CHAPTER 8.8

INFECTION WITH FOOT AND MOUTH DISEASE VIRUS

Article.8.8.1

General provisions

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

2. For the purposes of the *Terrestrial Code*, foot and mouth disease (FMD) is defined as an *infection* of the following *animals* (hereafter 'susceptible *animals*') with FMDV:

- *animals* of the family *Suidae*;

- *animals* of the subfamilies *bovinae*, *caprinae* and *antilopinae* of the family *Bovidae* and family *Cervidae* (hereafter 'ruminants'); and

- *Camelus bactrianus.*

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

    a. FMDV has been isolated and identified as such from a sample from a susceptible *animal*; or

    b. antigen or nucleic acid specific to FMDV has been detected in a sample from a susceptible *animal*, showing clinical signs consistent with FMD, or epidemiologically linked to a confirmed or suspected *case*of FMD, or giving cause for suspicion of previous association or contact with FMDV; or

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

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

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

6. FMDV may persist in the pharynx and associated lymph nodes of some ruminants beyond 28 days after *infection*, but not indefinitely. Such *animals* have been termed carriers. However, the only species for which transmission of FMDV has been proven from carriers is the African buffalo *(Syncerus caffer)*, and transmission of FMDV from African buffalo to domestic livestock is rare.

7. Standards for diagnosis and vaccines, as well as information on the epidemiology, are described in the *Terrestrial Manual*.

Article.8.8.2

Safe commodities

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

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1. Ultra-high temperature (UHT) *milk* and derivatives thereof;
2. heat-treated *meat products* in a hermetically sealed *container* with a F_0 value of 3 or above;
3. *protein meal*;
4. gelatine;
5. *in vivo* derived bovine embryos collected, processed and stored in accordance with Chapter 4.8.;
6. limed hides, pickled pelts, and semi-processed leather;
7. extruded dry pet food.

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

Article.8.8.3

Country or zone free from FMD where vaccination is not practised

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

1. there has been no *case* of *infection* with FMDV;
2. the *Veterinary Authority* has current knowledge of, and authority over, all *herds* of domestic and *captive wild* susceptible *animals* in the country or *zone*;
3. the *Veterinary Authority* has current knowledge of the distribution and habitat of *wild* and *feral* susceptible *animals* in the country or *zone*;
4. appropriate *surveillance* has been implemented in accordance with:
    a. point 2 b) of Article 1.4.6. where historical freedom can be demonstrated; or
    b. Articles 8.8.43. to 8.8.45. where historical freedom cannot be demonstrated, which includes the detection of clinical signs of FMD and demonstrates:
        i. no *infection* with FMDV in unvaccinated *animals*;
        ii. no transmission of FMDV in previously vaccinated *animals*;
5. measures to prevent the introduction of the *infection* have been in place; in particular, the importations or movements of *commodities* into the country or *zone* have been carried out in accordance with this chapter or other relevant chapters of the *Terrestrial Code*, including Chapter 2.1. 'Import *risk analysis*'. Unless otherwise specified in this chapter, movements of *commodities* within a country between *zones* of different *animal health status* should comply with the same requirements as for importation;
6. *vaccination* against FMD is prohibited and the prohibition has been effectively implemented and supervised.

The country or *zone* will be included in the list of countries or *zones* free from FMD, where *vaccination* is not practised in accordance with Chapter 1.6.

Retention on the list requires annual reconfirmation of compliance with all points above and provisions under point 4 of Article 1.4.6. Documented evidence should be resubmitted annually for all points above. Any changes in the epidemiological situation or other significant events should be notified to WOAH in accordance with Chapter 1.1.

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

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that the following conditions are met:

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

- appropriate *biosecurity* is in place, including effective separation from other susceptible domestic *populations* or *wildlife*;

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

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

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

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

A country or *zone* free from FMD where *vaccination* is not practised may maintain its free status despite an incursion of African buffaloes from a neighbouring infected country or *zone* provided that it is demonstrated that the provisions in this article continue to be met and documented evidence has been submitted to and accepted by WOAH.

Article.8.8.4

Country or zone free from FMD where vaccination is practised

A country or *zone* may be considered free from FMD where *vaccination* is practised when the relevant provisions in point 2 of Article 1.4.6. have been complied with, and when within the country or *zone*:

1. for at least the past 12 months:
    a. there has been no transmission of FMDV;
    b. there has been no *case* of *infection* with FMDV;
    c. the *Veterinary Authority* has current knowledge of, and authority over, all *herds* of domestic and *captive wild* susceptible *animals* in the country or *zone*;
    d. the *Veterinary Authority* has current knowledge of the distribution and habitat of *wild* and *feral* susceptible *animals* in the country or *zone*;
    e. compulsory systematic *vaccination* in the target *population* has been carried out to achieve adequate *vaccination* coverage and *population* immunity; based on the epidemiology of FMD in the country or *zone*, the target *population* should be defined in accordance with Chapter 4.18.;
    f. *vaccination* has been carried out following appropriate vaccine strain selection;
    g. measures to prevent the introduction of *infection* have been in place; in particular, the importations or movements of *commodities* into the country or *zone* have been carried out in accordance with this chapter or other relevant chapters of the *Terrestrial Code*, including Chapter 2.1. 'Import *risk analysis*';
2. for the past 24 months appropriate *surveillance* has been implemented in accordance with Articles 8.8.43. to 8.8.45. and demonstrates points 1 a) and 1 b) above.

