Annex 12

CHAPTER 1.11.

**APPLICATION FOR OFFICIAL RECOGNITION BY WOAH OF FREE STATUS FOR FOOT AND MOUTH DISEASE**

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Article 1.11.3.

Zone free from infection with foot and mouth disease virus where vaccination is not practised

The following information should be provided by WOAH Member Countries to support applications for official recognition of status as a *zone* where *vaccination* is not practised that is free from *infection* with foot and mouth disease (FMD) virus in accordance with Chapter 8.8. of the *Terrestrial Code*.

The dossier provided to WOAH should address concisely all the following topics under the headings provided to describe the actual situation in the country and procedures currently applied, explaining how these comply with the *Terrestrial Code*.

The terminology defined in the *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the WOAH official languages. Weblinks to supporting documents in one of the official languages of WOAH may also be provided, where they exist.

All annexes should be provided in one of the WOAH official languages.

The Delegate of the Member Country applying for recognition of FMD zonal freedom must demonstrate compliance with the *Terrestrial Code*. That is, the Delegate should submit documentary evidence that the provisions of Article 8.8.2. have been properly implemented and supervised.

In addition, the Delegate of the Member Country must submit a declaration indicating ~~that~~ for at least the past 12 months:

1) there has been no *case* of *infection* with FMDV ~~during the past 12 months~~;

2) there has been no evidence of FMDV transmission in previously vaccinated animals;

3) *surveillance* for FMD and FMDV transmission in accordance with Articles 8.8.40. to 8.8.42. is in operation, and that regulatory measures for the prevention and control of FMD have been implemented;

4) ~~no~~ *vaccination* against FMD has been prohibited and the prohibition has been effectively implemented and supervised ~~carried out during the past 12 months~~.

In addition, the Delegate of the Member Country applying for recognition of historical zonal freedom must also submit documentary evidence that the provisions in Article 1.4.6. of the *Terrestrial Code* have been properly implemented and supervised.

1. Introduction

a) Geographical features (rivers, mountain ranges, etc.). Provide a general description of the country and the *zone*, and where relevant of the region, including physical, geographical and other factors that are relevant to introduction of *infection* and spread of FMD virus, taking into account the countries or *zones* sharing common borders and other epidemiologic pathways for the potential introduction of the *infection*.

The boundaries of the *zone* must be clearly defined, including a *protection zone* if applied. Provide maps identifying the features above, including a digitalised, geo-referenced map with a ~~precise text~~ description of the geographical boundaries of the *zone*.

b) Livestock demographics. Describe the composition of the livestock industry in the country and the *zone*. In particular, describe:

i) the susceptible animal *population* by species and types of production systems in the country and the *zone*;

ii) the number of *herds* or *flocks*, etc. of each susceptible species;

iii) their geographical distribution;

iv) *herd* or *flock* density;

v) the degree of integration and role of producer organisations in the different production systems;

vi) any recent significant changes observed in the production (attach relevant documents if available).

Provide tables and maps.

c) *Wildlife* demographics. What susceptible *captive wild*, *wild* or *feral* 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 susceptible *wildlife* species?

d) *Slaughterhouses/abattoirs*, markets and events associated with the congregation of susceptible livestock (e.g. fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movement of susceptible domestic species for marketing within the country or *zone*, and between *zones* of the same or different status? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

a) Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislation, regulations and *Veterinary Authority* directives in relation to FMD and a brief description of the relevance of each. The table should include, but not be limited to, the legislation on disease control measures and compensation systems.

b) *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with Chapters 1.1., 3.2. and 3.3. of the *Terrestrial Code*. Describe how the *Veterinary Services* supervise, control, enforce and monitor all FMD-related activities. Provide maps, figures and tables wherever possible.

c) Provide information on any PVS evaluation conducted in the country and follow-up steps within the PVS Pathway and highlight the results relevant to FMD and the susceptible species.

d) Provide a description of the involvement and the participation of industry, producers, farmers, including subsistence and small-scale producers, keepers, *veterinary paraprofessionals* including community animal health workers, and other relevant groups in FMD *surveillance* and control. Provide a description of the role and structure of the private veterinary sector, including the number of *veterinarians* and their distribution, in FMD *surveillance* and control. Include a description of continuing education and awareness programmes on FMD at all relevant levels.

e) *Animal identification*, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the traceability system, including methods of *animal identification* and *establishment* or *herd* or *flock* registration, applicable to all susceptible species. How are movements of all susceptible species controlled in and between *zones* of the same or different status ~~for all production systems~~? Provide evidence of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past 24 months. Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (e.g. seasonal migration).

