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MEETING OF THE OIE AD HOC GROUP ON THE EVALUATION OF FOOT AND MOUTH DISEASE STATUS OF MEMBERS[1]

Paris, 6 – 9 November 2017

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A meeting of the OIE *ad hoc* Group on the Evaluation of Foot and Mouth Disease (FMD) Status of Members (hereafter the Group) was held at the OIE Headquarters from 6 to 9 November 2017.

1. Opening

Dr Monique Eloit, Director General of the OIE, welcomed and thanked the Group for its commitment and its extensive support towards the OIE in fulfilling the mandates given by Members. She extended her appreciation to the institutions that kindly allowed the experts to participate in the meeting.

Dr Eloit acknowledged the work and efforts required in reviewing the applications, and made a remark on the recently published procedures for assessing the OIE official status recognition with a vision to increase the transparency and international acceptance of the evaluation process. The OIE was working, in collaboration with the World Trade Organization (WTO), to ensure that the procedure for official status recognition granted by the World Assembly of Delegates to eligible Members was considered an international standard. Dr Eloit also mentioned the ongoing work on the development of similar documented procedures for the publication of self-declarations of freedom from OIE-listed diseases, which excludes the six diseases that are part of the OIE official status recognition procedure.

Dr Eloit reminded the Group on the sensitivity and confidentiality of the dossiers received for official recognition and thanked the experts for having signed the forms for undertaking of confidentiality and also mentioned that if any members of the Group had any conflict of interest in the evaluation of a dossier, the expert(s) should withdraw from the discussions and decision making of the particular application.

Dr Eloit encouraged the Group to continue providing detailed feedback to all countries, and highlighted the importance of the quality of the public report to be scrutinised by Members before adopting the proposed list of countries and zones free from FMD and of countries having an endorsed official control programmes for FMD by the OIE.

Dr Min-Kyung Park, Chargée de mission of the Status Department, introduced Dr Hernán Oliver Daza, who joined the Status Department to work on the activities related to official disease status recognition.

2. Adoption of the agenda and appointment of chairperson and rapporteur

The Group was chaired by Dr David Paton and Dr Wilna Vosloo acted as rapporteur, with the support of the OIE Secretariat. The Group endorsed the proposed agenda.

The terms of reference, agenda and list of participants are presented as Appendices I, II and II, respectively.

[1] Note: This *ad hoc* Group report reflects the views of its members and may not necessarily reflect the views of the OIE. This report should be read in conjunction with the February 2018 report of the Scientific Commission for Animal Diseases because this report provides its considerations and comments. It is available at: http://www.oie.int/en/international-standard-setting/specialists-commissions-groups/scientific-commission-reports/meetings-reports/

3. Evaluation of requests from Members for the status recognition of FMD free countries where vaccination is not practised

3.1 Peru

Peru was recognised as having two separate zones free from FMD, officially recognised by the OIE and covering its entire territory, since May 2013. One zone consists of three merged zones, as designated by the Delegate of Peru in the documents addressed to the Director General in December 2004, in January 2007 and in August 2012, where vaccination is not practised. The other zone consists of the regions of Tumbes and parts of Piura and Cajamarca regions where vaccination is practised as designated by the Delegate of Peru in a document addressed to the Director General in August 2012 (hereafter, the north-western zone).

In January 2017, the Delegate of Peru informed the OIE of the cessation of vaccination in the north-western zone, as of 1 January 2017, in accordance with the provisions of Article 8.8.3. of the Terrestrial Animal Health Code (Terrestrial Code).

In September 2017, Peru submitted an application to change the current FMD free status of the north-western zone where vaccination is practised to a FMD free zone where vaccination is not practised, as well as to merge this zone with the current FMD free zone where vaccination is not practised, implying a request for Peru to be officially recognised as a country free from FMD where vaccination is not practised. The Delegate of Peru confirmed the application as such.