The country or *zone* will be included in the list of countries or *zones* free from FMD where *vaccination* is practised in accordance with Chapter 1.6.

Retention on the list requires annual reconfirmation of compliance with all points above and relevant provisions under point 4 of Article 1.4.6. Documented evidence should be resubmitted annually for all points above. Any changes in the epidemiological situation or other significant events should be notified to WOAH in accordance with Chapter 1.1.

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Article.8.8.5

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

As recommended in Article 4.18.10., *vaccination* programmes may include an exit strategy.

If a Member Country that meets the requirements of a country or *zone* free from FMD where *vaccination* is practised and is recognised by WOAH as such, wishes to change its status to country or *zone* free from FMD where *vaccination* is not practised, it should notify WOAH in advance of the intended date of cessation of *vaccination* and apply for the new status within 24 months of the cessation. The status of this country or *zone* remains unchanged until compliance with Article 8.8.3. is *approved* by WOAH. If the application for the new status is not provided within 24 months of the cessation or if the compliance is not *approved* by WOAH, then evidence should be provided that it complies with Article 8.8.4. Otherwise, the status of the country or *zone* as being free from FMD where *vaccination* is practised is suspended.

If a Member Country that meets the requirements of a country or *zone* free from FMD where *vaccination* is not practised and is recognised by WOAH as such, wishes to change its status to country or *zone* free from FMD where *vaccination* is practised, it should provide WOAH with an application in accordance with Chapter 1.11. The status of the country or *zone* as free from FMD where *vaccination* is not practised remains unchanged until the application and plan are *approved* by WOAH. As soon as it is recognised as free from FMD where *vaccination* is practised, the country or *zone* should begin the *vaccination*. Then the Member Country should provide evidence within six months that it has complied with Article 8.8.4. Otherwise, the status is suspended.

Article.8.8.6

Compartment free from FMD where vaccination is not practised

A *compartment* free from FMD where *vaccination* is not practised can be established in any country or *zone*. In defining such a *compartment* the principles of Chapters 4.4. and 4.5. should be followed. Susceptible *animals* in the free *compartment* should be separated from any other susceptible *animals* by the effective application of a *biosecurity plan*.

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

1. have a record of regular and prompt *animal* disease reporting and, if not free, have an *official control programme* and a *surveillance* system for FMD in place in accordance with Articles 8.8.43. to 8.8.45. that allows knowledge of the *prevalence*, distribution and characteristics of FMD in the country or *zone*;

2. declare for the free *compartment* that:

    a. no *infection* with FMDV has occurred during the past 12 months;

    b. *vaccination* against FMD is prohibited;

    c. no *animal* vaccinated against FMD within the past 12 months is in the *compartment*;

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

    e. documented evidence shows that *surveillance* in accordance with Articles 8.8.43. to 8.8.45. is in operation;

    f. an *animal identification* and *traceability* system in accordance with Chapters 4.2. and 4.3. is in place;

3. describe in detail:

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

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

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

Article.8.8.7

Compartment free from FMD where vaccination is practised

A *compartment* free from FMD where *vaccination* is practised can be established in either a free country or *zone* where *vaccination* is practised or in an infected country or *zone*. In defining such a *compartment* the principles of Chapters 4.4. and 4.5. should be followed. Susceptible *animals* in the free *compartment* should be separated from any other susceptible *animals* by the application of an effective *biosecurity plan*.

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

1. have a record of regular and prompt *animal* disease reporting and, if not free, have an *official control programme* and a *surveillance* system for FMD in place in accordance with Articles 8.8.43. to 8.8.45. that allows knowledge of the *prevalence*, distribution and characteristics of FMD in the country or *zone*;

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

    a. no *infection* or transmission of FMDV has occurred during the past 12 months;

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

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

    d. documented evidence shows that regular clinical, serological and virological *surveillance* in accordance with Articles 8.8.43. to 8.8.45. is in operation, so as to detect *infection* or transmission at an early stage with a high level of confidence;

    e. an *animal identification* and *traceability* system in accordance with Chapters 4.2. and 4.3. is in place;

3. describe in detail:

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

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

    c. implementation of points 2 b), 2 d) and 2 e).

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

Article.8.8.8

Country or zone infected with FMDV

A country or *zone* shall be considered as infected with FMDV when the conditions in points 1 to 6 of Article 8.8.3. or points 1 and 2 of 8.8.4. are not met.