Describe the actions available under national legislation. Provide information on illegal movements detected in the past 24 months and the action taken.

3. FMD eradication

a) History. If *infection* has never occurred in the country, or has not occurred within the last 25 years, state explicitly whether or not the *zone* is applying for recognition of historical freedom according to Article 1.4.6. of the *Terrestrial Code*.

If *infection* has occurred in the *zone* within the past 25 years, provide a description of the FMD history in the country and *zone*, with emphasis on recent years. If applicable, provide tables and maps showing the date of first detection, the sources and routes of introduction of *infection*, the temporal and spatial distribution (number and location of *outbreaks* per year), the susceptible species involved, the date of last *case* or *eradication* and the types and strains in the country.

b) Strategy. Describe how FMD was controlled and eradicated in the *zone* (e.g. *stamping-out policy*, modified *stamping-out policy*, zoning, *vaccination*, movement control). Provide the time frame for *eradication*. Describe and justify the corrective actions that have been implemented to prevent future *outbreaks* of FMD in response to any past incursions of FMD virus.

c) Vaccines and *vaccination*. Briefly answer the following:

i) Is there any legislation that prohibits *vaccination*? If so:

‒ Provide the date when *vaccination* was formally prohibited;

‒ Provide information on cases of detection of illegal *vaccination* during the reporting period and actions taken in response to the detection.

ii) Was *vaccination* ever used in the *zone*? If so:

‒ Provide the date when the last *vaccination* was carried out;

‒ What type of vaccine was used?

‒ What species were vaccinated?

‒ How were vaccinated animals identified?

‒ What was the fate of those animals?

iii) In addition, if *vaccination* was applied during the past 24 months, provide a description and justification of the *vaccination* strategy and programme, including the following:

‒ the vaccine strains;

‒ potency and formulation, purity, details of any vaccine matching performed;

‒ the species vaccinated;

‒ identification of vaccinated animals;

‒ the way in which the *vaccination* of animals was certified or reported and the records maintained;

‒ evidence that the vaccine used complies with Chapter 3.1.8. of the *Terrestrial Manual*.

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

d) Provide a description of the legislation, organisation and implementation of the *eradication* campaign. Outline the legislation applicable to the *eradication* and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.

4. FMD diagnosis

Provide documentary evidence that the relevant provisions of Chapters 1.1.2., 1.1.3. and 3.1.8. of the *Terrestrial Manual* are applied. The following points should be addressed:

a) Is FMD *laboratory* diagnosis carried out in the country? If so, provide an overview of the FMD-approved *laboratories* in the country. Indicate the *laboratories* where samples originating from the *zone* are diagnosed. Address the following points:

i) How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for reporting results;

ii) Details of test capability and the types of tests undertaken and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of FMD tests performed in the last 24 months in national *laboratories* and in *laboratories* in other countries, if relevant;

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

iv) Provide details of performance in inter-*laboratory* validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;

v) Provide details of the handling of live pathogenic agent, including a description of the biosecurity and biosafety measures applied;

vi) Provide a table identifying the tests carried out by each of the *laboratories* where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.

b) If FMD *laboratory* diagnosis is not carried out in the country, provide the names of the *laboratories* in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the *zone* complies with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code*, and Chapter 3.1.8. of the *Terrestrial Manual*. The following information should be included:

a) What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?

b) Describe how clinical *surveillance* is conducted, including which sectors of the livestock production system are included in clinical *surveillance*, such as *establishments*, markets, fairs, *slaughterhouses/abattoirs*, check points, etc.

Provide a summary table indicating, for the past 24 months, the number of suspected *cases*, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis). Provide an indication of the timelines of the response including completion of testing to confirm or exclude FMD. Provide details of follow-up actions taken on all suspicious and positive results.

c) Serological or virological *surveillance*. Are serological or virological surveys conducted? If so, provide detailed information on the target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used in accordance with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code*. How frequently are surveys conducted? Are susceptible *wildlife* species included in serological or virological surveys? If not, explain the rationale. Describe how previously vaccinated or newly introduced vaccinated animals are considered in the strategy and design of the surveillance programme, if applicable.

