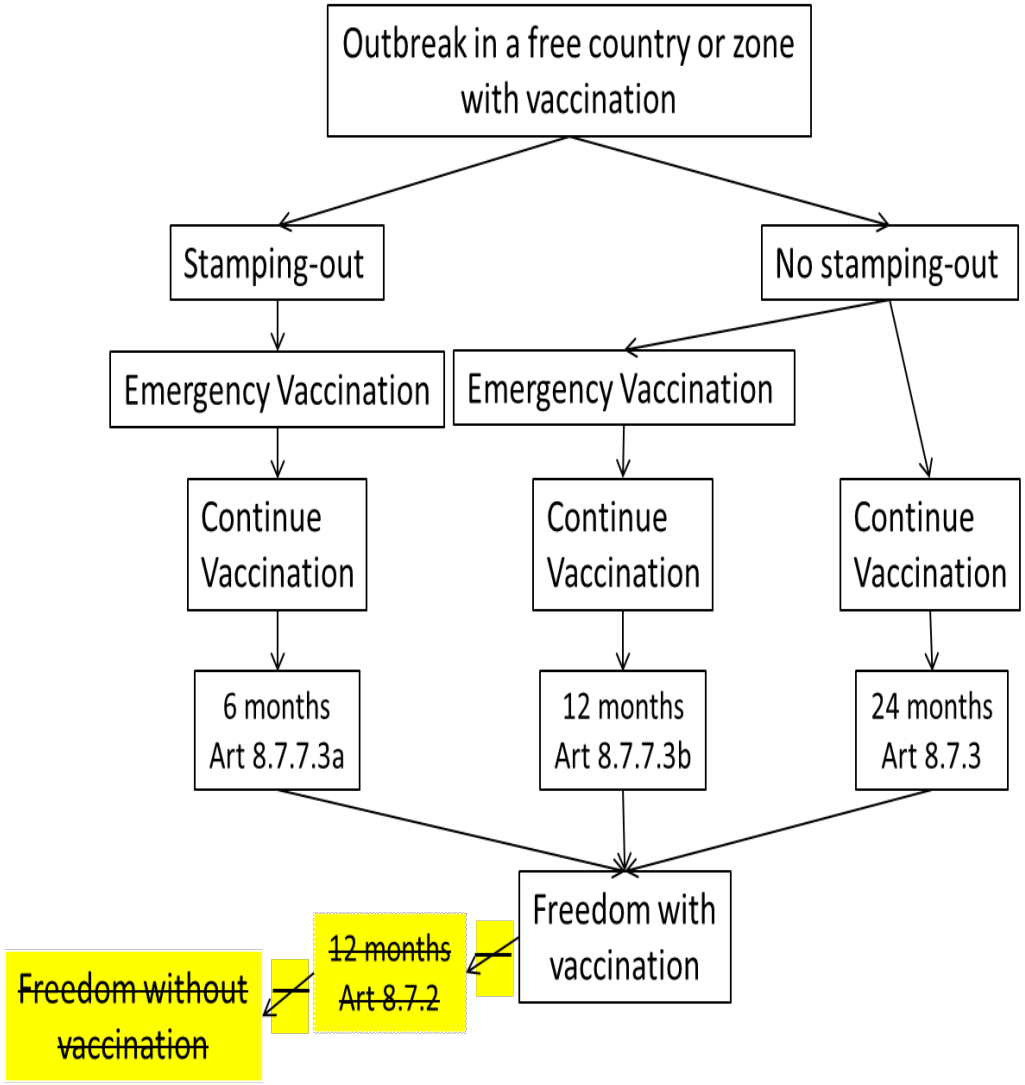
Annex XVI (B) (contd)

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.

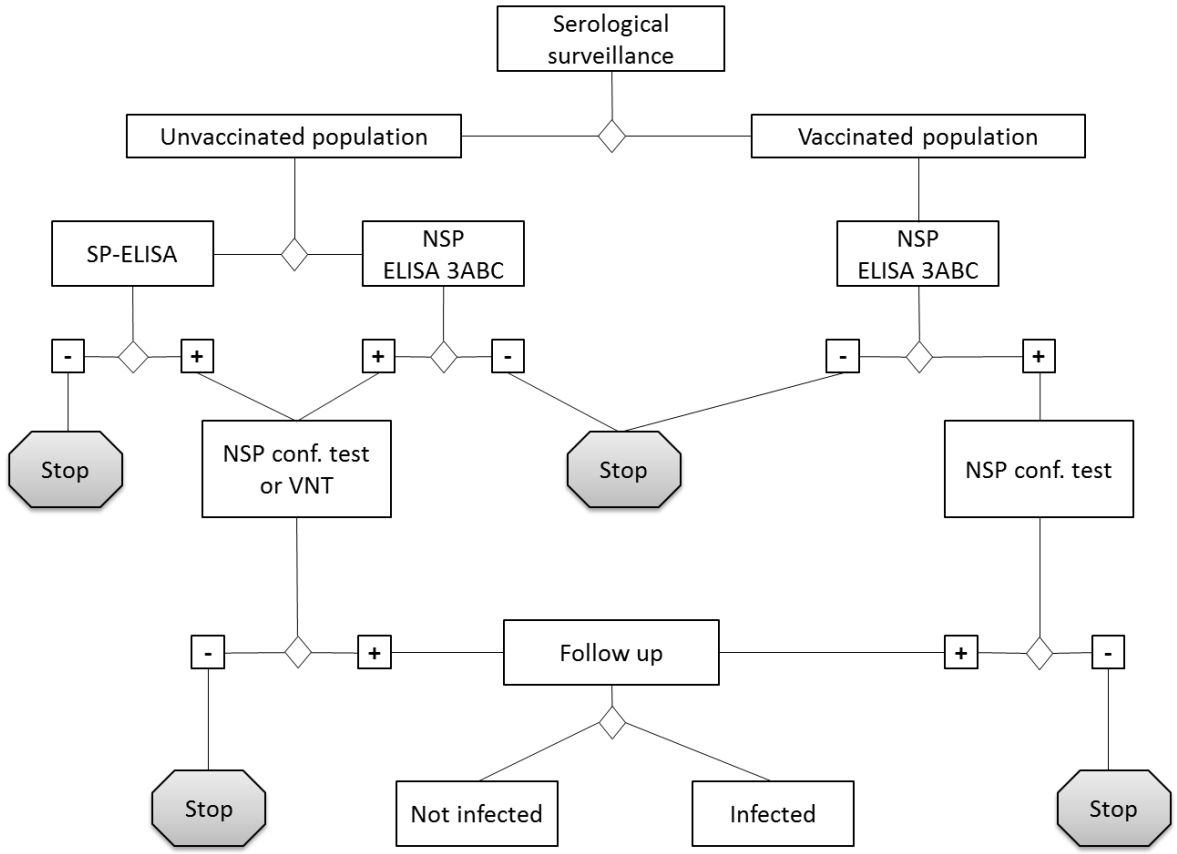
Figure 2. Schematic representation of the minimum waiting periods and pathways for recovery of FMD free status after an outbreak in a free country or zone where vaccination is practised



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.

Annex XVI (B) (contd)

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

CHAPTER 1.6.

PROCEDURES FOR SELF DECLARATION AND FOR OFFICIAL RECOGNITION BY THE OIE

Article 1.6.1.

General principles

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

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

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

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

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

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

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

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

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

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

When requesting official recognition of disease status, the Member Country should submit to the OIE Scientific and Technical Department a dossier providing the information requested (as appropriate) in Articles 1.6.5. (for BSE), 1.6.6. (for FMD), 1.6.7. (for CBPP), 1.6.8. (for AHS), 1.6.9. (for PPR) or 1.6.10. (for CSF).

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

Article 1.6.2.

Endorsement by the OIE of an official control programme for FMD

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

When requesting endorsement by the OIE of an *official control programme* for FMD, the Member Country should submit to the OIE Scientific and Technical Department a dossier providing the information requested in Article 1.6.11.

Annex XVI (B) (contd)

[Article 1.6.3.]

[Article 1.6.4.]

[Article 1.6.5.]

Article 1.6.6.

Questionnaires on FMD

FMD FREE COUNTRY WHERE VACCINATION IS NOT PRACTISED
Report of a Member Country which applies for recognition of status,
under Chapter 8.7. of the *Terrestrial Code*,
as a FMD free country not practising vaccination

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

1. Introduction

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

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

2. Veterinary system

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

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

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

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

3. FMD eradication

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

   b) Strategy. Describe how FMD was controlled and eradicated (e.g. *stamping-out policy*, *modified stamping-out policy*, zoning).

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

      In addition, if *vaccination* was conducted during the past two years, provide a description and justification of the *vaccination* strategy, including the selection of vaccine strain, potency and type, purity, details of any vaccine matching performed, the animal species vaccinated, identification of vaccinated animals, the way in which the *vaccination* of animals was certified or reported and the records maintained. Also provide evidence that the vaccine used complies with Chapter 2.1.5. of the *Terrestrial Manual*.

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

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

4. FMD diagnosis

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

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

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

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

ii) Give details of performance in inter-laboratory proficiency tests.

iii) Provide details on the handling of live virus.

iv) Biosecurity measures applied.

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

vi) Laboratory capacity in processing tests and samples.

5. FMD surveillance

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

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

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

Annex XVI (B) (contd)

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

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

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

6. FMD prevention

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

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

c) Import control procedures

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

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

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

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

– animals,

– genetic material (semen and embryos),

– animal products,

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

– other ~~FMD risk~~ materials at risk of being contaminated with FMDV ~~(e.g. stock feed and animal bedding)~~.

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

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

7. Contingency planning and outbreak response programmes

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

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

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

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

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

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

iv) describe the procedures to be used to confirm successful control or eradication, including any restocking provisions, sentinel animal and serological *surveillance* programmes;

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

8. Compliance with the *Terrestrial Code*

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

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

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

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

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

9. Recovery of status

Member Countries applying for recovery of status should comply with the provisions of Article 8.7.7., point 1) of Article 8.7.2., point 3) of Article 8.7.2. and point 4) of 8.7.2. in the *Terrestrial Code* and provide information as specified in sections 1–7 (inclusive) of this questionnaire. Particular emphasis should be given to FMD eradication (section 3.), FMD diagnosis (section 4.), FMD serological surveillance (section 5.b.), FMD prevention (section 6.) and contingency planning and outbreak response programmes (section 7.).

Annex XVI (B) (contd)

FMD FREE COUNTRY WHERE VACCINATION IS PRACTISED
Report of a Member Country which applies for recognition of status,
under Chapter 8.7. of the *Terrestrial Code*,
as a FMD free country practising vaccination

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

1. Introduction

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

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

2. Veterinary system

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

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

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

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

3. FMD eradication

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

   b) Strategy. Describe how FMD was controlled and eradicated (e.g. *stamping-out policy*, *modified stamping-out policy*, zoning).

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

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

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

4. FMD diagnosis

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

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   ii) Give details of performance in inter-laboratory proficiency tests.

   iii) Provide details on the handling of live virus.

   iv) Biosecurity measures applied.

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

   vi) Laboratory capacity in processing tests and samples.

5. FMD surveillance

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

b) *Surveillance*. Are serological and virological surveys conducted to demonstrate freedom from *infection*, in particular applying the provisions of Article 8.7.42.? If so, provide detailed information on the survey design (target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used). How frequently are they conducted? Are ~~*wildlife*~~ susceptible *wildlife* species included in serological surveys? Provide a summary table indicating, for the past two years, the number of samples tested for FMD and FMDV, species, type of sample, testing methods and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted *surveillance* based on the risk and numbers of animals examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.

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

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

Annex XVI (B) (contd)

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

6. FMD prevention

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

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

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

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

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– animal products,

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

– other ~~FMD risk~~ materials at risk of being contaminated with FMDV ~~(e.g. stock feed and animal bedding).~~

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

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

7. Contingency planning and outbreak response programmes

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

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

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

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

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

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

iv) describe the procedures to be used to confirm successful control or eradication, including any restocking provisions, sentinel animal and serosurveillance programmes;

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

8. Compliance with the *Terrestrial Code*

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

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

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

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

9. Recovery of status

Member Countries applying for recovery of status should comply with the provisions of Article 8.7.7., point 1) of Article 8.7.3., point 3) of Article 8.7.3. and point 4) of Article 8.7.3. in the *Terrestrial Code* and provide information as specified in sections 1–7 (inclusive) of this questionnaire. Particular emphasis should be given to FMD eradication (section 3.), FMD diagnosis (section 4.), FMD serological surveillance (section 5.b.), FMD prevention (section 6.) and contingency planning and outbreak response programmes (section 7.).