Article.8.8.9

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

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

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

1. the susceptible *animal populations* within the *protection zone* are clearly identified as belonging to the *protection zone*;
2. strict movement control of susceptible *animals* and their products is in place in line with the relevant provisions of this chapter;
3. increased *surveillance* in accordance with Articles 8.8.43. to 8.8.45. is in place in the *protection zone* and enhanced awareness in the rest of the country or *zone*;
4. intensified *biosecurity* in the *protection zone* is in place;
5. awareness campaigns aimed at the general public, breeders, traders, *veterinarians* and other relevant stakeholders are implemented;
6. a *biosecurity plan* is in place, which may include the implementation of emergency *vaccination*, in particular when the *protection zone* is established in a country or *zone* free from FMD where *vaccination* is not practised.

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

If *vaccination* is implemented in the *protection zone* established within a country or *zone* free from FMD where *vaccination* is not practised, the free status of the *protection zone* is suspended and the free status of the rest of the country or *zone* is not affected. The status of the *protection zone* can be recovered following point 1 of Article 8.8.11. Alternatively, should the Member Country wish to maintain *vaccination* in the *protection zone*, Article 8.8.5. applies.

In the event of an *outbreak* within a previously free *protection zone*, the free status of the *protection zone* is suspended and the status of the *protection zone* can be recovered following Article 8.8.11., while the free status of the rest of the country or *zone* is not affected. Alternatively, if the *Veterinary Authority* establishes a *containment zone* after an *outbreak* in the protection *zone*, an application in accordance with Articles 4.4.7. and 8.8.10. should be submitted as soon as possible. In particular, when applying for a *containment zone*, it should be stated whether the boundaries would be the same as the boundaries of the protection *zone* or within the boundaries of the protection *zone*.

A *protection zone*, in which the free status has remained unchanged, should not last more than 24 months from the date of its approval by WOAH. During this period, the Member Country should either inform WOAH of the lifting of the *protection zone* or apply for its official recognition of the *protection zone* as a *zone* in accordance with either Article 8.8.3. or Article 8.8.4.

Article.8.8.10

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

In the event of *outbreaks* within a country or *zone* previously free from FMD where *vaccination* is either practised or not, including within a *protection zone*, a *containment zone*, which includes all epidemiologically linked *outbreaks*, may be established, in accordance with Article 4.4.7., to minimise the impact on the 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 WOAH, in addition to the requirements of Article 4.4.7. documented evidence that:

1. on suspicion, a standstill has been imposed on the suspected *establishments* and effective controls on the movement of *animals* and other *commodities* are in place in the country or *zone*;

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2. on confirmation, the standstill and movement controls described in point 1 have been reinforced;

3. epidemiological investigations into the likely source of the *outbreaks* have been carried out;

4. *surveillance* in accordance with Articles 8.8.43. to 8.8.45. is in place in the *containment zone* and in the rest of the country or *zone*;

5. 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 8.8.11., once the *containment zone* has been *approved* by WOAH as complying with points 1 to 5 above.

In the event of recurrence of *infection* with FMDV in unvaccinated *animals* or transmission of FMDV in vaccinated *animals* in the *containment zone*, established in accordance with point 4 a) of Article 4.4.7., the approval of the *containment zone* is withdrawn and the free status of the whole country or *zone* is suspended until the relevant requirements of Article 8.8.11. are fulfilled.

In the event of occurrence of *infection* with FMDV in unvaccinated *animals* or transmission of FMDV in vaccinated *animals* in the outer *zone* of a *containment zone* established in accordance with point 4 b) of Article 4.4.7., the approval of the *containment zone* is withdrawn and the free status of the whole country or *zone* is suspended until the relevant requirements of Article 8.8.11. are fulfilled.

The recovery of the free status of the *containment zone* should be achieved within 24 months of its approval and follow the provisions of Article 8.8.11., otherwise the status of the rest of the country or *zone* is suspended.

Article.8.8.11

Recovery of free status

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

    a. three months after the disposal of the last *animal* killed where a *stamping-out policy*, without emergency *vaccination*, and *surveillance* are applied in accordance with Articles 8.8.43. to 8.8.45.; or

    b. three months after the disposal of the last *animal* killed or the *slaughter* of all vaccinated *animals*, whichever occurred last, where a *stamping-out policy*, emergency *vaccination* and *surveillance* in accordance with Articles 8.8.43. to 8.8.45. are applied; or

    c. six months after the disposal of the last *animal* killed or the last *vaccination*, whichever occurred last, where a *stamping-out policy*, emergency *vaccination* not followed by the slaughtering of all vaccinated *animals*, and *surveillance* in accordance with Articles 8.8.43. to 8.8.45. are applied. However, this requires a serological survey based on the detection of antibodies to NSP of FMDV to demonstrate no transmission of FMDV in the vaccinated *population*. This period can be reduced to a minimum of three months if a country can submit sufficient evidence demonstrating absence of *infection* in the non-vaccinated *population*, and absence of transmission in the emergency vaccinated *population* based on the provisions of point 7 of Article 8.8.43.

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

    The time periods in points 1 a) to 1 c) are not affected if official emergency *vaccination* of zoological collections has been carried out following the relevant provisions of Article 8.8.3.