The Group requested additional information and received clarification from Peru.

i. Animal disease reporting

The Group acknowledged that Peru had a record of regular and prompt animal disease reporting.

ii. Veterinary Services

The Group agreed that the Veterinary Authority had current knowledge of and authority over FMD susceptible animals in the country. The Group was informed of the OIE FMD missions in Peru with regard to FMD that took place in 2012 and in 2014. The dossier indicated the collaborative efforts of Peru in recent years with a bordering country in improving the control of the movement of animals and the animal health situation. The Group encouraged the continuation of these efforts.

iii. Situation of FMD in the past 12 months

The Group noted that the last FMD outbreak in the north-western zone was in 1999 in Piura. The last FMD outbreak in the country was reported in 2004 in the district of Lurin, situated in the other zone.

iv. Absence of vaccination and entry of vaccinated animals in the past 12 months

The Group noted that in the north-western zone, which represents 1.64% of Peru's territory and 2.4% of the national cattle population, systematic vaccination had ceased in January 2017. The intended cessation of vaccination in this zone was communicated to the OIE in Peru's 2016 annual reconfirmation of its FMD free zone status and this cessation was confirmed in a letter of the Delegate of Peru to the OIE Director General in January 2017.

The Group noted that, by the time the application is assessed by the Scientific Commission for Animal Diseases (Scientific Commission), it would be 12 months since vaccination had ceased and Peru would therefore comply with Article 8.8.2. (point 2b). Since the cessation of vaccination, introduction of vaccinated animals has not been allowed into the north-western zone.

v. Surveillance for FMD and FMDV infection in accordance with Articles 8.8.40. to 8.8.42.

The Group was informed that active and passive surveillance were in place in the entire country, with the participation of private veterinarians who are legally bound to report any suspicions of vesicular diseases. The Group received details on the design of the non-structural protein (NSP) serological survey and on population immunity in the north-western zone performed during July and August 2017. The Group noted that population immunity levels were low. However, this was no longer of concern to the Group as vaccination had ceased. Surveillance in slaughterhouses was registered and supervised by the veterinary authority of Peru.

Peru stated that, since small ruminants are not vaccinated, clinical signs should be obvious. The Group would draw the attention of Peru to the fact that subclinical FMD infection in these species is common.

vi. Regulatory measures for the early detection, prevention and control of FMD

The Group received sufficient assurance of regulatory measures described in the dossier for the early detection, prevention and control of FMD in the north-western zone. The additional information submitted by Peru also clarified the use of diagnostic tests, procedures on sampling and management of results.

The Group strongly encouraged Peru for continuous training of laboratory staff for maintenance of laboratory capacity and recommended a PCR be established and added to the available suite of tests for FMD diagnosis.

vii. Description of the boundaries and measures of a protection zone, if applicable

Not applicable.

viii. Description of the system for preventing the entry of the virus

The Group noted that official procedures were in place for the control of movements. Peru's current legislation indicates that animals should be identified by branding, and ear tags should be used to identify cattle from intensive cattle breeding establishments. Since 2012, progress had been made on an individual animal identification and traceability system, as a key method for animal movement control in the north-western zone.

The additional information submitted by Peru also described the quarantine procedures and border control with confiscation of illegally introduced animals, animal products and veterinary medicinal products.

The Group strongly reminded Peru that the import of vaccinated animals would not be allowed, in accordance with Article 8.8.2. of the *Terrestrial Code*, and noted the availability of an animal identification system supporting the early detection of illegal introduction of live animals.

ix. Compliance with the questionnaire in Article 1.6.6.

The Group agreed that the format of the dossier was compliant with the questionnaire in Article 1.6.6.

Conclusion

Considering the information submitted in the dossier and the answers from Peru to the questions raised, the Group considered that the application was compliant with the requirements of Chapter 8.8. and with the questionnaire in Article 1.6.6. of the Terrestrial Code. The Group therefore recommended that Peru be recognised as a FMD free country where vaccination is not practised.

The Group underlined that, having a FMD free country status where vaccination is not practised, introduction of vaccinated animals or incursion of FMD into Peru would now lead to the suspension of the official FMD free status of the entire country.

Finally, the Group emphasised that movement control between the two separate officially recognised zones should be maintained until the FMD free country status is officially recognised by the World Assembly.

3.2 Suriname

In September 2017, the Delegate of Suriname submitted an application to the OIE to be officially recognised as a country free from FMD where vaccination is not practised.