Annex XVI (B) (contd)

FMD FREE ZONE WHERE VACCINATION IS NOT PRACTISED
Report of a Member Country which applies for recognition of status,
under Chapter 8.7. of the *Terrestrial Code*,
as a FMD free zone not practising vaccination

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

1. Introduction

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

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

2. Veterinary system

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

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

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

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

3. FMD eradication

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

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

   c) Vaccines and *vaccination*. ~~If~~

      i) Was *vaccination* ~~is~~ ever used in the *zone*? If so, when was the last *vaccination* carried out? When was *vaccination* formally prohibited? What species were vaccinated? What was the fate of those animals? ~~rest of the country,~~

      ii) In addition, if *vaccination* was conducted during the past two years, provide a description and justification of the *vaccination* strategy, including the selection of vaccine strain, potency and type, purity, details of any vaccine matching performed, the animal species vaccinated, identification of vaccinated animals, the way in which the *vaccination* of animals was certified or reported and the records maintained~~.~~ ~~the date on which the last vaccination was performed, and the disposition of vaccinated animals (e.g. removed from or retained in the population). Provide evidence to show its effectiveness (e.g. vaccination coverage, serosurveillance, etc.).~~ Also provide evidence that the vaccine used complies with Chapter 2.1.5. in the *Terrestrial Manual*.

      iii) If *vaccination* continues to be used in the rest of the country, give details on the post-*vaccination* monitoring programme.

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

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

4. FMD diagnosis

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

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

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

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

ii) Give details of performance in inter-laboratory proficiency tests.

iii) Provide details on the handling of live virus.

iv) Biosecurity measures applied.

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

vi) Laboratory capacity in processing tests and samples.

5. FMD surveillance

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

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

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

Annex XVI (B) (contd)

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

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

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

6. FMD prevention

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

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

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

c) Import control procedures

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

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

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

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

– animals,

– genetic material (semen and embryos),

– animal products,

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

– other ~~FMD risk~~ materials at risk of being contaminated with FMDV ~~(e.g. stock feed and animal bedding).~~

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

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

7. Contingency planning and outbreak response programmes

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

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

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

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

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

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

iv) describe the procedures to be used to confirm successful control or eradication, including any restocking provisions, sentinel animal and serosurveillance programmes;

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

8. Compliance with the *Terrestrial Code*

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

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

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

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

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

9. Recovery of status

Member Countries applying for recovery of status should comply with the provisions of Article 8.7.7., point 1) of Article 8.7.2., point 3) of Article 8.7.2. and point 4) of Article 8.7.2. in the *Terrestrial Code* and provide information as specified in sections 1–7 (inclusive) of this questionnaire. Particular emphasis should be given to FMD eradication (section 3.), FMD diagnosis (section 4.), FMD serological surveillance (section 5.b.), FMD prevention (section 6.) and contingency planning and outbreak response programmes (section 7.).

Annex XVI (B) (contd)

FMD FREE ZONE WHERE VACCINATION IS PRACTISED
Report of a Member Country which applies for recognition of status,
under Chapter 8.7. of the *Terrestrial Code*,
as a FMD free zone practising vaccination

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

1. Introduction

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

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

2. Veterinary system

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

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

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

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

3. FMD eradication

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

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

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

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

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

4. FMD diagnosis

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

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

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

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

ii) Give details of performance in inter-laboratory proficiency tests.

iii) Provide details on the handling of live virus.

iv) Biosecurity measures applied.

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

vi) Laboratory capacity in processing tests and samples.

5. FMD surveillance

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

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

b) *Surveillance*. Are serological and virological surveys conducted to demonstrate freedom from *infection*, in particular applying the provisions of Article 8.7.42.? If so, provide detailed information on the survey design (target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used). How frequently are they conducted? Are *wildlife* susceptible species included in serological surveys? Provide a summary table indicating, for the past two years, the number of samples tested for FMD and FMDV, species, type of sample, testing methods and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted *surveillance* based on the risk and numbers of animals examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.

Annex XVI (B) (contd)

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

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

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

6. FMD prevention

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

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

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

c) Import control procedures

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

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

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

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

– animals,

– genetic material (semen and embryos),

– animal products,

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

– other ~~FMD risk~~ materials at risk of being contaminated with FMDV ~~(e.g. stock feed and animal bedding)~~.

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

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

7. Contingency planning and outbreak response programmes

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

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

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

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

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

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

iv) describe the procedures to be used to confirm successful control or eradication, including any restocking provisions, sentinel animal and serosurveillance programmes;

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

8. Compliance with the *Terrestrial Code*

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

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

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

c) *surveillance* for FMD and FMDV transmission in accordance with Articles 8.7.40. to 8.7.42. is in operation.

9. Recovery of status

Member Countries applying for recovery of status should comply with the provisions of Article 8.7.7., point 1) of Article 8.7.3., point 3) of Article 8.7.3. and point 4) of Article 8.7.3. in the *Terrestrial Code* and provide information as specified in sections 1–7 (inclusive) of this questionnaire. Particular emphasis should be given to FMD eradication (section 3.), FMD diagnosis (section 4.), FMD serological surveillance (section 5.b.), FMD prevention (section 6.) and contingency planning and outbreak response programmes (section 7.).

[Article 1.6.7.]

[Article 1.6.8.]

[Article 1.6.9.]

[Article 1.6.10.]

Annex XVI (B) (contd)

Article 1.6.11.

Questionnaire on FMD

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

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

1. Introduction

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

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

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

2. Veterinary system

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

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

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

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

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

3. FMD control

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

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

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

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

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

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

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

4. FMD surveillance

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

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

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

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

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

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

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

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

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

5. FMD laboratory diagnosis

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

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

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

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

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

   iii) Is live virus handled?

   iv) Biosecurity measures applied.

   v) Details of the type of tests undertaken.

6. FMD prevention

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

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

b) What measures are taken to limit access of susceptible domestic, *feral* and *wild* animals to waste products of animal origin? Are there controls in place for the feeding of swill containing animal products to pigs? If so, provide information on the extent of the practice, and describe controls and *surveillance* measures.

c) Provide information on countries or *zones* from which the country authorises the import of susceptible animals or their products into the country or *zone*. Describe the criteria applied to approve such countries or *zones*, the controls applied on entry of such animals and products, and subsequent internal movement. Describe the import conditions and test procedures required. Advise whether imported animals of susceptible species are required to undergo a quarantine or isolation period and, if so, the duration and location of quarantine. Advise whether import permits and health certificates are required. Describe any other procedures used. Provide summary statistics on imports of susceptible animals and their products for at least the past two years, specifying country or *zone* of origin, the species and the number or volume. Provide evidence that the import policy and the improved border controls have contributed to reducing the number of outbreaks or that *outbreaks* are not related to imports or transboundary movements of domestic animals.

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

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

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

– animals,

– genetic material (semen and embryos),

– animal products,

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

– other livestock related goods potentially contaminated with FMDV including bedding, litter and feeds.

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

7. Control measures and emergency response

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

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

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

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

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

Annex XVI (B) (contd)

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

iv) indicate the control or eradication procedures, such as *vaccination*, *stamping-out policy*, partial *slaughter* or *vaccination*, including *vaccination* delivery and cold chain, movement control, control of *wildlife*, pastured livestock and livestock as pets, control of the livestock waste, campaign to promote awareness of farmers, etc. that would be taken;

v) describe the procedures used to confirm that an *outbreak* has been successfully controlled or eradicated, including any restrictions on restocking;

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

vii) describe how control efforts, including *vaccination* and biosecurity measures, have been targeted at critical risk control points.

8. Official control programme for FMD submitted for OIE endorsement

Submit a detailed plan on the measures, in addition to those described in point 3), for the control and eventual eradication of FMD in the Member Country, including:

a) objectives,

b) expected status to be achieved,

c) timelines of the control programme,

d) performance indicators and methods for their measurement and verification, including the progressive reduction in *outbreak* incidence towards elimination of FMDV transmission in all susceptible livestock in at least one *zone* of the country,

e) description of the funding for the control programme and annual budgets for its duration,

f) details, if applicable, on a proposed timeline for the transition to the use of vaccines, which are fully compliant with in the *Terrestrial Manual* in order to enable demonstration of ~~absence~~ no evidence of FMDV transmission.

9. Recovery of official endorsement of the national FMD control programme

Member Countries applying for recovery of the official endorsement of the national FMD control programme should provide updated information in compliance with the provisions of Article 8.7.39. in the *Terrestrial Code*.

第 8.7 章

口蹄疫ウイルス感染症

第 8.7.1 条

1) 多様な分類学上の目に属する多くの種々の動物種が、口蹄疫ウイルス（FMDV）の*感染*に感受性があることが知られている。それらの疫学的重要性は、感受性の程度、畜産システム、個体群の密度及び大きさ並びにそれらとの接触性によって決まってくる。ラクダ科の中では、フタコブラクダ（*Camelus bactrianus*）のみが、疫学的に重要な可能性のある十分な感受性を有している。ヒトコブラクダ（*Camelus dromerarius*）は、FMDV に感受性がない一方で、南アメリカのラクダ科動物は、疫学的に重要であるとはみなされない。

2) *陸生コード*においては、口蹄疫（FMD）は、反芻亜目及び偶蹄目イノシシ科の動物並びに *Camelus bactrianus* の FMDV 感染と定義される。

3) FMDV *感染*の発生とは、以下のいずれかであると定義される。

   a) FMDV が、第 2 項に掲げる動物の試料から分離されること。

   b) FMDV に特異的なウイルス抗原又はウイルスリボ核酸が、FMD と整合する臨床症状を呈している、又は FMD の疑似若しくは確定*発生*と疫学的に関連している、又は以前に FMDV と関連していた若しくは接触した疑いのある、第 2 項に掲げる動物の試料中に同定されること。

   c) *ワクチン接種*によるものではない FMDV 構造又は非構造タンパク質に対する抗体が、FMD と整合する臨床症状を呈している、又は FMD の疑似若しくは確定*発生*と疫学的に関連している、又は以前に FMDV と関連していた若しくは接触した疑いのある、第 2 項に掲げる動物の試料中に同定されること。

4) ワクチン接種個体群内の FMDV の伝搬は、たとえ臨床症状を呈していない場合であっても、新しい*感染*を示唆するウイルス学的又は血清学的証拠の変化によって立証される。

5) *陸生コード*においては、FMD の潜伏期間は 14 日であるものとする。

6) FMDV の*感染*によって、重症度不定の*疾病*及び FMDV 伝搬が生じることになる。FMDV が、28 日を超える不定だが限定的な期間、反芻動物の咽頭及び関連リンパ節中に持続する場合がある。そのような動物は、キャリアと呼ばれている。ただし、FMDV の伝搬が証明された唯一の持続感染動物種は、アフリカ野牛（*Syncerus caffer*）である。

7) 本章は、FMDV による臨床症状の発生のみならず、臨床症状を呈さない FMDV *感染*及び伝搬の存在も対象とする。

8) 診断試験及びワクチンの基準は、*陸生マニュアル*に規定される。

第 8.7.2 条

ワクチン接種非実施 FMD 清浄国又は地域

*ワクチン接種*非実施*地域*の境界を定める場合には、第 4.3 章の原則に従うものとする。

*ワクチン接種*非実施 FMD 清浄国又は*地域*の感受性動物は、当該清浄国又は*地域*への FMDV の侵入を予防するバイオセキュリティ措置の適用によって保護されるものとする。隣接する汚染国又は*地域*との物理的又は地理的障壁を考慮して、当該措置には、*防護地域*を含ませることができる。

*ワクチン接種*非実施 FMD 清浄国又は*地域*の一覧表に入るための資格を得るためには、加盟国は以下を満たすものとする。

1) 定期的及び即時の動物*疾病*報告の記録を有していること。

2) 当該予定 FMD 清浄国又は*地域*が、過去 12 ヶ月間、以下を満たしていることを申し立てた宣言が OIE に送付されていること。

   a) FMD の*症例*がいないこと。

   b) FMD に対する*ワクチン接種*が実施されていないこと。

3) 過去 12 ヶ月間、以下を満たしていることの文書による証拠を提出すること。

   a) 第 8.7.40 条から第 8.7.42 条に従う*サーベイランス*が、FMD の臨床症状の発見及び以下の証拠がないことを立証するために実施されていること。

      i) 非ワクチン接種動物の FMDV *感染*

      ii) *ワクチン接種*実施 FMD 清浄国又は*地域*が、*ワクチン接種*非実施 FMD 清浄国又は*地域*になることを求めている場合には、以前にワクチン接種を受けた動物の FMDV 伝搬

   b) FMD を予防及び早期発見するための規制措置が実施されていること。

4) 過去 12 ヶ月間、以下の項目が適切に実行され、指揮されたことを詳細に記述し、文書による証拠を提出すること。

   a) FMD 清浄*地域*の場合には、当該予定 FMD 清浄*地域*の境界線

   b) それが当てはまる場合には、*防護地域*の境界線及び措置

c) 当該予定 FMD 清浄国又は*地域*への FMDV の侵入を予防するためのシステム

d) 感受性動物、その*肉*及びその他の産物の当該予定 FMD 清浄国又は*地域*への移動の管理、とりわけ、第 8.7.8 条、第 8.7.9 条及び第 8.7.12 条に規定される措置

e) 第 8.7.8 条及び第 8.7.9 条に従う場合を除き、ワクチン接種動物が導入されていないこと。

当該加盟国又は当該予定清浄*地域*は、第 1.6.6 条の規定に基づき提出された証拠が OIE に受理されてはじめて、*ワクチン接種*非実施 FMD 清浄国又は*地域*の一覧表に記入されることになる。