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

2. When *infection* with FMDV occurs in a country or *zone* previously free from FMD where *vaccination* is not practised, the following waiting period is required to gain the status of country or *zone* free from FMD where *vaccination* is practised: six months after the disposal of the last *animal* killed where a *stamping-out policy* has been applied and a continued *vaccination* policy has been adopted, provided that *surveillance* is applied in accordance with Articles 8.8.43. to 8.8.45., and a serological survey based on the detection of antibodies to NSP of FMDV demonstrates no transmission of FMDV.

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The country or *zone* can gain the status of free from FMD where *vaccination* is practised only after the submitted evidence, based on the provisions of Chapter 1.11. has been accepted by WOAH.

Where a *stamping-out policy* is not practised, the above waiting period does not apply, and Article 8.8.4. applies.

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

    a. six months after the disposal of the last *animal* killed where a *stamping-out policy*, with emergency *vaccination*, and *surveillance* in accordance with Articles 8.8.43. to 8.8.45. are applied, provided that serological *surveillance* based on the detection of antibodies to NSP of FMDV demonstrates no transmission of FMDV. This period can be reduced to a minimum of three months if a country can submit sufficient evidence demonstrating absence of *infection* in the non-vaccinated *population* and absence of transmission of FMDV in the vaccinated *population* based on the provisions of points 7 and 8 of Article 8.8.43. as appropriate; or

    b. 12 months after the detection of the last *case* where a *stamping-out policy* is not applied, but where emergency *vaccination* and *surveillance* in accordance with Articles 8.8.43. to 8.8.45. are applied, provided that serological *surveillance* based on the detection of antibodies to NSP of FMDV demonstrates no evidence of transmission of FMDV.

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

    When emergency *vaccination* is not applied, the above waiting periods do not apply, and Article 8.8.4. applies.

4. When *infection* with FMDV occurs in a *compartment* free from FMD, Article 8.8.6. or Article 8.8.7. 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 only when FMD has been successfully eradicated within the *containment zone* and status has been regained following the provisions in this article.

For Member Countries not applying for recovery within 24 months after suspension of status, the provisions of Article 8.8.3., Article 8.8.4., Article 8.8.5. or Article 8.8.6. apply.

Article.8.8.12

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

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

1. no 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* are transported under the supervision of the *Veterinary Authority* in a *vehicle*, which was cleansed and disinfected before *loading*, directly from the *establishment* of origin to the *slaughterhouse/abattoir* without coming into contact with other susceptible *animals*;

5. the *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* are subjected to thorough cleansing and *disinfection* immediately after use.

The *animals* should have been subjected to ante- and post-mortem inspection within 24 hours before and after *slaughter* with no evidence of FMD, and the *meat* derived from them treated in accordance with point 2 of Article 8.8.24. or Article 8.8.27. For ruminants, the head, including the pharynx, tongue and associated lymph nodes, was either destroyed or treated in accordance with Article 8.8.34.

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Other products obtained from the *animals* and any products coming into contact with them should be treated in accordance with Articles 8.8.34. to 8.8.41. in order to inactivate any FMDV potentially present.

Article.8.8.13

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

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 country, *zone* or *compartment* free from FMD where *vaccination* is not practised;
3. if transiting an infected *zone*, were not exposed to any source of FMDV during transportation to the *place of shipment*;
4. if previously vaccinated, comply with point 4 of Article 8.8.14.

Article.8.8.14

Recommendations for importation of susceptible animals from countries, zones or compartments free from FMD where vaccination is practised

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 country, *zone* or *compartment* free from FMD where *vaccination* is practised;
3. if not vaccinated were subjected to a virological test for FMD with negative result on a sample collected not earlier than 14 days before shipment;
4. if vaccinated were subjected to virological and NSP serological tests for FMD with negative results on samples collected not earlier than 14 days before shipment;
5. if transiting an infected *zone*, were not exposed to any source of FMDV during transportation to the *place of shipment*.

Article.8.8.15

Recommendations for the importation of vaccinated susceptible animals destined for slaughter from a country, zone or compartment free from FMD where vaccination is practised

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

1. no *animal* in the *establishment* of origin has shown clinical signs of FMD for at least 30 days prior to shipment;
2. the *animals* were kept in the country, *zone* or *compartment* of origin since birth or for at least three months prior to shipment;
3. the *animals* were transported under the supervision of the *Veterinary Authority* directly from the *establishment* of origin in sealed vehicles/vessels;
4. if transiting an *infected zone*, the *animals* were not exposed to any source of FMDV during transportation to the *place of shipment*.

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Article.8.8.16

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

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. if pigs, they have not been fed *swill* not complying with Article 8.8.35.;
3. prior to *isolation*, the *animals* were kept in the *establishment* of origin:
    a. for 30 days, or since birth if younger than 30 days, if a *stamping-out policy* is applied to control FMD in the *exporting country* or *zone*, or
    b. for three months, or since birth if younger than three months if a *stamping-out policy* is not applied to control FMD in the *exporting country* or *zone*;
4. the *establishment* of origin is covered by the *official control programme* and FMD has not occurred within it for the relevant period as defined in points 3 a) and 3 b) above;
5. the *animals* were isolated for the 30 days prior to shipment:
    a. in a quarantine station, 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, or
    b. in an *establishment* that is not a quarantine station, *infection* with FMDV did not occur within a 10-kilometre radius of the *establishment* during that period, 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;
6. the *animals* were not exposed to any source of FMDV during their transportation from the *establishment* to the *place of shipment*.