The Group took note of the favourable location of Suriname as it borders officially recognised FMD free countries or zones with the exception of a 50-km border with the State of Amapá of Brazil, which is in a densely forested and sparsely populated area. In addition, FMD had never been reported in Suriname.

In accordance with the established procedures, the participating expert working in Brazil expressed a possible conflict of interest and withdrew from the decision process on Suriname's dossier.

The Group requested additional information and received clarification from Suriname.

i. Animal disease reporting

The Group acknowledged that FMD is a notifiable disease in the country as per legislation since 1954. Whilst FMD was never reported in Suriname, occurrence of other major diseases listed under the legislation had been reported to the OIE. The Group considered that Suriname had a system of regular and prompt animal disease reporting. The Group encouraged Suriname to keep systematic records of information on the investigations and outcome of events giving rise to suspicion of FMD or other vesicular diseases.

ii. Veterinary Services

The dossier provided a description of the organisation of the Veterinary Services of Suriname including the small number of veterinarians and veterinary paraprofessionals of the country. It was reported that Suriname's official Veterinary Services is under the Ministry of Agriculture Animal Husbandry and Fisheries; a department of animal production and health has a technical division responsible for animal disease surveillance and food safety in the country.

The Group considered the PVS report of Suriname in 2012. The dossier provided information on the progress made in the past five years, particularly in the important areas for a country having an official recognition of FMD free status.

iii. Situation of FMD in the past 12 months

The Group noted that FMD had never been reported in the country, neither in domestic nor in wild animals. Therefore, Suriname was eligible for historical freedom from FMD as described in Article 1.4.6. of the *Terrestrial Code*.

iv. Absence of vaccination and entry of vaccinated animals in the past 12 months

The Group noted that vaccination against FMD had never been carried out in Suriname. The Group also acknowledged that there was no introduction of vaccinated animals into Suriname for at least the last 24 months. The Group strongly recommended that Suriname considers, in its official regulations, preventing importation of vaccinated animals into the country, as introduction of vaccinated animals is not allowed, in accordance with the requirements of Article 8.8.2. of the *Terrestrial Code*.

v. Surveillance for FMD and FMDV infection in accordance with Articles 8.8.40. to 8.8.42.

The Group noted that surveillance was based on inspection in slaughterhouses and by field units, veterinary laboratory results, and passive surveillance. Whilst pathogen-specific surveillance was not mandatory according to Article 1.4.6. of the Terrestrial Code, the Group commended the efforts of Suriname in conducting active surveillance through a serological survey in 2017 and providing supportive information substantiating the absence of FMDV infection in the country. While the Group noted that the survey design prevalence between herds was rather high, considering the historical FMD situation and unvaccinated population, the Group considered the overall surveillance as satisfactory to substantiate absence of FMDV infection.

vi. Regulatory measures for the early detection, prevention and control of FMD

The Group noted that most of the livestock and people are resident in the northern coastal part of the country. The dossier described investigative and periodic farm visits by the Veterinary Services as part of clinical surveillance activities for the early detection of FMD in the field.

The Group noted that Suriname had no formal legislation on swill feeding, and recommended that regulations be developed according to Article 8.8.31. of the *Terrestrial Code*. Furthermore, considering the fact that Suriname had acquired PCR equipment and had received relevant training, the Group strongly encouraged that RT-PCR be employed for strengthening the FMD diagnostic capacity as part of the early detection system.

In general, the Group considered that sufficient regulatory measures were described in the dossier for the early detection, prevention and control of FMD.

vii. Description of the boundaries and measures of a protection zone, if applicable

Not applicable.

viii. Description of the system for preventing the entry of the virus

The Group noted that the Port Health Unit was in charge of border control and the Veterinary Services did not have inspectors permanently stationed at every port of entry. Nevertheless, a strong working relationship appeared to be in place between the Customs Services and Police at the ports of entry and internal control posts. Furthermore, from the additional information submitted by Suriname, the Group noted the directions on waste disposal from international traffic as part of the recently updated contingency plan. The Group would strongly recommend that these procedures are fully implemented, and documented evidence be submitted to the OIE.