当該一覧表に保持されるためには、本条第 2 号、第 3 号及び第 4 号の情報が毎年再提出されることを必要とし、第 3 号の b 及び第 4 号に関連するものを含む疫学的状況その他重要な事象の変化は、第 1.1 章の要件に従い OIE に報告されるものとする。

第 1 号から第 4 号の条件が満たされた場合には、国又は*地域*のステイタスは、以下の条件が満たされているときには、当該*獣医当局*が同定した FMD の脅威に直面して、動物学的コレクション中の FMD 感受性動物に対する公的緊急*ワクチン接種*を適用したとしても、それによる影響を受けることはない。

－ 当該動物学的コレクションが、動物の展示又は希少動物種の保全を目的としており、当該施設の境界を含めて明確に区別され、当該国の FMD 緊急時対応計画に含まれていること。

－ 他の感受性家畜個体群又は*野生生物*からの効果的な分離等、適切なバイオセキュリティ措置が整備されていること。

－ 当該動物が、当該コレクション中に同定され、いかなる移動も追跡調査できること。

－ 使用されるワクチンが、*陸生マニュアル*に規定される基準を遵守していること。

－ *ワクチン接種*が、*獣医当局*の監督下で実施されること。

－ 当該動物学的コレクションが、*ワクチン接種*後少なくとも 12 ヶ月間、*サーベイランス*下に置かれること。

*ワクチン接種*非実施 FMD 清浄*地域*のステイタスの申請を他の*ワクチン接種*非実施 FMD 清浄*地域*と隣接する新たな*地域*に対し行う場合には、当該新*地域*が隣接*地域*と統合されて、ひとつの拡大*地域*になるか否かについて申し立てるものとする。当該 2 *地域*が依然として分かれたまま置かれる場合には、当該分離*地域*のステイタスを維持するために適用される管理措置、並びに、とりわけ、個体識別、及び第 4.3 章に従う当該同一ステイタス*地域*間の動物の移動管理に関する詳細を提出するものとする。

第 8.7.3 条

ワクチン接種実施 FMD 清浄国又は地域

*ワクチン接種*実施*地域*の境界を定める場合には、第 4.3 章の原則に従うものとする。

*ワクチン接種*実施 FMD 清浄国又は*地域*の感受性動物は、当該清浄国又は*地域*への FMDV の侵入を予防するバイオセキュリティ措置の適用によって保護されるものとする。隣接する汚染国又は*地域*との物理的又は地理的障壁を考慮して、当該措置には、*防護地域*を含ませることができる。

当該国の FMD の疫学に基づき、一定の動物種から構成される明瞭なサブ個体群のみを対象とするか、又は全感受性個体群のその他の集合体も対象に含めてワクチン接種するかが決定される場合がある。

*ワクチン接種*実施 FMD 清浄国又は*地域*の一覧表に入るための資格を得るためには、加盟国は以下を満たすものとする。

1) 定期的及び即時の動物*疾病*報告の記録を有していること。

2) 当該予定 FMD 清浄国又は*地域*が、第 3 号に規定される*サーベイランス*に基づき、以下を満たしていることを申し立てた宣言が OIE に送付されていること。

   a) 過去 2 年間、FMD の*症例*がいないこと。

   b) 過去 12 ヶ月間、FMDV 伝搬の証拠がないこと。

3) 以下を満たしていることの文書による証拠を提出すること。

   a) 第 8.7.40 条から第 8.7.42 条に従う*サーベイランス*が、FMD の臨床症状の発見及び以下の証拠がないことを立証するために実施されていること。

      i) 非ワクチン接種動物の FMDV *感染*

      ii) ワクチン接種を受けた動物の FMDV 伝搬

   b) FMD を予防及び早期発見するための規制措置が実施されていること。

   c) 対象個体群における強制的な体系的*ワクチン接種*が実施され、適切な*ワクチン接種*適用範囲及び群免疫を達成していること。

   d) *ワクチン接種*が、適切なワクチン株選択に従い実施されていること。

4) 以下の項目が適切に実行され、指揮されたことを詳細に記述し、文書による証拠を提出すること。

   a) FMD 清浄*地域*の場合には、当該予定 FMD 清浄*地域*の境界線

   b) それが当てはまる場合には、*防護地域*の境界線及び措置

c)　当該予定 FMD 清浄国又は*地域*への FMDV の侵入を予防するためのシステム、とりわけ、第 8.7.8 条、第 8.7.9 条及び第 8.7.12 条に規定される措置

d)　感受性動物及びその産物の当該予定 FMD 清浄国又は*地域*への移動管理

当該加盟国又は当該予定清浄*地域*は、第 1.6.6 条の規定に基づき提出された証拠が OIE に受理されてはじめて、*ワクチン接種*実施 FMD 清浄国又は*地域*の一覧表に記入されることになる。

当該一覧表に保持されるためには、本条第 2 号、第 3 号及び第 4 号の情報が毎年再提出されることを必要とし、第 3 号の b 及び第 4 号に関連するものを含む疫学的状況その他重要な事象の変化は、第 1.1 章の要件に従い OIE に報告されるものとする。

*ワクチン接種*実施 FMD 清浄国又は*地域*の要件を満たす加盟国が、ワクチン接種非実施 FMD 清浄国又は*地域*へとそのステイタスの変更を望む場合には、あらかじめ OIE に対し、*ワクチン接種*中止の予定日を通知し、当該中止の 24 ヶ月以内に新たなステイタスを申請するものとする。当該国又は*地域*のステイタスは、第 8.7.2 条の遵守が OIE によって承認されるまで従前のままである。新ステイタスのための一連書類が 24 ヶ月以内に提出されない場合には、当該国又は地域の*ワクチン接種*清浄としてのステイタスは、一時停止される。当該国が、第 8.7.2 条の要件を遵守していない場合には、第 8.7.3 条を遵守している証拠が 3 ヶ月以内に提出されるものとする。それが行われない場合には、当該ステイタスは取り消されることになる。

*ワクチン接種*実施 FMD 清浄*地域*のステイタスの申請を他の*ワクチン接種*実施 FMD 清浄*地域*と隣接する新たな*地域*に対し行う場合には、当該新*地域*が隣接*地域*と統合されて、ひとつの拡大地域になるか否かについて申し立てるものとする。当該 2 *地域*が依然として分かれたまま置かれる場合には、当該分離*地域*のステイタスを維持するために適用される管理措置、並びに、とりわけ、個体識別、及び第 4.3 章に従う当該同一ステイタス*地域*間の*動物*の移動管理に関する詳細を提出するものとする。

第 8.7.4 条

FMD 清浄コンパートメント

FMD 清浄*コンパートメント*は、FMD 清浄国若しくは*地域*又は汚染国若しくは*地域*のいずれにも設置することができる。そのような*コンパートメント*の輪郭を明瞭に定める場合には、第 4.3 章及び第 4.4 章の原則に従うものとする。FMD 清浄コンパートメントの感受性動物は、効果的なバイオセキュリティ管理システムを適用することによって、他の感受性動物から分離されるものとする。

FMD 清浄*コンパートメント*を設定したい加盟国は、以下を満たすものとする。

1)　定期的及び即時の動物*疾病*報告の記録を有しており、FMD 清浄ではない場合には、当該国又は*地域*の FMD の感染率、分布及び特性に関する理解を可能にする第 8.7.40 条から第 8.7.42 条に従い整備された FMD の*公的管理プログラム*及び*サーベイラン*

*ス*システムを保持していること。

2) 当該 FMD 清浄*コンパートメント*に関し、以下を宣言していること。

a) 過去 12 ヶ月間、FMD の*症例*がいないこと。

b) 過去 12 ヶ月間、FMDV 感染の証拠が認められないこと。

c) FMD に対する*ワクチン接種*が禁止されていること。

d) 過去 12 ヶ月以内に FMD に対するワクチン接種を受けた動物が当該*コンパートメント*内にいないこと。

e) 動物、精液、受精卵及び動物産物は、本章関連条に従う場合に限り、当該*コンパートメント*に導入することができる。

f) 文書による証拠が、第 8.7.40 条から第 8.7.42 条に従う*サーベイランス*が運用されていることを示していること。

g) 第 4.1 章及び第 4.2 章に従い*動物個体識別*及びトレーサビリティシステムが整備されていること。

3) 以下を詳細に記述すること。

a) 当該*コンパートメント*の動物*サブ個体群*

b) 第 1 号に従い実施された*サーベイランス*によって同定されたリスクを緩和する*バイオセキュリティプラン*

当該*コンパートメント*は*獣医当局*が承認するものとする。最初の承認は、過去 3 ヶ月間、当該*コンパートメント*の半径 10 キロメートル以内に FMD の*症例*の発生がない場合にもっぱら与えられるものとする。

第 8.7.5 条

FMD 汚染国又は地域

本章においては、FMD 汚染国又は*地域*は、*ワクチン接種*非実施 FMD 清浄又は*ワクチン接種*実施 FMD 清浄の資格を得る要件を満たさない国又は*地域*である。

第 8.7.6 条

FMD 清浄国又は地域内の封じ込め地域の設定

*ワクチン接種*の有無にかかわらず、*防護地域*内を含む FMD 清浄国又は*地域*内に限定的な*発生*がある場合には、国又は*地域*の全域に対する影響を最小限に抑える目的で、すべての*発生*を含む単一の*封じ込め地域*を設定することができる。

これを達成し、当該加盟国がこのプロセスを十分に利用するため、獣医当局は、当該申請を支持するため、可能な限りすみやかに、OIE に対し、以下の文書による証拠を提出するものとする。

1) 疑似の時点において、発生の疑われる当該*飼育施設*に対し、完全な業務停止が課されて、当該国又は*地域*に対しては、動物の移動管理が課され、及び本章に言及される他の*物品*の移動の効果的な管理が施行されること。

2) 確定時点においては、当該*封じ込め地域*全域に対し、感受性動物の追加的な移動停止が課されて、第 1 号に述べられる移動管理が強化されること。

3) （川上、川下の）疫学調査によって、当該発生が疫学的に関連しており、発生数及び地理的分布が限定的であることを立証された後に、当該*封じ込め地域*の確定境界が設定されていること。

4) 当該*発生*の感染源のおそれがあるものに対する調査が実施されていること。

5) 緊急*ワクチン接種*の活用の有無にかかわりなく、*摘発淘汰政策*が適用されていること。

6) 最終発見症例に対する*摘発淘汰政策*の適用後、第 8.7.1 条に規定される*潜伏期間*の最短でも 2 倍の期間内に、当該*封じ込め地域*内に新たな*症例*が認められないこと。

7) 当該*封じ込め地域*内の感受性家畜及び*飼育野生*動物個体群が、当該*封じ込め地域*に属していると明瞭に同定されていること。

8) 第 8.7.40 条から第 8.7.42 条に従う*サーベイランス*が、当該*封じ込め地域*及び当該国又は*地域*の他の地域内で施行されていること。

9) 物理的及び地理的障壁を考慮した、当該国又は*地域*の他の地域への FMDV のまん延を予防する措置が施行されていること。

当該*封じ込め地域*の外側の区域の清浄ステイタスは、当該*封じ込め地域*が設定されつつある間、一時停止される。当該区域の清浄ステイタスは、当該*封じ込め地域*が本条第 1 号から第 9 号を遵守していると OIE が承認してはじめて、第 8.7.7 条の規定にかかわらず、回復することができる。感受性動物に由来する*国際貿易*用*物品*は、当該封じ込め地域の内外によらず、その原産地が同定されるものとする。

当該*封じ込め地域*内で、非ワクチン接種動物における FMDV の*感染*又はワクチン接種動物における FMDV の伝搬の再発があった場合には、当該*封じ込め地域*の承認は取り消され、当該国又は*地域*全域の FMD ステイタスは、第 8.7.7 条の関連要件が満たされるまで一時停止される。