Article.8.8.17

Recommendations for importation of fresh and frozen semen of domestic ruminants and pigs from countries, zones or compartments free from FMD where vaccination is not practised

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

1. the donor males:
    a. showed no clinical sign of FMD on the day of collection of the semen;
    b. were kept for at least three months prior to collection in a country, *zone* or *compartment* free from FMD where *vaccination* is not practised;
2. the semen was collected, processed and stored in accordance with Chapters 4.6. and 4.7.

Article.8.8.18

Recommendations for importation of frozen semen of domestic ruminants and pigs from countries, zones or compartments free from FMD where vaccination is practised

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

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1. the donor males:

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

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

    c. either

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

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

2. the semen:

    a. was collected, processed and stored in accordance with Chapters 4.6. and 4.7.;

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

Article.8.8.19

Recommendations for importation of frozen semen of domestic ruminants and pigs from countries or zones infected with FMDV

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

1. the donor males:

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

    b. were kept in a *semen collection centre* to which no *animal* had been added in the 30 days before collection, and within a 10-kilometre radius of which FMD has not occurred in the 30 days before and after collection;

    c. either

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

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

2. the semen:

    a. was collected, processed and stored in accordance with Chapters 4.6. and 4.7.;

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

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

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Article.8.8.20

Recommendations for importation of in vitro produced bovine embryos from countries, zones or compartments free from FMD where vaccination is not practised

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 country, *zone* or *compartment* free from FMD where *vaccination* is not practised;
2. fertilisation was achieved with semen meeting the conditions referred to in Articles 8.8.17., 8.8.18. or 8.8.19., as relevant;
3. the oocytes were collected, and the embryos were processed and stored in accordance with Chapters 4.8., 4.9., and 4.10., as relevant.

Article.8.8.21

Recommendations for importation of in vitro produced bovine embryos from countries, zones or compartments free from FMD where vaccination is practised

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 country, *zone* or *compartment* free from FMD where *vaccination* is practised;
    c. either
        i. have been vaccinated at least twice with the last *vaccination* not more than six months, unless protective immunity has been demonstrated for more than six months, and not less than one month prior to collection;
        or
        ii. were subjected, not less than 21 days and not more than 60 days after collection, to tests for antibodies against FMDV, with negative results;
2. fertilisation was achieved with semen meeting the conditions referred to in Articles 8.8.17., 8.8.18. or 8.8.19., as relevant;
3. the oocytes were collected, and the embryos were processed and stored in accordance with Chapters 4.8., 4.9., and 4.10. as relevant.

Article.8.8.22

Recommendations for importation of fresh meat or meat products of susceptible animals from countries, zones or compartments free from FMD where vaccination is not practised

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

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1. have been kept in a country, *zone* or *compartment* free from FMD where *vaccination* is not practised or have been imported in accordance with Article 8.8.13., Article 8.8.14., Article 8.8.15. or Article 8.8.16.;

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

Article.8.8.23

Recommendations for importation of fresh meat and meat products of susceptible animals from countries, zones or compartments free from FMD where vaccination is practised

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

1. that have been kept in the country, *zone* or *compartment* free from FMD where *vaccination* is practised, or which have been imported in accordance with Article 8.8.13., Article 8.8.14., Article 8.8.15. or Article 8.8.16.;

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

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

Article.8.8.24

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

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

EITHER

1. comes from bovines that comply with Article 8.8.13., 8.8.14., 8.8.15. or 8.8.16.; and the carcasses were not released earlier than 24 hours after *slaughter* and not before *Veterinary Authorities* have confirmed that FMD has not occurred in the *establishment* of origin;

   OR

2.

   a. comes from bovines which:

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

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

      iii. were kept for the past 30 days in:

         - a quarantine station; or

         - an *establishment*, within a 10-kilometre radius of which FMD has not occurred during that period;

      iv. have been transported, in a *vehicle* which was cleaned and disinfected before *loading*, directly from the *establishment* of origin or quarantine station to the *approved slaughterhouse/abattoir* without coming into contact with other FMD susceptible *animals* which do not fulfil the required conditions for export;

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v. have been slaughtered in an *approved slaughterhouse/abattoir*:

- which is officially designated for export;

- 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;

vi. were subjected to ante- and post-mortem inspections in accordance with Chapter 6.3., with favourable results;

b. comes from deboned carcasses:

i. from which feet, head, viscera and the major lymphatic nodes have been removed;

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

Article.8.8.25

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

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

1. the *meat* comes from pigs complying with Article 8.8.13., 8.8.14., 8.8.15. or 8.8.16.;

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

3. the pigs were slaughtered in an *approved slaughterhouse/abattoir*:

   a. which is officially designated for export;

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

4. the pigs were subjected to ante- and post-mortem inspections in accordance with Chapter 6.3., with favourable results;

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

Article.8.8.26

Recommendations for importation of fresh meat of sheep and goats from FMD infected countries or zones where an official control programme exists