The Group also took note that the legislation of 1961 for importing products of animal origin had been recently updated and a detailed list of the updated changes were provided.

ix. Compliance with the questionnaire in Article 1.6.6.

The Group agreed that the format of the dossier was compliant with the questionnaire in Article 1.6.6.

Conclusion

Considering the information submitted in the dossier and the answers from Suriname to the questions raised, as well on the basis of historical freedom, the Group considered that the application was compliant with the requirements of Chapter 8.8., Article 1.4.6 and with the questionnaire in Article 1.6.6. of the Terrestrial Code. The Group therefore recommended that Suriname be recognised as a FMD free country where vaccination is not practised.

The Group recommended that the following information be submitted to the OIE when Suriname reconfirms its FMD status (also detailed in the relevant sections above) in November 2018 and 2019:

- Established official regulations on preventing introduction of vaccinated animals into the country, in accordance with the requirements of Article 8.8.2. of the *Terrestrial Code*;
- Established regulations on swill feeding, according to Article 8.8.31. of the *Terrestrial Code*;
- Compiled comprehensive records of FMD suspicions and follow-up investigations;
- Full implementation of the recently updated measures for disposal of waste from international traffic;
- Evidence on training of laboratory staff and utilisation of RT-PCR for strengthening the FMD diagnostic capacity as part of the early detection system.

4. Evaluation of requests from Members for the status recognition of FMD free zones where vaccination is practised

4.1 Brazil

In September 2017, Brazil submitted an application for the recognition of an extended FMD free zone practising vaccination. This included the states of Amapá, Amazonas, Roraima and two parts in the State of Pará that acted as protection zones. There are two non-contiguous parts to this area, described in the dossier as: one comprising of Amapá and part of the State of Pará (Region 1), and the other comprising Roraima (Region 2), and Amazonas and another part of the State of Pará (Region 3) (hereafter "the proposed FMD free area"; see **Figure 1**).

Figure 1 – Proposed FMD free areas without an OIE official status for FMD (in hash marks), and already officially recognised FMD free zones with and without vaccination (in colours)

Figure 2 – Proposed FMD free areas to be merged with two zones already recognised as FMD free with vaccination for potential recognition in May 2018 (in yellow)

The Group noted that the proposed FMD free area is heavily forested with localised human and livestock populations and large areas that contain few people or domestic animals. Overall, the livestock population is less than 2.5 million, mainly cattle and buffalo representing less than 1% of the Brazilian herds. Buffalo are particularly found in Amapá. There are few small ruminants and pigs. The dossier indicated that the area is a net importer of meat from the rest of Brazil.

Brazil also requested that this new FMD-free area be merged with two zones already officially recognised as free from FMD and practising vaccination: a zone consisting of the states of Rondônia and Acre along with two adjacent municipalities of the state of Amazonas and a zone consisting of the states of Espírito Santo, Minas Gerais, Rio de Janeiro, Sergipe, Distrito Federal, Goiás, Mato Grosso, Paraná, São Paulo, Bahia, Tocantins, Alagoas, Ceará, Maranhão, Paraíba, Pernambuco, Piauí, Rio Grande do Norte, and parts of Pará and Mato Grosso do Sul. The Group noted that the new merged zone comprises most of Brazil, apart from State of Rio Grande de Sul and the former high surveillance zone covering part of Mato Grosso do Sul (FMD free zones where vaccination is practised) and the State of Santa Catarina (FMD free zone where vaccination is not practised) (see **Figure 2**).

The Group also noted that with the submitted application of an extended FMD free zone, the entire territory of Brazil would have an OIE recognised FMD free status, with or without vaccination.

In accordance with the established procedures, the participating expert working in Brazil expressed a possible conflict of interest and withdrew from the decision making on Brazil's dossier.