Provide a summary table indicating, for the past 24 months, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis). Provide details of follow-up actions taken on all suspicious and positive results and how these findings are acted upon. Provide criteria for selection of *populations* for targeted surveillance based on the risk and numbers of animals examined and samples tested in diagnostic *laboratories*. Provide details of the methods selected and applied for monitoring the performance of the *surveillance* programme including indicators.

d) Provide information on risks 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.). Provide evidence of how the knowledge acquired through these activities assisted in more effective implementation of control measures.

e) Provide details of the oversight of *surveillance* programmes by the *Veterinary Services* including training programmes for personnel involved in clinical, serological and virological *surveillance*, and the approaches used to increase community involvement in FMD *surveillance* programmes.

6. FMD prevention

Describe the procedures in place to prevent the introduction of FMD into the country or *zone*, including details of:

a) Coordination with other countries. Describe any relevant factors in neighbouring countries and *zones* that should be taken into account (e.g. size, distance from the border to affected *herds*, *flocks* or animals). Describe coordination, collaboration and information-sharing activities with other countries and *zones* in the same region or ecosystem.

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

Are *protection zones* in place? If so, indicate whether or not the *protection zone* are included in the proposed FMD free *zones*. Provide details of the measures that are applied (e.g. *vaccination*, intensified *surveillance*, density control of susceptible species), and provide a geo-referenced map of the *zones*.

b) Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the spread of the pathogenic agent within the country or *zone*. Provide evidence that measures to reduce transmission of FMD are in place at markets, such as enhancing awareness of FMD transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity*, hygiene 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).

c) What measures are taken to limit access of susceptible domestic, *feral* and *wild* animals to waste products of animal origin? Is the feeding of swill to pigs regulated? If so, provide information on the extent of the practice, and describe controls and *surveillance* measures.

d) Import control procedures

Provide information on countries, *zones* or *compartments* from which the country authorises the import of susceptible animals or their products into the *zone*. Describe the criteria applied to approve such countries, *zones* or *compartments*, the controls applied to entry of such animals and products, and subsequent internal movement. Describe the import measures (e.g. quarantine) 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 *international veterinary certificates* are required.

Describe any other procedures used for assessing the [*risks*](https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/index.php?id=169&L=1&htmfile=glossaire.htm#terme_risque) posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past 24 months, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species, vaccination status, and the quantity or volume and eventual destination in the country. Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic animals.

i) Provide a map with the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the *border posts*, and between *border posts*.

ii) Provide a description of the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past 24 months, of the quantity disposed of and the disposal locations. What are the biosecurity measures in place at waste disposal sites?

iii) Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the *zone* or their final destination, concerning the import and follow-up of the following:

‒ animals;

‒ genetic material (semen, oocytes and embryos);

‒ *animal products;*

‒ *veterinary medicinal products*;

‒ other materials at risk of being contaminated with FMD virus, including bedding, litter and *feed*.

7. Control measures and contingency planning

a) List any written guidelines, including contingency plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of FMD. The contingency plan should be attached as an annex in one of the WOAH official languages. If not available, provide a brief summary of what is covered. Provide information on any simulation exercise for FMD that was conducted in the country in the past five years.

b) In the event of a suspected or confirmed FMD *outbreak*:

i) Are quarantine measures imposed on *establishments* with suspected *cases*, pending final diagnosis? What other procedures are followed with respect to suspected *cases* (e.g. livestock standstills)?

ii) Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the pathogenic agent;

iii) Describe the actions that would be taken to control the disease situation in and around the *establishments* where the *outbreak* is confirmed;

iv) Provide a detailed description of the control or *eradication* procedures (e.g. forward and backward tracing, movement control, *disinfection* of *establishments*, *vehicles* and equipment, including verification methods, *vaccination* including vaccine delivery and cold chain, *stamping-out policy*, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken. In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;

v) Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological *surveillance* programmes, etc.;

vi) Give details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payments;

vii) Describe how control efforts, including *vaccination* and *biosecurity*, would target critical risk control points.

8. Recovery of free status

Member Countries applying for recognition of recovery of free status for a *zone* where *vaccination* is not practised should comply with the provisions of Article 8.8.7. and points 4, 5 and 6 ~~1, 3 and 4~~ of Article 8.8.2. of the *Terrestrial Code* and provide detailed information as specified in Sections 3, 5 and 6 ~~1-7 (inclusive)~~ of this questionnaire.

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