当該*封じ込め地域*の FMD 清浄ステイタスの回復は、その承認後 12 ヶ月以内に達成され、第 8.7.7 条の規定に従うものとする。

第 8.7.7 条

清浄ステイタスの回復（図 1 及び図 2 を参照）

1) *ワクチン接種*非実施 FMD 清浄国又は*地域*で FMD *症例*が発生した場合には、以下の待機期間のいずれかひとつが、その清浄ステイタスの回復には必要である。

   a) 緊急*ワクチン接種*を伴わない*摘発淘汰政策*及び*サーベイランス*が第 8.7.40 条から第 8.7.42 条に従い適用される場合には、最終殺処分動物の廃棄後 3 ヶ月

   b) *摘発淘汰政策*、緊急*ワクチン接種*及び第 8.7.40 条から第 8.7.42 条に従うサーベイランスが適用される場合には、最終殺処分動物の廃棄又はすべてのワクチン接種動物のと畜のうちいずれか遅い方から 3 ヶ月

   c) *摘発淘汰政策*、すべてのワクチン接種動物の事後のと畜を伴わない緊急*ワクチン接種*及び第 8.7.40 条から第 8.7.42 条に従う*サーベイランス*が適用される場合には、最終殺処分動物の廃棄又は最終ワクチン接種のうちいずれか遅い方から 6 ヶ月。ただし、これには、残されたワクチン接種個体群に*感染*の証拠がないことを立証する、FMDV 非構造タンパク質の抗体検出に基づく血清学的調査を必要とする。

   当該国又は*地域*は、第 1.6.6 条の規定に基づき提出された証拠が OIE に受理されてはじめて、*ワクチン接種*非実施 FMD 清浄国又は*地域*のステイタスを回復することになる。

   第 1 号の a から c の期間は、動物学的コレクションの公的緊急ワクチン接種が第 8.7.2 条の関連規定に従い実施された場合には、影響を受けない。

   摘発淘汰政策が実施されない場合には、本項の待機期間は適用されず、第 8.7.2 条が適用される。

2) *ワクチン接種*非実施 FMD 清浄国又は*地域*で FMD *症例*が発生した場合には、以下の待機期間が、ワクチン接種実施 FMD 清浄国又は*地域*のステイタスの取得には必要である。摘発淘汰政策が適用され、継続的なワクチン接種政策が採用されている場合であって、サーベイランスが第 8.7.40 条から第 8.7.42 条に従い適用され、FMDV 非構造タンパク質に対する抗体検出に基づいた血清学的調査によって FMDV 伝搬の証拠がないことを立証しているときには、最終殺処分動物の廃棄後 6 ヶ月

   当該国又は*地域*は、第 1.6.6 条の規定に基づき提出された証拠が OIE に受理されてはじめて、*ワクチン接種*実施 FMD 清浄国又は*地域*のステイタスを取得することになる。

   *摘発淘汰政策*が実施されない場合には、本項の待機期間は適用されず、第 8.7.3 条が適用される。

3) *ワクチン接種*実施 FMD 清浄国又は*地域*で FMD *症例*が発生した場合には、以下の待機期間のいずれかひとつが、その清浄ステイタスの回復には必要である。

a) 緊急*ワクチン接種*を伴う*摘発淘汰政策*及び第 8.7.40 条から第 8.7.42 条に従う*サーベイランス*が適用される場合であって、FMDV 非構造タンパク質に対する抗体検出に基づいた血清学的調査によってウイルス伝搬の証拠がないことを立証しているときには、最終殺処分動物の廃棄後 6 ヶ月

b) *摘発淘汰政策*が適用されないものの、緊急ワクチン接種及び第 8.7.40 条から第 8.7.42 条に従う*サーベイランス*が適用される場合であって、FMDV 非構造タンパク質に対する抗体検出に基づいた血清学的調査によってウイルス伝搬の証拠がないことを立証しているときには、最終症例の廃棄後 12 ヶ月

緊急*ワクチン接種*が適用されない場合には、本項の待機期間は適用されず、第 8.7.3 条が適用される。

当該国又は*地域*は、第 1.6.6 条の規定に基づき提出された証拠が OIE に受理されてはじめて、*ワクチン接種*実施 FMD 清浄国又は*地域*のステイタスを回復することになる。

4) FMD 清浄*コンパートメント*で FMD *症例*が発生した場合には、第 8.7.4 条が適用される。

5) ステイタスの回復しようとする加盟国は、当該ステイタスの回復のための関連要件が満たされてはじめて、申請するものとする。封じ込め地域が設定された場合には、当該封じ込め地域内の制限は、当該封じ込め地域内の当該疾病の撲滅が成功してはじめて、本条の要件に従い解除されるものとする。

一時停止後 24 ヶ月以内に回復の申請をしない加盟国に対しては、第 8.7.2 条、第 8.7.3 条又は第 8.7.4 条が適用される。

第 8.7.8 条

（ワクチン接種実施又は非実施いずれかの）清浄地域におけると畜を目的とする FMD 感受性動物の汚染地域からの直接輸送

清浄*地域*のステイタスを危険にさらさないため、FMD 感受性動物は、直近の指定*と畜場/食肉処理場*で*と畜*することを目的として以下の条件の下で直接輸送される場合に限り、*汚染地域*を離れるものとする。

1) 移動前少なくとも 30 日間、FMD 感受性動物が仕出地の*飼育施設*に導入されたことがなく、当該仕出*飼育施設*の動物で、FMD の臨床症状を呈したものがいないこと。

2) 移動前少なくとも 30 日間、当該動物が当該仕出*飼育施設*で飼育されていたこと。

3) 移動前少なくとも 4 週間、当該仕出*飼育施設*の半径 10 キロメートル以内に FMD の発生がなかったこと。

4) 当該動物が、*積載*前に浄化及び*消毒*された*輸送機関*によって、*獣医当局*の監督下において、途中他の感受性動物と接触することなく、当該仕出*飼育施設*から当該*と畜場/食肉処理場*まで直接輸送されること。

5) 当該*汚染地域*からの動物の*肉*を取り扱っている間、その*と畜場/食肉処理場*が、*生鮮肉*の輸出が承認されないこと。

6) *輸送機関*及び当該*と畜場/食肉処理場*が、使用後直ちに徹底した浄化及び*消毒*を受ける対象になっていること。

当該動物は、*と畜*前及び*と畜*後 24 時間以内に、と畜前及びと畜後の検査を受けて、FMD の証拠がなく、それに由来する*肉*は、第 8.7.22 条又は第 8.7.23 条の第 2 号に従い処理されるものとする。当該動物由来のその他の産物及びそれらと接触したあらゆる産物は、存在するおそれのある FMDV を殺滅するため第 8.7.31 条から第 8,7,38 条に従い処理されるものとする。

第 8.7.9 条

（ワクチン接種実施又は非実施いずれかの）清浄地域におけると畜を目的とする FMD 感受性動物の封じ込め地域からの直接輸送

清浄*地域*のステイタスを危険にさらさないため、FMD 感受性動物は、直近の指定*と畜場/食肉処理場*で*と畜*することを目的として以下の条件の下で直接輸送される場合に限り、*封じ込め地域*を離れるものとする。

1) 当該封じ込め地域は、第 8.7.6 条の要件に従い公式に設定されていること。

2) 当該動物が、*積載*前に浄化及び*消毒*された*輸送機関*によって、*獣医当局*の監督下において、途中他の感受性動物と接触することなく、当該仕出*飼育施設*から当該*と畜場/食肉処理場*まで直接輸送されること。

3) 当該*封じ込め地域*からの動物の*肉*を取り扱っている間、その*と畜場/食肉処理場*が、*生鮮肉*の輸出が承認されないこと。

4) *輸送機関*及び当該*と畜場/食肉処理場*が、使用後直ちに徹底した浄化及び*消毒*を受ける対象になっていること。

当該動物は、*と畜*前及び*と畜*後 24 時間以内に、と畜前及びと畜後の検査を受けて、FMD の証拠がなく、それに由来する*肉*は、第 8.7.22 条又は第 8.7.23 条の第 2 号に従い処理されるものとする。当該動物由来のその他の産物及びそれらと接触したあらゆる産物は、存在するおそれのある FMDV を殺滅するため第 8.7.31 条から第 8,7,38 条に従い処理さ

れるものとする。

第 8.7.10 条

ワクチン接種非実施 FMD 清浄国若しくは地域又は FMD 清浄コンパートメントからの輸入に関する勧告

FMD 感受性動物

*獣医当局*は、当該動物が以下を満たすことを証明する*国際動物衛生証明書*の提示を求めるものとする。

1) 発送日に FMD の臨床症状を呈していなかったこと。

2) 誕生以来又は少なくとも過去 3 ヶ月間、*ワクチン接種*非実施 FMD 清浄国若しくは*地域*又は FMD 清浄*コンパートメント*で飼育されていたこと。

3) 汚染*地域*を経由する場合には、*発送場所*までの輸送の間、FMDV の感染源に暴露しなかったこと。

第 8.7.11 条

ワクチン接種実施 FMD 清浄国又は地域からの輸入に関する勧告

家畜反芻動物及び豚

*獣医当局*は、当該動物が以下を満たすことを証明する*国際動物衛生証明書*の提示を求めるものとする。

1) 発送日に FMD の臨床症状を呈していなかったこと。

2) 誕生以来又は少なくとも過去 3 ヶ月間、*ワクチン接種*実施 FMD 清浄国又は*地域*で飼育されていたこと。

3) FMD の検査を受けて、陰性の結果であったこと。

4) 汚染*地域*を経由する場合には、*発送場所*までの輸送の間、FMDV の感染源に暴露しなかったこと。

第 8.7.12 条

公的管理プログラムが存在する FMD 汚染国又は地域からの輸入に関する勧告

家畜反芻動物及び豚

*獣医当局*は、以下を満たすことを証明する*国際動物衛生証明書*の提示を求めるものとする。

1) 当該動物が、発送日に FMD の臨床症状を呈していなかったこと。

2) 隔離されるまでの以下のいずれかの期間、当該動物が当該仕出*飼育施設*に飼育されていたこと。

   a) *輸出国*又は*地域*で*摘発淘汰政策*が FMD の管理に適用されている場合には、30 日間、又は 30 日齢より若いときには誕生以来

   b) *輸出国*又は*地域*で*摘発淘汰政策*が FMD の管理に適用されていない場合には、3 ヶ月間、又は 3 ヶ月齢より若いときには誕生以来

3) 本条第 2 号 a 及び b に定める相当期間、当該仕出*飼育施設*内に FMD の発生がないこと。

4) 当該動物が、発送前 30 日間、ひとつの*飼育施設*内で隔離され、隔離中のすべての動物が、隔離期間開始後少なくとも 28 日の時点で採取された試料に関し、FMDV の証拠を求めるウイルス学的及び血清学的診断検査を受けて、陰性の結果であり、当該期間中当該*飼育施設*の半径 10 キロメートル以内に FMD の発生がなかった又は当該*飼育施設*が*検疫所*であること。

5) 当該動物が、当該*飼育施設*から*発送場所*までの輸送の間、FMDV の感染源に暴露しなかったこと。

第 8.7.13 条

ワクチン接種非実施 FMD 清浄国若しくは地域又は FMD 清浄コンパートメントからの輸入に関する勧告

<u>家畜反芻動物及び豚の非冷凍精液</u>

*獣医当局*は、以下を満たすことを証明する*国際動物衛生証明書*の提示を求めるものとする。

1) 当該供与雄畜が、以下を満たすこと。

   a) 当該精液採取日に FMD の臨床症状を呈していなかったこと。

   b) 採取前少なくとも 3 ヶ月間、*ワクチン接種*非実施 FMD 清浄国若しくは*地域*又は FMD 清浄*コンパートメント*で飼育されていたこと。

   c) FMDV の*感染*履歴がある動物がいない*人工授精センター*で飼育されていたこと。

2) 当該精液が、第 4.5 条及び第 4.6 条の規定に準じて、採取、処理及び保管されていたこと。

第 8.7.13 条

ワクチン接種非実施 FMD 清浄国若しくは地域又は FMD 清浄コンパートメントからの輸入に関する勧告

家畜反芻動物及び豚の冷凍精液

*獣医当局*は、以下を満たすことを証明する*国際動物衛生証明書*の提示を求めるものとする。

1) 当該供与雄畜が、以下を満たすこと。

   a) 当該精液採取日及びその後の 30 日間、FMD の臨床症状を呈していなかったこと。

   b) 採取前少なくとも 3 ヶ月間、*ワクチン接種*非実施 FMD 清浄国若しくは*地域*又は FMD 清浄*コンパートメント*で飼育されていたこと。

2) 当該精液が、第 4.5 条及び第 4.6 条の規定に準じて、採取、処理及び保管されていたこと。

第 8.7.15 条

ワクチン接種実施 FMD 清浄国又は地域からの輸入に関する勧告

家畜反芻動物及び豚の冷凍精液

*獣医当局*は、以下を満たすことを証明する*国際動物衛生証明書*の提示を求めるものとする。

1) 当該供与雄畜が、以下を満たすこと。

   a) 当該精液採取日及びその後の 30 日間、FMD の臨床症状を呈していなかったこと。

   b) 採取前少なくとも 3 ヶ月間、*ワクチン接種*実施 FMD 清浄国又は*地域*で飼育されていたこと。

   c) 以下のいずれかを満たすこと。

      i) 少なくとも 2 回ワクチン接種を受けており、防護免疫が 6 ヶ月を超えることが立証されていない場合には、最後の*ワクチン接種*が、採取前 1 ヶ月以上 6 ヶ月以下の時点であること。

      ii) 当該精液の採取後 21 日以上の時点で、FMDV に対する抗体検査を受けて、陰性の結果であること。

2) 当該精液が、以下を満たすこと。

a) 当該精液が、第 4.5 条及び第 4.6 条の規定に従い、採取、処理及び保管されていたこと。

b) 採取後少なくとも 1 ヶ月間、仕出国で保管されており、当該期間中、当該供与動物が飼育されていた*飼育施設*の動物に FMD の症状を呈したものがいなかったこと。