The Group requested additional information and received clarification from Brazil.

i. Animal disease reporting

The Group considered that Brazil had a record of regular and prompt animal disease reporting.

ii. Veterinary Services

The Group was informed that Brazil had received a PVS follow-up evaluation mission in 2014. The PVS report provided additional guarantee that the Veterinary Services were compliant with the requirements for a country having FMD free zones. Furthermore, according to the dossier, in the last five years, Brazil had received at least 19 missions in the animal health field, during which the official veterinary services was evaluated, often leading to adjustments in further strengthening the capacity of the Veterinary Services.

iii. Situation of FMD in the past 2 years

The last FMD outbreaks in the proposed FMD free area, previously not having a FMD free status, were in 2004 (Amazonas, serotype C), 2001 (Roraima, serotype A) and 1999 (Amapá, serotype A).

iv. Routine vaccination and vaccines

The dossier mentioned that cattle and buffalo should be vaccinated against FMD.

The Group noted that the characteristics of the vaccine and the standards for producing it are laid down by the Ministry of Agriculture, Livestock and Food Supply (MAPA), following OIE recommendations given in its *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (*Terrestrial Manual*). The vaccine authorised for use in Brazil is inactivated and trivalent, with an oil adjuvant and containing viral strains A24 Cruzeiro, O1 Campos and C3 Indaial. These vaccine strains were selected on the basis of analyses performed by the Pan-American Center for Foot-and-Mouth Disease (PANAFTOSA), in order to provide suitable immunological correspondence with field strains prevalent in South America. Most recently, an assessment had been made of the suitability of O1 Campos for use against the serotype O viruses obtained from Colombia in 2017; an expectancy of protection value of 76% was obtained, which was above the 75%-threshold for acceptance.

As mentioned in the dossier, a recent study by PANAFTOSA concluded that there was negligible risk of circulation of FMDV serotype C in the region, and during the meeting of COSALFA 44, held this year, the countries signed a Resolution IV, recommending suspension of vaccination for that serotype. The Group took note that in Brazil, removal of strain C3 Indaial from the vaccine will be coordinated by MAPA, following a schedule yet to be defined.

The Group noted that in the proposed FMD free area there is a strategy of twice yearly herd vaccination of cattle and buffalo, except for Region 1, where vaccination is annual, since the predominant climate characteristics enable cattle handling only for a limited period in the year. Vaccine coverage rates were estimated from farmer reports backed up by veterinary spot-checks. The average percentage of holdings with vaccination records was 91% (standard deviation = 9%), and the percentage of cattle and buffalo notified as vaccinated was 96% (standard deviation = 3%). A population immunity survey was conducted using a subset of the sera collected in 2015 for a NSP sero-survey. Sampling was mostly carried out within a couple of months of vaccination, irrespective of vaccination status. This showed immunity levels of between 33% and 69% in 6-12 month old animals, rising to 58% to 90% in 18-24 months old animals.

v. Surveillance for FMD and FMDV transmission in accordance with Articles 8.8.40. to 8.8.42.

The Group was given details of the active and passive surveillance that were in place. For example, substantial numbers of suspect vesicular cases were investigated in the last two years, and the targeting of clinical patrols to high risk holdings and the inspections at slaughterhouses were described in the dossier. NSP sero-surveys to detect FMDV transmission were carried out in 2014/15 and 2017. The 2014/15 survey was a large randomised one with a design prevalence of 1% at the between herd level and 5-10% at the within herd level. In total, 34,693 animals were sampled. The survey and its findings were reported in detail in the dossier and follow-up clarifications provided to the Group.

Differences in the overall low seroprevalence rates between the three Regions (ranging from 0%, in Region 1, to 0.41% in the Rio Solimões subpopulation within Region 3) of the proposed FMD free area remain unexplained, but it was concluded that there was no virus circulation, after follow-up of the NSP sero-reactor animals including a possible clustering effect. The 2017 survey was a smaller and risk-based study in which 3,982 animals were sampled, in which no evidence of FMDV transmission was found.