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

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

2. sheep and goats that were slaughtered in an *approved slaughterhouse/abattoir*:

   a. which is officially designated for export;

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

3. sheep and goats that were subjected to ante- and post-mortem inspections in accordance with Chapter 6.3., with favourable results; and

EITHER

4. sheep and goats that comply with Article 8.8.13., 8.8.14., 8.8.15. or 8.8.16.; and the carcasses were not released earlier than 24 hours after *slaughter* and not before *Veterinary Authorities* have confirmed that FMD has not occurred in the *establishment* of origin;

OR

5. sheep and goats that:

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

b. were kept for the past 30 days in:

– a quarantine station; or

– an *establishment*, within a ten-kilometre radius of which FMD has not occurred during that period, and no susceptible *animals* were introduced into the *establishment* during that period;

c. had their carcasses deboned:

i. from which feet, head, viscera and the major lymphatic nodes have been removed;

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

Article.8.8.27

Recommendations for importation of meat products of susceptible animals from countries or zones infected with FMDV

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

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

2. the *meat products* come from *meat* that complies with Articles 8.8.24., 8.8.25. or 8.8.26., or they have been processed to ensure the inactivation of FMDV in accordance with one of the procedures in Article 8.8.34.;

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

Article.8.8.28

Recommendations for importation of animal products (other than those covered by other articles) from countries, zones or compartments free from FMD whether vaccination is practised or not

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products come from *animals* which have been kept in a country, *zone* or *compartment* free from FMD, or which have been imported in accordance with Article 8.8.13., Article 8.8.14., Article 8.8.15. or Article 8.8.16.

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Article.8.8.29

Recommendations for importation of milk and milk products (other than those listed in Article 8.8.2.) from countries or zones infected with FMDV

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

1. these products:
    a. originate from *herds* which at the time of *milk* collection were not infected or suspected of being infected with FMDV, and comes from *milk* that:
        i. has a pH less than 7 or has been tested for FMDV with negative results, and
        ii. has been heated at a minimum temperature of 72°C for at least 15 seconds;
    or
    b. have been processed to ensure the inactivation of FMDV in accordance with one of the procedures in Article 8.8.39.;
2. the necessary precautions were taken after processing to avoid contact of the products with any potential source of FMDV.

Article.8.8.30

Recommendations for importation of wool, hair, bristles, raw hides and skins from domestic susceptible animals from countries or zones infected with FMDV

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

1. these products have been processed to ensure the inactivation of FMDV in accordance with one of the procedures in Articles 8.8.36., 8.8.37. and 8.8.38.;
2. the necessary precautions were taken after collection and processing to avoid contact of the products with any potential source of FMDV.

Article.8.8.31

Recommendations for importation of straw and forage from countries or zones infected with FMDV

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

1. are free of grossly identified contamination with material of *animal* origin;
2. have been subjected to one of the following treatments, which, in the *case* of material sent in bales, has been shown to penetrate to the centre of the bale:
    a. either to the action of steam in a closed chamber such that the centre of the bales has reached a minimum temperature of 80°C for at least 10 minutes,
    b. or to the action of formalin fumes (formaldehyde gas) produced by its commercial solution at 35-40% in a chamber kept closed for at least eight hours and at a minimum temperature of 19°C;

OR

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

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Article.8.8.32

Recommendations for importation of skins and trophies derived from susceptible animals (other than those listed in Article 8.8.2.) from countries, zones or compartments free from FMD, whether vaccination is practised or not

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

Article.8.8.33

Recommendations for importation of skins and trophies derived from susceptible animals (other than those listed in Article 8.8.2.) from countries or zones infected with FMDV

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products have been processed to ensure the inactivation of FMDV in accordance with one of the procedures in Article 8.8.40.

Article.8.8.34

Procedures for the inactivation of FMDV in meat and meat products of susceptible animals

For the inactivation of FMDV present in *meat* and *meat products* of susceptible *animals*, 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.

2. Thorough cooking

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

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

3. Drying after salting

   When *rigor mortis* is complete, the *meat* is deboned, treated with salt (NaCl) and 'completely dried', so that the moisture protein ratio is not greater than 2.25:1 or the water activity (a_w) is not greater than 0.85.

4. Any equivalent treatment which has been demonstrated to inactivate FMDV in *meat* and *meat* product.

Article.8.8.35

Procedures for the inactivation of FMDV in swill

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

1. the *swill* is maintained at a temperature of at least 90°C for at least 60 minutes, with continuous stirring; or
2. the *swill* is maintained at a temperature of at least 121°C for at least ten minutes at an absolute pressure of 3 bar; or
3. the *swill* is subjected to an equivalent treatment that has been demonstrated to inactivate FMDV.

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Article.8.8.36

Procedures for the inactivation of FMDV in wool and hair

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

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

Article.8.8.37

Procedures for the inactivation of FMDV in bristles

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

1. boiling for at least one hour; or
2. immersion for at least 24 hours in a 1% aqueous solution of formaldehyde.