第 8.7.16 条

FMD 汚染国又は地域からの輸入に関する勧告

家畜反芻動物及び豚の冷凍精液

*獣医当局*は、以下を満たすことを証明する*国際動物衛生証明書*の提示を求めるものとする。

1) 当該供与雄畜が、以下を満たすこと。

a) 当該精液採取日及びその後の 30 日間、FMD の臨床症状を呈していなかったこと。

b) 採取前 30 日間に動物が追加されてなく、採取前及び採取後 30 日間、半径 10 キロメートル以内で FMD の発生がない*人工授精センター*で飼育されていたこと。

c) 以下のいずれかを満たすこと。

i) 少なくとも 2 回ワクチン接種を受けており、防護免疫が 6 ヶ月を超えることが立証されていない場合には、最後の*ワクチン接種*が、採取前 1 ヶ月以上 6 ヶ月以下の時点であること。

ii) 当該精液の採取後 21 日以上の時点で、FMDV に対する抗体検査を受けて、陰性の結果であること。

2) 当該精液が、以下を満たすこと。

a) 当該精液が、第 4.5 条及び第 4.6 条の規定に従い、採取、処理及び保管されていたこと。

b) 当該供与雄畜が採取前 12 ヶ月以内にワクチン接種を受けた場合には、FMDV の証拠を求めるための検査を受けて、陰性の結果であること。

c) 採取後少なくとも 1 ヶ月間、仕出国で保管されており、当該期間中、当該供与雄畜が飼育されていた*飼育施設*の動物に FMD の症状を呈したものがいなかったこと。

第 8.7.17 条

生体内由来牛受精卵の輸入に関する勧告

輸出国、*地域*又は*コンパートメント*の FMD ステイタスにかかわりなく、*獣医当局*は、第 4.7 章及び 4.9 章の規定に適宜従い当該受精卵が収集、処理及び保管されたことを証明する*国際動物衛生証明書*の提示を条件として、FMD を理由とする制限を課すことなく、生体内由来牛受精卵の自国の領土への輸入又は経由を認めるものとする。

第 8.7.18 条

ワクチン接種非実施 FMD 清浄国若しくは地域又は FMD 清浄コンパートメントからの輸入に関する勧告

試験管内作成牛受精卵

*獣医当局*は、以下を満たすことを証明する*国際動物衛生証明書*の提示を求めるものとする。

1) 当該供与雌畜が以下を満たすこと。

   a) 卵母細胞採取時に FMD の臨床症状を呈していなかったこと。

   b) 採取前少なくとも 3 ヶ月間、*ワクチン接種*非実施 FMD 清浄国若しくは*地域*又は FMD 清浄*コンパートメント*で飼育されていたこと。

2) 第 8.7.13 条、第 8.7.14 条、第 8.7.15 条又は第 8,7,16 条の条件を適宜満たした精液を用いて受精が行われたこと。

3) 第 4.8 章及び第 4.9 章の規定に適宜従い、当該卵母細胞が収集され、当該受精卵が処理及び保管されたこと。

第 8.7.19 条

ワクチン接種実施 FMD 清浄国又は地域からの輸入に関する勧告

試験管内作成牛受精卵

*獣医当局*は、以下を満たすことを証明する*国際動物衛生証明書*の提示を求めるものとする。

1) 当該供与雌畜が、以下を満たすこと。

   a) 卵母細胞採取時に FMD の臨床症状を呈していなかったこと。

   b) 採取前少なくとも 3 ヶ月間、*ワクチン接種*実施 FMD 清浄国又は*地域*で飼育されていたこと。

   c) 以下のいずれかを満たすこと。

i) 少なくとも 2 回ワクチン接種を受けており、防護免疫が 6 ヶ月を超えることが立証されていない場合には、最後の*ワクチン接種*が、採取前 1 ヶ月以上 6 ヶ月以下の時点であること。

ii) 当該精液の採取後 21 日以上の時点で、FMDV に対する抗体検査を受けて、陰性の結果であること。

2) 第 8.7.13 条、第 8.7.14 条、第 8.7.15 条又は第 8,7,16 条の条件を適宜満たした精液を用いて受精が行われたこと。

3) 第 4.8 章及び第 4.9 章の規定に適宜従い、当該卵母細胞が収集され、当該受精卵が処理及び保管されたこと。

第 8.7.20 条

ワクチン接種非実施 FMD 清浄国若しくは地域又は FMD 清浄コンパートメントからの輸入に関する勧告

FMD 感受性動物の生鮮肉及び肉製品

*獣医当局*は、当該全*肉*積送品が以下を満たす動物に由来することを証明する*国際動物衛生証明書*の提示を求めるものとする。

1) *ワクチン接種*非実施 FMD 清浄国若しくは*地域*又は FMD 清浄*コンパートメント*で飼育されたいたこと、又は第 8.7.10 条、第 8.7.11 条若しくは第 8,7.2 条に従い輸入されたこと。

2) 認可*と畜場/食肉処理場*でと畜され、と畜前及びと畜後の検査を受けて良い結果であること。

第 8.7.21 条

ワクチン接種実施 FMD 清浄国又は地域からの輸入に関する勧告

FMD 感受性動物の生鮮肉及び肉製品

*獣医当局*は、当該全*肉*積送品が、以下を満たす動物に由来することを証明する*国際動物衛生証明書*の提示を求めるものとする。

1) *ワクチン接種*実施 FMD 清浄国又は*地域*で飼育されたいたこと、又は第 8.7.10 条、第 8.7.11 条若しくは第 8,7.2 条に従い輸入されたこと。

2) 認可*と畜場/食肉処理場*でと畜され、と畜前及びと畜後の検査を受けて良い結果であること。

3) 反芻動物の場合には、咽頭、舌及び関連リンパ節を含む頭部が、発送から除外されていること。

第 8.7.22 条

公的管理プログラムが存在する FMD 汚染国又は地域からの輸入に関する勧告

牛又は水牛（*Bubalus bubalis*）の生鮮肉（脚部、頭部及び内臓を除く）

*獣医当局*は、当該全*肉*積送品が以下を満たすことを証明する*国際動物衛生証明書*の提示を求めるものとする。

1) 以下を満たす動物に由来すること。

a) 牛及び水牛が FMD に対するワクチン接種を定期的に受けており、*公的管理プログラム*が運用されている*輸出国*の*一地域*に、*と畜*前少なくとも 3 ヶ月間、留置されていたこと。

b) 少なくとも 2 回ワクチン接種を受けており、最後の*ワクチン接種*が、*と畜*前 1 ヶ月以上の時点であって、防護免疫が 6 ヶ月を超えることが立証されていない場合には、6 ヶ月以下の時点であること。

c) 当該動物が、過去 30 日間、当該期間中当該*飼育施設*の半径 10 キロメートル以内に FMD の発生がなかったひとつの*飼育施設*内で隔離されていたこと、又は当該*飼育施設*が*検疫所*であること。

d) 当該牛及び水牛が積載される前に浄化及び*消毒*された*輸送機関*によって、途中輸出に必要な条件を満たさない他の感受性動物と接触することなく、当該仕出*飼育施設*又は*検疫所*から当該認可*と畜場/食肉処理場*まで直接輸送されること。

e) 以下を満たす認可*と畜場/食肉処理場*でと畜されたこと。

i) 輸出向けとして公的に指定されていること。

ii) *と畜*前に実施された最後の*消毒*から輸出のための当該発送が終わるまでの期間中、FMD が発見されなかったこと。

f) と畜前及びと畜後 24 時間以内にと畜前及びと畜後の ~~FMD~~ 検査を受けて FMD の証拠がないこと。

2) 以下を満たす骨抜きと体に由来すること。

a) 主要リンパ節が取り除かれていること。

b) 骨抜き前に、＋2℃より高い温度で、と畜後最短 24 時間、熟成過程を受け、熟成中の pH 値が、両背最長筋の中間で検査して 6.0 未満であること。

第 8.7.23 条

FMD 汚染国又は地域からの輸入に関する勧告

FMD 感受性動物の肉製品

*獣医当局*は、以下を満たすことを証明する*国際動物衛生証明書*の提示を求めるものとする。

1) 当該全*肉製品*積送品が、認可*と畜場/食肉処理場*でと畜され、と畜前及びと畜後の FMD 検査を受けて良い結果であること。

2) 当該*肉製品*が、第 8.7.31 条の方法のひとつに従い、FMDV の殺滅を確保する処理を受けていること。

3) 当該*肉製品*と FMDV の潜在的感染源との接触を防止するため、必要な予防措置が処理後にとられていること。

第 8.7.24 条

ワクチン接種実施若しくは非実施 FMD 清浄国若しくは地域又は FMD 清浄コンパートメントからの輸入に関する勧告

人の消費用、及び動物飼料での使用又は農業若しくは工業利用を目的とする（FMD 感受性動物の）動物由来製品用の乳及び乳製品

*獣医当局*は、当該産物が、FMD 清浄国、*地域*若しくは*コンパートメント*で飼育されていた又は第 8.7.10 条、第 8,7.11 条若しくは第 8.7.12 条に従い輸入された動物に由来することを証明する*国際動物衛生証明書*の提示を求めるものとする。

第 8.7.25 条

公的管理プログラムが存在する FMD 汚染国又は地域からの輸入に関する勧告

乳及び乳製品

*獣医当局*は、以下を満たすことを証明する*国際動物衛生証明書*の提示を求めるものとする。

1) 当該産物が、以下を満たすこと。

   a) *乳*収集時に FMD に汚染していない又は汚染したおそれのない*飼育施設*に由来すること。

   b) 第 8.7.35 条及び第 8.7.36 条の方法のひとつに従い、FMDV の殺滅を確保する処理を受けていること。

2) 当該産物と FMDV の潜在的感染源との接触を防止するため、必要な予防措置が処理後にとられていること。

第 8.7.26 条

FMD 汚染国又は地域からの輸入に関する勧告

FMD 感受性動物の血粉及び肉粉

*獣医当局*は、当該産物の製造方法に最低中心温度 70℃で少なくとも 30 分間の加熱処理が含まれることを証明する*国際動物衛生証明書*の提示を求めるものとする。

第 8.7.27 条

FMD 汚染国又は地域からの輸入に関する勧告

FMD 感受性動物の羊毛、毛、剛毛、生皮及び皮革

*獣医当局*は、以下を満たすことを証明する*国際動物衛生証明書*の提示を求めるものとする。

1) 当該産物が、第 8.7.32 条、第 8.7.33 条及び第 8.7.34 条の方法のひとつに従い、FMDV の殺滅を確保する処理を受けていること。

2) 当該産物と FMDV の潜在的感染源との接触を防止するため、必要な予防措置が処理後にとられていること。

*獣医当局*は、当該産物が、製革業界で使用されている普通の化学的又は機械的処理を受けた場合には、制限を課すことなく、半加工皮及び皮革（石灰皮、ピックル皮及びクロムなめし、クラストレザー等の半加工革）の自国の領土への輸入又は経由を認めるものとする。

第 8.7.28 条

FMD 汚染国又は地域からの輸入に関する勧告

わら及びまぐさ

*獣医当局*は、当該*物品*が以下の 1 及び 2、又は 3 を満たすことを証明する*国際動物衛生証明書*の提示を求めるものとする。

1) 動物由来物によるはっきりと識別される汚染がないこと。

2) 以下の処理のいずれかひとつを受けて、俵で送付される物の場合には、当該俵の中心まで浸透することが示されたこと。

a) 当該俵の中心が、少なくとも 10 分間、最低温度 80℃に達する密閉室内の蒸気

作用

b) 最低温度 19℃で少なくとも 8 時間、密閉室内に置かれる、35-40 パーセントのホルマリン市販溶液によるホルマリン燻蒸（ホルムアルデヒドガス）作用

3) 輸出向けに解放されるまで少なくとも 4 ヶ月間保税倉庫に置かれたこと。

第 8.7.29 条

ワクチン接種実施又は非実施 FMD 清浄国又は地域からの輸入に関する勧告

FMD 感受性野生生物由来の皮革及び狩猟記念品

*獣医当局*は、当該産物が、そのような国又は地域で殺された又は FMD 清浄の国、地域若しくはコンパートメントから輸入された動物に由来することを証明する*国際動物衛生証明書*の提示を求めるものとする。