Considering the great costs and effort required to undertake large scale sero-surveys to detect FMDV transmission and infection (or demonstrate the absence of such), the Group encouraged Brazil to continue investigating all positive findings, and where necessary, further holdings and animals linked by proximity or other connections should be examined and sampled.

vi. Regulatory measures for the early detection, prevention and control of FMD

The Group noted sufficient regulatory measures in place described in the dossier for the early detection, prevention and control of FMD, as implemented in other zones already officially recognised as free from FMD.

vii. Description of the boundaries of the proposed free zone

The proposed extended zone includes the states of Amapá, Amazonas, Roraima and parts of the state of Pará and the two zones already officially recognised as free from FMD: a zone consisting of State of Rondônia, State of Acre along with two adjacent municipalities of State of Amazonas and a zone consisting of States of Espírito Santo, Minas Gerais, Rio de Janeiro, Sergipe, Distrito Federal, Goiás, Mato Grosso, Paraná, São Paulo, Bahia, Tocantins, Alagoas, Ceará, Maranhão, Paraíba, Pernambuco, Piauí, Rio Grande do Norte, and parts of Pará and Mato Grosso do Sul.

Three neighbouring countries to the north were not recognised free from FMD at the time when the application was assessed. The Group noted that the FMD outbreaks recently reported in Colombia in June/July 2017 were more than 500-km from the border to Brazil (Amazonas). Most border areas were considered low risk due to jungles and rivers and few livestock and people.

viii. Description of the boundaries and measures of a protection zone, if applicable

In the dossier, Brazil explained the need to establish a small protection zone at Pacaraima within Region 2, where there is a town and a main road crossing the border with a neighbouring country without an official FMD free status. The dossier provided its boundaries, which consisted of a 32-km strip of approximately 1-km width on the Brazilian side of the border. This protection zone was to be included as part of the extended FMD free zone, but Brazil described in the additional information that the separation of the protection zone could be achieved based on natural barriers in case of eventual disease introduction. This would facilitate the establishment of a containment zone in case of incursion of FMD in the protection zone. The Group noted from the dossier that within the protection zone the Veterinary Services take specific actions, the most important of which were stated as:

- long-term individual identification of all cattle, buffalo and small ruminants on holdings and in indigenous communities along the international border;
- supply of vaccine and performing official vaccination in herds on the international border;
- keeping mobile surveillance teams in the region to act in strategic locations and with a frequency established on the basis of local know-how and local risk estimates;
- specific controls of animal movements, demanding prior authorisation for movements of animals both inwards and outwards from the protection zone, with a description of the travel route, for which passage by fixed inspection posts is mandatory.

ix. Description of the system for preventing the entry of the virus

The proposed FMD free area was bordering three countries not recognised free from FMD.

The Group noted that specific surveillance actions were taken by Brazil's Veterinary Services at the border with a neighbouring country without an OIE officially recognised FMD status. The government authorities of both countries had set up inspection and control posts. The dossier described that a MAPA inspection post was in place, at the point of entry, along a single highway into Brazil, as well as specific army, federal police and customs posts. In addition, there was a State Veterinary Service inspection post at the point of exit from the municipality of Pacaraima to boost this inspection system for the ingress and flow of animals and animal products potentially posing risk for introduction of FMD.

The Group acknowledged that Brazil had sufficient measures for preventing the entry of FMDV with the implementation of fixed inspection posts and the establishment of a protection zone, in accordance with Point 2 of Article 4.3.3. of the *Terrestrial Code*, in a part of the border of the municipality of Pacaraima.

Regarding international trade, there were no entries of FMD-susceptible animals into the proposed FMD free area. The Group acknowledged that international imports of animal products were only from countries or zones recognised by the OIE as free from FMD.

x. Compliance with the questionnaire in Article 1.6.6.

The Group agreed that the format of the dossier was compliant with the questionnaire in Article 1.6.6.

Conclusion

Considering the information submitted in the dossier and the answers from Brazil to the questions raised, the Group considered that the application was compliant with the requirements of Chapter 8.8. and with the questionnaire in Article 1.6.6. of the Terrestrial Code. The Group therefore recommended that the extended zone of Brazil, including the states of Amapá, Amazonas, Roraima and parts of the state of Pará and merged with the two zones already officially recognised as free from FMD, be recognised as a single FMD free zone where vaccination is practised.

While noting that the new proposed FMD free area was to be merged with the two zones already officially recognised free from FMD with vaccination to create a single large zone, the Group underlined that, any introduction of FMD into the newly delineated free zone would now lead to the suspension of the official FMD free status of the entire extended free zone.