Article.8.8.38

Procedures for the inactivation of FMDV in raw hides and skins

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

Article.8.8.39

Procedures for the inactivation of FMDV in milk and milk products

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

1. a process applying a minimum temperature of 72°C for at least 15 seconds (high temperature - short time pasteurisation [HTST]) applied twice; or
2. any equivalent treatment that has been demonstrated to inactivate FMDV in *milk*.

Article.8.8.40

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

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

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

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

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

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

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

Article.8.8.41

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

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

Article.8.8.42

WOAH endorsed official control programme for FMD

A Member Country may, on a voluntary basis, apply for endorsement of its *official control programme* for FMD in accordance with Chapter 1.6., when it has implemented measures in accordance with this article.

For a Member Country"s *official control programme* for FMD to be endorsed by WOAH, the Member Country should provide a description of an *official control programme* for the control and eventual *eradication* of FMD in the country or *zone*. This document should address and provide documented evidence on the following:

1. epidemiology:

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

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

2. *surveillance* and diagnostic capabilities:

    a. FMD *surveillance* in place, in accordance with Chapter 1.4. and Articles 8.8.43. to 8.8.45.;

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

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

3. *vaccination*:

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

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

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

ii. target *populations* for *vaccination*;

iii. target geographical area for *vaccination*;

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

v. the strategy to identify vaccinated *animals*;

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

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

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

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

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

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

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

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

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

Retention on the list requires an annual update on the progress of the *official control programme* and information on significant changes concerning the points above.

Article.8.8.43

General principles of surveillance

Articles 8.8.43. to 8.8.45. define the principles and provide a guide for the *surveillance* of FMD in accordance with Chapter 1.4. applicable to Member Countries seeking *establishment*, maintenance or recovery of freedom from FMD at the country, *zone* or *compartment* level or seeking endorsement by WOAH of their *official control programme* for FMD, in accordance with Article 8.8.42. *Surveillance* aimed at identifying disease and *infection* with, or transmission of, FMDV should cover domestic and, where appropriate, *wildlife* species as indicated in point 2 of Article 8.8.1.

1. Early detection

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

2. Demonstration of freedom

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

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approach designed to demonstrate freedom from FMD in a country or *zone* where African buffaloes *(Syncerus caffer)* provide a potential reservoir of *infection*.
Surveillance for FMD should be in the form of a continuing programme. Programmes to demonstrate no evidence of *infection* with, and transmission of, FMDV should be carefully designed and implemented to avoid producing results that are insufficient to be accepted by WOAH 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 *vaccination* has been practised or not.

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

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

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

3. WOAH endorsed *official control programme*

Surveillance strategies employed in support of a WOAH endorsed *official control programme* should 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 *infection* with, and transmission of, FMDV and to understand the epidemiology of FMD as part of the *official control programme*.

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

4. *Surveillance* strategies

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

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

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

An effective *surveillance* system will identify suspected *cases* that require immediate follow-up and investigation to confirm or exclude that the cause of the condition is FMDV. Samples should be taken and submitted for diagnostic testing, unless the suspected *case* can be confirmed or ruled out by epidemiological and clinical investigation. Details of the occurrence of suspected

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cases and how they were investigated and dealt with should be documented. This should include the results of diagnostic testing and the control measures to which the *animals* concerned were subjected during the investigation.
The sensitivity and specificity of the diagnostic tests employed, including the performance of confirmatory tests, are key factors in the design, sample size determination and interpretation of the results obtained. Selection of diagnostic tests and interpretation of results should take into account the *vaccination* or *infection* history and production class of *animals* in the target *population*.

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

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

- characterisation of the existing production systems;

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

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

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

- identification and traceability of *animals* and control of their movements;

- other parameters of regional significance in historic transmission of FMDV.

6. Demonstration of *population* immunity

Following routine *vaccination*, evidence should be provided to demonstrate the effectiveness of the *vaccination* programme such as adequate *vaccination* coverage and *population* immunity. This can support the interpretation of post-*vaccination* surveys for residual *infection* and transmission.

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

7. Additional measures for early recovery of status free from FMD where *vaccination* is not practised or early recovery of status free from FMD where *vaccination* is practised in the area(s) where emergency *vaccination* has been applied but not followed by the slaughtering of all vaccinated *animals*

In addition to the general conditions described in this chapter, a Member Country seeking either recovery of status of a country or *zone* previously free from FMD where *vaccination* is not practised, including a *containment zone*, or recovery of status of a country or *zone* previously free from FMD where *vaccination* is practised, earlier than the six months as specified respectively under point 1 c) of Article 8.8.11. or under point 3 a) of Article 8.8.11. should justify the circumstances and measures that demonstrate sufficient confidence to substantiate a claim for freedom. This may be achieved when answering the relevant questionnaire in Chapter 1.11. by demonstrating compliance with either a) or b) and c) below, in the area(s) where emergency *vaccination* has been applied. It is advisable that the *Veterinary Authority* consider the different options for the recovery of a free status when control measures are first implemented at the onset of the *outbreak* in order to plan for the applicable requirements to be met.