第 8.7.30 条

FMD 汚染国又は地域からの輸入に関する勧告

FMD 感受性野生生物由来の皮革及び狩猟記念品

*獣医当局*は、当該産物が、第 8.7.37 条の方法に従い、FMDV の殺滅を確保する処理を受けていることを証明する*国際動物衛生証明書*の提示を求めるものとする。

第 8.7.31 条

肉及び肉製品中の FMDV 不活化方法

*肉*及び*肉製品*中の FMDV の存在を不活化するためには、以下の方法のひとつが使用されるものとする。

1. 缶詰化

*肉*及び*肉製品*が、最短で 30 分間、内部中心温度が少なくとも 70℃に達する密閉容器内での加熱処理又は FMDV を不活化することが立証されている同等の処理を受ける。

2. 徹底した調理

あらかじめ骨及び脂肪を取り除いた*肉*並びに*肉製品*が、最短で 30 分間、中心温度が少なくとも 70℃の結果になる加熱処理を受ける。

調理後は、FMDV の感染源に暴露することがない方法で梱包及び取り扱われるものとする。

3. 塩漬け後の乾燥

死後硬直完了時に、当該*肉*が、骨抜きされ、塩（NaCl）で処理され、完全に乾燥される。それは、室温で悪化しないものである。

‘完全に乾燥される’とは、2.25:1 を超えない含水タンパク質率又は 0.85 を超えない水分活性（Aw）と定義される。

第 8.7.32 条

羊毛及び毛の中の FMDV 不活化方法

産業用の羊毛及び毛の中に存在する FMDV の存在を不活化するためには、以下の方法のひとつが使用されるものとする。

1) 水、洗剤及び水酸化ナトリウム（ソーダ）又は水酸化カリウム（カリ）の一連の溶液中への当該羊毛の浸漬から構成される産業的洗浄

2) 消石灰又は亜硫酸ナトリウムを使用した化学的脱毛

3) 密閉室内でも少なくとも 24 時間のホルムアルデヒド燻蒸

4) 60-70℃に維持された水溶界面活性剤中への羊毛の浸漬から構成される産業的精錬

5) 4℃で 4 ヶ月間、18℃で 4 週間又は 37℃で 8 日間の保管

第 8.7.33 条

剛毛中の FMDV 不活化方法

産業用の剛毛中に存在する FMDV の存在を不活化するためには、以下の方法のひとつが使用されるものとする。

1) 少なくとも 1 時間の煮沸

2) 1 パーセントホルムアルデヒドの水性溶液への少なくとも 24 時間の浸漬

第 8.7.34 条

生皮及び皮革中の FMDV 不活化方法

産業用の生皮及び皮革中に存在する FMDV の存在を不活化するためには、以下の方法が使用されるものとする。2 パーセント炭酸ナトリウム（Na_2CO_3）を含有する塩による少なくとも 28 日間の処理

第 8.7.35 条

人の消費用の乳及びクリーム中の FMDV 不活化方法

人の消費用の*乳*及びクリーム中に存在する FMDV の存在を不活化するためには、以下の方法のひとつが使用されるものとする。

1) 最低温度 132℃で少なくとも 1 秒間の工程（超高温〔UHT〕）

2) 当該*乳*が 7.0 未満の pH である場合には、最低温度 72℃で少なくとも 15 秒間の工程（高温－短時間殺菌〔HTST〕）

3) 当該*乳*が 7.0 以上の pH である場合には、HTST 工程を 2 回適用

第 8.7.36 条

動物の消費用の乳及びクリーム中の FMDV 不活化方法

動物の消費用の*乳*及びクリーム中に存在する FMDV の存在を不活化するためには、以下の方法のひとつが使用されるものとする。

1) HTST 工程を 2 回適用

2) 少なくとも 1 時間 pH6 に維持、脱水処理を組み合わせた少なくとも 72℃の追加加熱等他の物理的処理を組み合わせた HTST

3) 本条第 2 号の他の物理的処理を組み合わせた UHT

第 8.7.37 条

当該疾病に感受性のある野生生物の皮革及び狩猟記念品中の FMDV 不活化方法

FMD に感受性のある*野生動物*の皮革及び狩猟記念品中に存在する FMDV の存在を不活化するためには、完全な剥製処理前に以下の方法のひとつが使用されるものとする。

1) 骨、角、蹄、爪、枝角又は歯以外の物質が確実に取り除かれる適切な時間の水中煮沸

2) 室温（20℃以上）での少なくとも 20 キログレイのガンマ線照射

3) pH11.5 以上に維持された 4 パーセント（重量/体積）炭酸ナトリウム（Na_2CO_3）溶液中に、攪拌しながら、少なくとも 48 時間浸漬

4) pH3.0 未満に維持された蟻酸溶液(1,000 リットルの水中 100 キログラムの塩〔NaCl〕及び 12 キログラムの蟻酸）中に、攪拌しながら、少なくとも 48 時間浸漬。湿潤剤及び仕上剤を添加しても良い。

5) 生皮の場合には、2 パーセント炭酸ナトリウム（Na_2CO_3）を含有する塩による少なく

とも 28 日間の処理

第 8.7.38 条

反芻動物及び豚のケーシング中の FMDV 不活化方法

反芻動物及び豚のケーシング中に存在する FMDV の存在を不活化するためには、以下の方法が使用されるものとする。当該全期間中 12℃を超える温度に維持された乾燥塩（NaCl）若しくは飽和塩水（NaCl, aw<0.80)、又は 88.5 重量パーセント NaCl、10.7 重量パーセント Na_2HPO_4 及び 2.8 重量パーセント Na_3PO_4 を含有する燐酸塩添加塩の乾燥物若しくは飽和塩水による少なくとも 30 日間の処理

第 8.7.39 条

OIE 保証 FMD 公的管理プログラム

OIE 保証 FMD *公的管理プログラム*の全般的な目的は、国が漸進的に状況を向上させ、最終的に FMD 清浄ステイタスを取得することである。当該*公的管理プログラム*は、たとえある措置が限定的な*サブ個体群*のみに向けられている場合であっても、国全体に適用可能なものであるものとする。

加盟国は、本条に従う措置を実施している場合には、自国の FMD *公的管理プログラム*の保証を任意で申請することができる。

加盟国の FMD *公的管理プログラム*が OIE の保証を得るためには、当該加盟国は以下を満たすものとする。

1) 第 1.1 章の要件に従う定期的及び即時の動物*疾病*報告の記録を有していること。

2) *獣医サービス*の FMD 管理能力の文書による証拠を提出すること。当該証拠を提供するひとつの方法は、OIE PVS Pathway を介することである。

3) 当該国又は*地域*の FMD を管理し、最終的に撲滅するための以下の項目を含む当該プログラムの詳細計画を提出すること。

   a) 予定表

   b) 当該管理措置が有効に実施されていることを評価するための業績指標

   c) 当該 FMD *公的管理プログラム*が国の全域に適用可能であることを示す証拠文書

4) 以下の項目を記述した当該国の FMD 疫学に関する一連書類を提出すること。

   a) 現在の知見及び相違並びに FMD 管理に関しなされた進歩を強調する当該国の全般的疫学

b) FMD の*発生*事例を減少され、当該国の少なくとも一*地域*における FMDV 伝搬を根絶することを目的とする、*感染*侵入予防のためとられた措置、すべての FMD 発生に対する早期発見及び対応

c) 主な家畜生産システム並びに当該国内及び当該国への FMD 感受性動物及びその産物の移動パターン

5) 以下を満たす FMD *サーベイランス*が実施されている証拠を提出すること。

a) 第 1.4 章の規定及び本章の*サーベイランス*に関する規定を考慮していること。

b) 診断能力、並びに診断及び株の更なる特性評価を実施する*検査施設*への試料の定期的な提出を含む手続を備えていること。

6) 当該*公的管理プログラム*の一部として*ワクチン接種*が実施されている場合には、以下を提出すること。

a) 選択個体群に対する*ワクチン接種*が強制的なものであることの証拠（法令の写し等）

b) とりわけ以下の項目に関する*ワクチン接種*キャンペーンの詳細情報

i) *ワクチン接種*の対象個体群

ii) 個体群免疫の血清学的監視を含む*ワクチン接種*適用範囲の監視

iii) 流行中の FMDV 株とのマッチングを含む使用ワクチンの技術的仕様及び施行中の承認手続に関する説明

iv) *陸生マニュアル*の基準及び方法を十分に満たすワクチン仕様への移行予定表

7) *発生*した場合に実施される緊急事態準備対応計画を提出すること。

当該加盟国の FMD *公的管理プログラム*は、第 1.6.11 条の規定に基づき提出された証拠が OIE に受理されてはじめて、OIE が保証するプログラムの一覧表に記入されることになる。当該一覧表に保持されるためには、当該公的管理プログラムの進捗及び本条各号に係る重要な変化の情報に関する年次最新情報を必要とする。疫学的状況その他重要な事象の変化は、第 1.1 章の要件に従い OIE に報告されるものとする。

OIE は、以下のいずれかの証拠がある場合には、当該*公的管理プログラム*の保証を取り下げることができる。

－　当該プログラムの予定表又は業績指標の不従順

－　*獣医サービス*能力の重大な問題

－　当該プログラムでは対応することができない FMD 発生の増加

第 8.7.40 条

サーベイランスの一般原則

第 8.7.40 条から第 8.7.47 条は、当該国、*地域*若しくは*コンパートメント*の段階で FMD の清浄性を確立、維持若しくは回復を求める又は第 8.7.39 条に従い自国の FMD *公的管理プログラム*の OIE による保証を求める加盟国に対し、第 1.4 章に従う適用可能な FMD *サーベイランス*の原則を明らかにし、指針を提供する。疾病及び FMDV 感染又は伝搬の同定を目的とする*サーベイランス*は、第 8.7.1 条第 2 項に規定される家畜及び適宜野生生物の動物種を対象に含むものとする。

1.　早期発見

第 1.4 章に従う*サーベイランス*システムは、*獣医当局*の所掌であるものとし、生産、販売及び加工系の全体を通じて疑似症例を報告する早期警戒システムを提供するものとする。試料の迅速な収集及び FMD 診断*検査施設*への輸送のための手順が整備されているものとする。このためには、*サーベイランス*の責任者が、試料採取キットその他の器具を利用できることが必要である。*サーベイランス*の責任者は、FMD の診断及び管理の専門家からなるチームの支援を求めることができるものとする。

2.　清浄性の立証

FMD の影響及び疫学は、世界のさまざまな地域で大きく異なっており、したがってすべての状況向けの具体的勧告を規定することは不適切である。当該国、*地域*又は*コンパートメント*の FMD 清浄性を受け入れ可能な信頼性の水準で立証するために展開される*サーベイランス*戦略は、地域の状況に合わせて調整されるものとする。たとえば、豚に馴化した FMDV 株による*発生*後の FMD 清浄性を立証するアプローチは、アフリカ野牛（*Syncerus caffer*）が*感染*の潜在的レゼルボアである国又は*地域*における FMD 清浄性を立証するため計画されたアプローチとは当然大きく異なる。

FMD *サーベイランス*は、継続的なプログラムの形態であるものとする。FMDV の*感染*及び伝搬の証拠がないことを立証するプログラムは、OIE 若しくは貿易相手国が受け入れるには不十分な結果を生む、又は過剰に費用がかかり、後方業務支援が複雑になるのを避けるため、慎重に計画及び実施されるものとする。

当該*サーベイランス*プログラムの戦略及び計画は、*ワクチン接種*の使用の有無を含む歴史的疫学環境に依存して決まることになる。

*ワクチン接種*非実施 FMD 清浄性を実証したい加盟国は、FMDV *感染*の証拠がないことを立証するものとする。

*ワクチン接種*実施 FMD 清浄性を実証したい加盟国は、いかなる感受性個体群内においても FMDV が伝搬していないことを立証するものとする。ワクチン接種を受けた個体群内においては、FMDV 伝搬の証拠がないことを立証する血清学的調査は、ワクチン接種回数が限定的な若齢動物、ワクチン非接種動物等、非構造タンパク質に対するワクチン由来抗体を示す可能性がより低い動物を対象にするものとする。*サーベイランス*は、いかなるワクチン非接種*サブ個体群*内においても、FMDV *感染*の証拠がないことを立証するものとする。

*コンパートメント*を設定及び維持するために展開される*サーベイランス*戦略は、当該*コンパートメント*外部の FMD の流行、分布及び特性を同定するものとする。

3. OIE 保証公的管理プログラム

OIE 保証*公的管理プログラム*の支持を得て展開される*サーベイランス*戦略は、使用された*ワクチン接種*の有効性及びすべての FMD 発生の早期発見能力の証拠を立証するものとする。

したがって、当該*公的管理プログラム*の一部として、その全領土又は一部には FMDV *感染*及び伝搬がないことを証明し、FMD の疫学を理解することを目的に*サーベイランス*を計画及び実施する場合には、加盟国にかなりの許容範囲が認められる。

加盟国は、関連する地域の FMD の疫学を説明するだけでなく、*野生生物*の役割を適宜含むすべてのリスク要因がどのようにして同定され、管理されているかを立証するその申請を裏付ける一連書類を OIE に提出するものとする。これには、科学に基づく裏付けデータの提供が含まれるものとする。

4. サーベイランス戦略

FMDV *感染*の流行を確定する又は FMDV *感染*若しくは伝搬がないことを実証するため展開される戦略は、第 1.4.4 条及び第 1.4.5 条に規定される受け入れ可能な統計学的信頼性の水準の無作為又は標的型臨床調査又は試料採取に基づいている。特定の地域又は動物種での*感染*の可能性が高まっていることが明らかにできる場合には、標的型試料採取が適切である場合もある。臨床検査が、明瞭な臨床症状を呈する可能性の高い特定の動物種（たとえば、牛及び豚）を標的にする場合もある。当該加盟国は、選択された*サーベイランス*戦略及び試料採取の頻度が、FMDV の*感染*又は伝搬の存在を発見するのに適切なものであると、第 1.4 章及び疫学的状況に従い正当化するものとする。

当該試料採取戦略の計画は、疫学的に適切な推定感染率を組み込むものとする。検査のために選択されたサンプル数は、前もって定めた最小の割合でそれが発生した場合であっても、*感染*又は伝搬を発見できる適切なものであるものとする。当該サンプル数及び推定*疾病*感染率が、当該調査結果の信頼性の水準を決定する。当該加盟国は、サーベイランスの目的及び一般的又は歴史的疫学状況に基づく推定感染率

及び信頼性の水準の選択を第 1.4 章に従い正当化するものとする。

5. 疑似症例の追跡調査及び結果の解釈

有効な*サーベイランス*システムは、当該状況の原因が FMDV であると確定する又はそれを排除する緊急の追跡及び調査が必要になる疑似*症例*を同定することになる。当該疑似症例が、疫学的及び臨床調査によって確定又は排除できる場合を除いて、試料が採取され、診断試験のため送付されるものとする。疑似*症例*の発生及びそれがどのように調査され、取り扱われたかについても詳細は、文書化されるものとする。これには、診断試験の結果及び当該関連動物が調査中に受けた管理措置が含まれるものとする。

確認検査の能力を含む、採用された診断試験の感受性及び特異性は、当該計画、サンプル数の決定及び得られた結果の解釈における重要な要素である。使用された試験の感受性及び特異性は、標的個体群の動物の*ワクチン接種*又は*感染*履歴及び生産分類に応じて確認されるものとする。

*サーベイランス*計画は、偽の陽性反応の発生を予期するものとする。試験システムの特性が既知の場合には、これら偽の陽性が発生する割合は、あらかじめ計算することができる。それが*感染*又は伝搬を示唆するか否かを高い信頼性の水準で決定する、陽性事例を追跡調査する有効な方法があるものとする。これには、補助試験、並びに原産*疫学単位*及びそれと疫学的な関連がある*動物群*から診断材料を収集する追跡調査が含まれるものとする。

*検査施設*結果は、疫学的状況に照らして検討されるものとする。血清学的調査を補足し、ウイルス伝搬の可能性を評価するために必要な推論情報には以下の項目が含まれるが、これらに限定されない。

- 既存生産システムの特性
- 疑似例及びそのコホートの臨床サーベイランス結果
- 評価中の区域で実施されるワクチン接種の数及びプロトコルの説明
- 反応*飼育施設*のバイオセキュリティ及び沿革
- 動物の個体識別及びトレーサビリティ並びにその移動の管理
- 歴史的に有名な FMDV 伝播において地域的に重要なその他のパラメータ

6. 個体群免疫の立証

慣例の*ワクチン接種*後に、適切なワクチン接種適用範囲、個体群免疫等、当該*ワクチン接種*プログラムの有効性を立証する証拠が提供されるものとする。これは、残余の*感染*又は伝搬に関する*ワクチン接種*後調査への依存を弱めるのに役立つこと

ができる。

個体群免疫を推定する血清学的調査の計画に当たっては、当該動物が受ける*ワクチン接種*の回数を考慮するため、血液試料採取は、月齢別に層化されるものとする。最終*ワクチン接種*から試料採取までの間隔は、意図する目的によって決まってくる。ワクチン接種後 1 又は 2 ヶ月後の試料採取は、当該ワクチン接種プログラムの有効性に関する情報を提供し、再ワクチン接種前又は時点での試料採取は、免疫期間に関する情報を提供する。多価ワクチンが使用される場合には、当該ワクチンに混合された各抗原に対してではないにしても、少なくとも各血清型に対する抗体価を決定するための試験が実施されるものとする。受け入れ可能な抗体価に関する検査限界値が、関連抗原に関するワクチン・攻撃試験結果によって立証された保護水準を参照して、決定されるものとする。流行ウイルスの脅威が、当該ワクチンウイルスと大きく異なる抗原特性を有する野外ウイルスの結果である場合には、個体群免疫の防護効果を解釈するときに、それを考慮するものとする。個体群免疫の数値は、所与の*サブ個体群*の全感受性動物を参照し、ワクチン接種動物の部分集合と関連付けて、見積もられるものとする。

調査の全プロセスは、*サーベイランス*プログラムの中に文書化されるものとする。

すべての疫学情報は実証されるものとし、その結果は、最終報告に順序正しくまとめられるものとする。

第 8.7.41 条

サーベイランスの方法

1. <u>臨床サーベイランス</u>

日々家畜と接する農家及び作業者並びに*動物看護士*、*獣医師*及び診断技術者は、FMD の疑似例を直ちに報告するものとする。*獣医当局*は、これらの者を啓蒙するプログラムを実施するものとする。

臨床サーベイランスは、感受性動物の身体検査を必要とする。大規模血清学的スクリーニングの診断価値が重視されているものの、十分な数の臨床的感受性動物が適切な頻度で検査を受け、調査が記録及び定量化される場合には、臨床検査に基づく*サーベイランス*が、高い信頼性の水準での*疾病*発見を提供することがある。

疑似*症例*の状態を明確化するためには、臨床検査及び診断試験が適用されるものとする。診断試験が臨床的疑似例を確定する場合もあれば、臨床*サーベイランス*が検査施設試験の陽性結果の確定に貢献する場合もある。*野生生物*及び通常臨床症状を呈さない家畜動物種、又は十分な観察を許さない飼養システムでは、臨床*サーベイランス*が不十分な場合がある。そのような状況においては、血清学的*サーベイランス*が使用されるものとする。*野生生物*の動物種から情報及び診断試料を得る目的で、狩猟、捕獲並びに非侵襲的試料採取及び観察法を利用することができる。

2. ウイルス学的サーベイランス

病原ウイルスの分子学的、抗原学的その他生物学的特性並びにその感染源の確定は、試料を提供する臨床*サーベイランス*に主として依存している。FMDV の分離株は、定期的に OIE リファレンスラボラトリーに送付されるものとする。

ウイルス学的サーベイランスは以下を目的とする。

a) 臨床的疑似*症例*を確定診断すること。

b) 血清学的陽性結果を追跡調査すること。

c) 疫学調査及びワクチンマッチングのため分離株を特徴付けること。

d) 当該ウイルスの存在及び伝搬のリスクが高い個体群を監視すること。

3. 血清学的サーベイランス

血清学的*サーベイランス*は、非構造タンパク質検査又は構造タンパク質検査を使用した*感染*又は*ワクチン接種*の結果による抗体を検出することを目的とする。

血清学的*サーベイランス*は、以下の目的で使用される。

a) 感染率を推定する又は FMDV の*感染*若しくは伝搬がないことを実証すること。

b) 個体群免疫を監視すること。

他の目的で収集された血清は、本章に規定される調査計画の原則を満たす場合には、FMD *サーベイランス*に利用することができる。

無作為又は標的型血清学的調査の結果は、国、地域又はコンパートメントにおける FMD の状況に係る信頼できる証拠を提供する上で重要である。したがって、当該調査は、徹底的に文書化されることが不可欠である。

第 8.7.42 条

血清学的試験の使用及び解釈（図 3 参照）

血清学的試験の選択及び解釈は、疫学的状況に照らして考慮されるものとする。使用されるすべての試験の試験プロトコル、試薬、性能特性及び検証が、周知されるものとする。試験が組み合わせて使用される場合には、全体的な試験システムの性能特性もまた周知されるものとする。

FMDV に感染した動物は、当該ウイルスの構造タンパク質及び非構造タンパク質両方の抗体を産生する。ワクチン接種動物は、ワクチンの精製度合いに応じて、当該ウイルスの構造タンパク質に対する抗体を主に又はもっぱら産生する。構造タンパク

質検査は、血清型特異的であり、感受性を最適化するためには、予期される野外株に近縁の抗原又はウイルスを選択するものとする。ワクチン非接種個体群では、FMDV *感染*若しくは伝搬の証拠を求めて血清をふるいにかける又はワクチン接種動物の侵入を発見するため、構造タンパク質検査を使用することができる。ワクチン接種個体群では、当該ワクチン接種に対する血清学的反応を監視するため、構造タンパク質検査を使用することができる。

非構造タンパク質検査は、当該ワクチンが精製に関し*陸生マニュアル*の基準を遵守している場合には、当該動物の*ワクチン接種*ステイタスにかかわりなく、すべての血清型の FMDV の*感染*又は伝搬の証拠を求めて血清をふるいにかけるのに使用することができる。ただし、ワクチン接種を受け、その後に FMDV に感染した動物は非構造タンパク質に対する抗体を産生するものの、その水準は、ワクチン接種を受けていない感染動物に認められるものよりも低い場合がある。FMDV に接触したすべての動物が血清学的に陽性になるよう確保するためには、各ワクチン接種区域において、非構造タンパク質抗体検査のための試料が、最終症例後 30 日以降、いかなる場合であっても、最終ワクチン接種後 30 日以降に採取されることが推奨される。

FMDV 抗体検査の陽性結果には、以下の４つの原因の可能性がある。

a) FMDV の*感染*

b) FMD に対する*ワクチン接種*

c) 母子移行抗体（牛の母子移行抗体は、通常 6 ヶ月齢まで認められるが、個体によっては及び別の動物種によっては、母子移行抗体がさらに長い期間検出される場合がある。）

d) 使用された検査における当該血清の非特異反応

<u>検査で陽性結果である場合の方法</u>

それが検査で確認された陽性反応である又はさらなる調査及び検査が必要であるか否かの決定をする場合には、血清学的陽性反応の割合及び強さが考慮されるものとする。

偽の陽性結果が疑われた場合には、血清学的陽性反応は、同じ検査の繰り返し及び確定診断検査を使用して当該*検査施設*内で再試験されるものとする。確定診断のため使用された検査は、偽の陽性検査結果を最小限に抑えるため、高い診断特異性を持つものとする。確定検査の診断感受性は、ふるい分け検査のそれと同じ水準又はそれを超えるものであるものとする。

検査で確認された陽性反応が少なくとも一例あるすべての*動物群*は、調査されるものとする。当該調査は、当初の調査で展開された血清学的検査の陽性結果が FMDV の伝搬によるものであるとの仮説を確定又は論駁するかもしれないウ

イルス学的検査及び血清学的追加検査の結果が含まれる場合もあるすべての証拠を検討するものとする。当該調査は、各陽性*動物群*のステイタスに証拠書類を提供するものとする。疫学的調査は、同時に継続されるものとする。

*動物群*内又は地域内の血清学的陽性結果のクラスター化は、それが、試料採取個体群の統計学、ワクチンの暴露又は*感染*若しくは伝搬の存在等、一連の事象を反映しているおそれがあることから、調査されるものとする。クラスター化は*感染*又は伝搬を示唆するおそれがあることから、当該調査計画には、すべての事例の調査が組み込まれるものとする。

血清学的陽性動物の数の増加又は二次試料採取時の抗体価の増加を立証することによる FMDV 伝搬同定のため、ペア血清学が使用されるものとする。

当該調査には、陽性反応動物、同一*疫学単位*の感受性動物、及び当該陽性反応動物と接触した、さもなければ疫学的に関連した感受性動物を含むものとする。試料採取された動物は、検査結果までの間、当該*飼育施設内*に留置され、明瞭に同定され、接近可能であり、適切な期間後に再検査が可能になるよう当該調査期間中はワクチン接種を受けないものとする。臨床検査に続いて、適切な期間が経過後に、当該陽性反応と直接接触した動物を重点化した最初の調査で検査を受けた動物から二回目の試料が採取されるものとする。当該動物が個別に同定されていない場合には、最初の調査計画を繰り返し適用し、適切な期間の後、当該*飼育施設*内で新たな血清学的調査が行われるものとする。FMDV が循環していない場合には、観察される抗体活性の大きさ及び広がりは、当初の試料のそれと比較して、統計学的有意差をもって当然異なっている。