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

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

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

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

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

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

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

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

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

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

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

i. Vaccine efficacy

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

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

ii. *Vaccination* effectiveness

- objective and strategy of the emergency *vaccination* deployed;

- evidence of the timeliness of the emergency *vaccination* (start and completion dates);

- evidence of *vaccination* delivery including preservation of vaccine (e.g., cold chain) and at least 95% *vaccination* coverage achieved in the targeted and eligible *population*;

- evidence of high *population* immunity at *herd* and individual level through serological *surveillance*.

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

In addition to the general conditions described in this chapter, a Member Country seeking recovery of status of a country or *zone* previously free from FMD where *vaccination* is practised in the area outside of the area(s) where emergency *vaccination* has been applied, earlier than six months as specified under point 3 a) of Article 8.8.11. should justify the circumstances and measures that demonstrate sufficient confidence to substantiate a claim for freedom. This may be achieved either by meeting the requirements

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listed in a) below or by demonstrating compliance with the requirements listed in b) and c) below, when answering the questionnaire in Article 1.11.2. or Article 1.11.4.
With regard to the *surveillance* requirements listed in b), it should be noted that clinical signs may not be apparent in the routinely vaccinated *population*. The expression of clinical signs would depend on the relationship between the virus strain used in the routine *vaccination* to the virus that caused the *outbreak*. For example, following an incursion of a new serotype it would be expected that the routinely vaccinated *animals* would show clinical signs if infected. In contrast, following an incursion of a serotype or strain covered by the vaccine it would be expected that most of the routinely vaccinated *animals* would be protected and therefore less likely to be infected and to show clinical signs if infected. Other factors such as *vaccination* coverage and timing of *vaccination* could influence the likelihood of *infection* and expression of clinical signs.

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

a. *Establishment* of a *containment zone*

   A *containment zone* that includes all emergency *vaccination* area(s) has been established based on the provisions of Article 8.8.10. to provide assurance that FMD has not occurred in the area outside the emergency *vaccination* area(s).

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

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

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

   iii. intensified clinical and *slaughterhouse/abattoirsurveillance*;

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

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

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

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

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

Article.8.8.44

Methods of surveillance

1. Clinical *surveillance*

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

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

Clinical examination and diagnostic testing should be applied to clarify the status of suspected *cases*. Diagnostic testing may confirm clinical suspicion, while clinical *surveillance* may contribute to confirmation of positive *laboratory* test results. Clinical *surveillance* may be insufficient in 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. However, recognising the difficulty in sampling *wildlife*, *surveillance* of domestic species in close contact with susceptible *wildlife* can provide supportive evidence of the *animal health status* of these *wildlife populations*. Hunting, capture and non-invasive sampling and observation methods can also 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 a WOAH Reference *Laboratory*.

Virological *surveillance* aims to:

a. confirm clinically suspected *cases*;

b. follow up positive serological results;

c. characterise isolates for epidemiological studies and vaccine matching;

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

3. Serological *surveillance*

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

Serological *surveillance* may be used to:

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

b. monitor *population* immunity.

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

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

Article.8.8.45

The use and interpretation of serological tests

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 SP and the NSP of the virus. Vaccinated *animals* produce antibodies mainly or entirely to the SP of the virus depending upon vaccine purity. In unvaccinated *populations*, SP tests may be used to screen sera for evidence of *infection* with, FMDV or to detect the introduction of vaccinated *animals*. In vaccinated *populations*, SP tests may be used to monitor the serological response to the *vaccination*. The SP tests are serotype specific. For optimal sensitivity an antigen or virus closely related to the field strain expected should be selected.

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

Positive FMDV antibody test results can have four possible causes:

- *infection* with FMDV;

- *vaccination* against FMD;

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

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

1. Procedure in *case* of positive test results

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

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

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

Clustering of seropositive results within *herds* or within a region should be investigated as it may reflect any of a series of factors or 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 transmission of FMDV by demonstrating an increase in the number of seropositive *animals* or an increase in antibody titre at the second sampling.

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

In some circumstances, unvaccinated sentinel *animals* may also be used. These can be young *animals* from unvaccinated dams or *animals* in which maternally conferred immunity has lapsed and preferably of the same species as in the positive sampling *units*. If other susceptible, unvaccinated *animals* are present, they could act as sentinels to provide additional serological evidence. The sentinels should be kept in close contact with the *animals* of the *epidemiological unit* under investigation for at least two *incubation periods*. If there is no transmission of FMDV, they will remain serologically negative.

2. Follow-up of field and *laboratory* findings

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

It is difficult to determine the significance of small numbers of seropositive *animals* in the absence of current FMDV transmission. 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 NSP may be induced by repeated *vaccination* with vaccines that do not comply with the requirements for purity. However, the use of such vaccines is not permissible in countries or *zones* applying for an official status. In the absence of evidence of *infection* with, and transmission of, FMDV, such findings do not warrant the declaration of a new *outbreak* and the follow-up investigations may be considered complete.

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

NB: FIRST ADOPTED IN 1968; MOST RECENT UPDATE ADOPTED IN 2024.

nb: first adopted in 1968; most recent update adopted in 2026.

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