状況によっては、ワクチン非接種のおとり動物もまた使用することができる。それは、ワクチン非接種母畜由来の若齢動物又は母子移行免疫が消滅した動物であって、当該陽性試料採取単位と同じ動物種であることが望ましい。他の感受性ワクチン非接種動物が存在する場合には、それは追加の血清学的証拠を提供するおとりとして作用する。当該おとりは、少なくとも*潜伏期間*の二倍の期間、調査中の*疫学単位*の動物と密接に接触して飼育されるものとし、FMDV が循環していない場合には、当然血清学的に陰性のままである。

<u>野外及び検査施設所見の追跡調査</u>

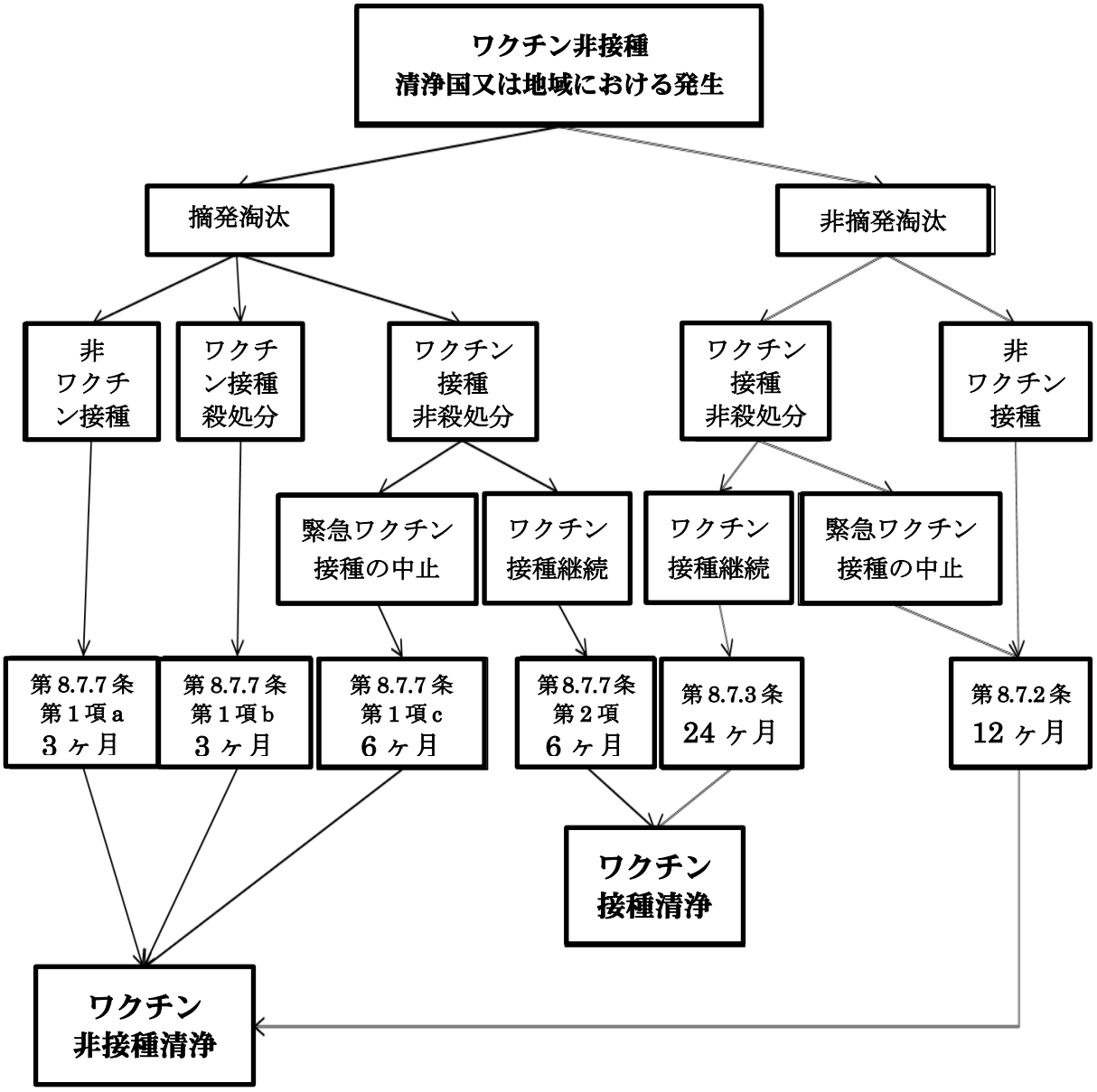
伝搬が立証される場合には、*発生*が宣言される。

現時の FMDV 伝搬がない場合の少数の血清学的陽性動物の重要性を決定することは困難である。そのような所見が、反芻動物においては、過去の*感染*からの回復を示唆する場合もあれば、キャリア状態への発展を示唆している場合もあり、又は非特異血清学的反応による場合もある。非構造タンパク質に対する抗体が、精製性の条件を満たさないワクチンによる*ワクチン接種*を繰り返したことによって誘導される場合もある。ただし、そのようなワクチンの使用は、公式ステイタスを申請する国又は*地域*では許可されない。FMDV の*感染*及び伝搬の

証拠がない場合には、そのような所見が、新たな*発生*の宣言を正当化することにはならず、追跡調査によって完全なものになるとみなされる場合もある。

ただし、血清学的陽性動物の数が、使用された診断試験の感受性から予想される偽の陽性結果の数よりも大きい場合には、当該陽性反応動物と接触した、さもなければ疫学的に関連した感受性動物は、追加的に調査を受けるものとする。

図 1　ワクチン接種非実施清浄国又は地域における発生後の FMD 清浄ステイタス回復の最短待機期間及び経路の概略図



待機期間は、関係条文に規定されるサーベイランス結果に応じた最短のものである。異なる管理措置によっていくつかの待機期間が当てはまる場合には、最長の待機期間が適用される。

図２　ワクチン接種実施清浄国又は地域における発生後の FMD 清浄ステイタス回復の最短待機期間及び経路の概略図

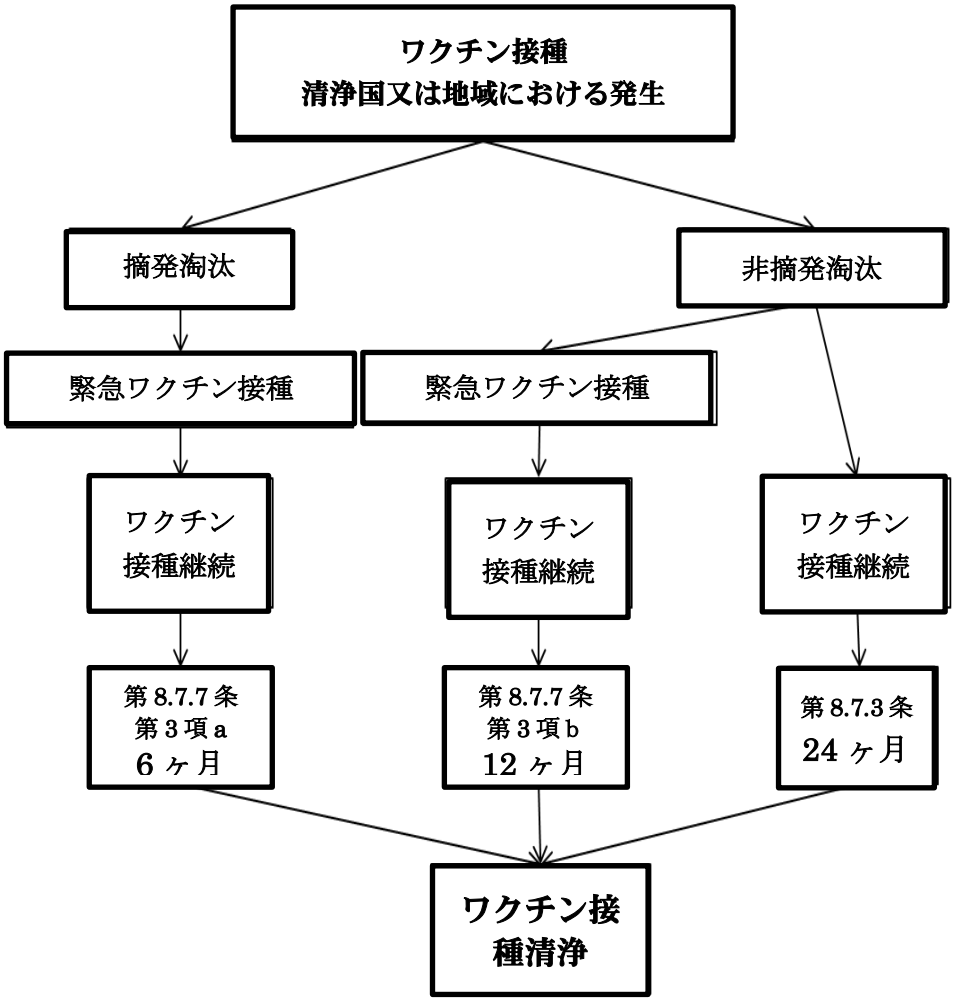


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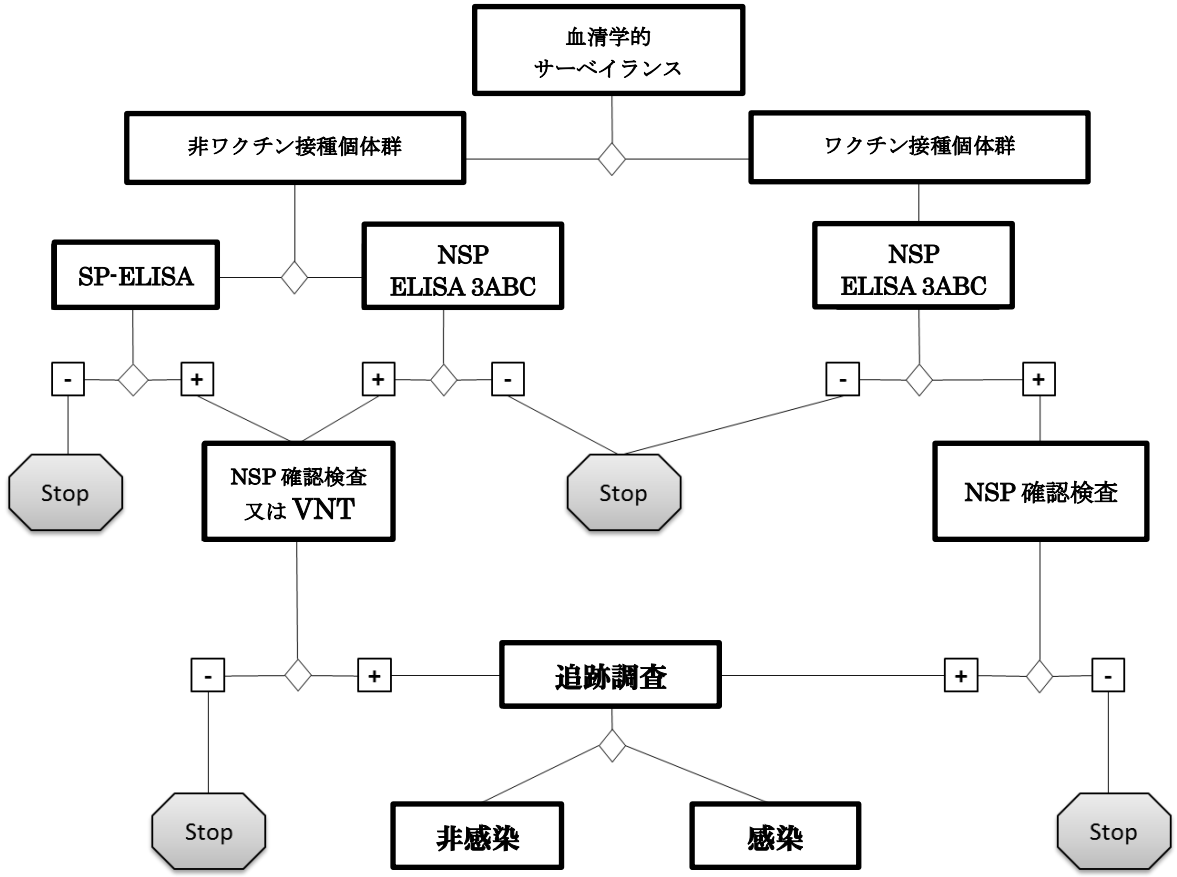
図３ 血清学的調査による FMDV 感染の証拠を確定するための検査施設試験の概略図



略語及び頭字語	
ELISA	酵素結合免疫吸着法
VNT	ウイルス中和試験
NSP	口蹄疫ウイルス非構造タンパク質
3ABC	NSP抗体試験
SP	口蹄疫ウイルス構造タンパク質