The Group recommended that Brazil take into consideration the following points when presenting information on sero-surveys in future dossiers or annual reconfirmations for FMD status:

- Information on vaccine coverage and population immunity should be maintained and available at municipal level and stratified by age;

- Since immunity wanes between vaccination campaigns, it should be clear when samples were taken in the vaccination cycle for estimating population immunity and whether or not the sampled animals include both vaccinated and unvaccinated animals.

4.2 Chinese Taipei

Chinese Taipei was recognised as having a zone free from FMD where vaccination is practised in May 2017; this zone covers Taiwan, Penghu and Matsu areas, which refers to the entire Province of Taiwan and Matsu County, but excludes Kinmen County.

In September 2017, Chinese Taipei submitted an application for the recognition of a separate zone free from FMD where vaccination is practised which consists of Kinmen County. The county includes 14 islands, of which only Kinmen Island, Lieyu Island and Wuqiu Township have FMD susceptible animals.

The Group requested additional information and received clarification from Chinese Taipei.

i. Animal disease reporting

The Group considered that Chinese Taipei had a record of regular and prompt animal disease reporting. The Group acknowledged that Chinese Taipei had reported to the OIE outbreaks detected through NSP serological surveys in the absence of clinical disease.

ii. Veterinary Services

The Group acknowledged that the Veterinary Authority had current knowledge of and authority over FMD susceptible animals in the zone. A statute for Prevention and Control of Infectious Animal Disease was in place to prevent the occurrence and spread of infectious animal diseases by giving veterinary services the mandate for animal disease control and quarantine in the entire country.

iii. Situation of FMD in the past 2 years

The last outbreak (caused by serotype A) in the proposed zone was in June 2015. There had been no case of FMD in the past 2 years and no evidence of virus transmission in the last 12 months.

iv. Routine vaccination and vaccines

The FMD vaccines used in Kinmen contained O/Taiwan/98 since 2000 and either O/Taiwan/98 or O/Campos from 2013. The Group acknowledged that no FMD vaccine was manufactured in Chinese Taipei and that vaccines were imported. The Group commended the Animal Health Research Institute (AHRI) for testing the vaccine batches for potency by serology and noted that vaccine matching results from the OIE Reference Laboratory for FMD (the Pirbright Institute, United Kingdom) were used to decide on vaccine strains.

It was noted from the dossier that all cloven-hoofed animals in Kinmen were vaccinated against FMD; pigs were vaccinated once between 12 and 14 weeks of age; cattle, goats and deer were vaccinated twice at 4 and 12 months of age, respectively. Thereafter, pigs, cattle and goats were boosted every 6 months and deer annually. Vaccination was performed by the veterinary services or under the supervision of these services and was free of charge. Official FMD vaccination records were maintained.

Indicators of vaccination efficiency such as vaccination coverage and population immunity were not clearly presented in the dossier. Follow-up actions were in place when low immunity levels were detected. The vaccination coverage was calculated from the total doses of vaccine used divided by the total number of susceptible animals that should be vaccinated. The Group noted that this may result in percentages over 100%, and despite the explanation provided, it was difficult to interpret whether or not this was sufficient and compatible with the estimated population immunity of 96%. The Group would recommend that the vaccination coverage be calculated to determine the proportion of animals vaccinated at a given time, in order to identify how many animals were not being vaccinated at the prescribed time. For population immunity, the Group recommended stratification according to age.

Following the Group's request, Chinese Taipei clarified that serotypes A and O were the main threats for introduction and provided as rationale for not vaccinating against serotype A: the cost-benefit analysis and plan to progress to FMD free status without vaccination. The dossier also described existence of a vaccine reserve and bank, which included serotypes A, O and Asia 1, that could be readily available in case of emergency.

Nevertheless, the Group would encourage Chinese Taipei to consider including a serotype A strain in the vaccine, particularly for Kinmen, based on risk analysis considering the circulating viruses in the region and the fact that the last incursion was caused by FMDV serotype A.

v. Surveillance for FMD and FMDV transmission in accordance with Articles 8.8.40. to 8.8.42.

The Group was informed that active and passive surveillance were in place, and performed in general schemes as well as in several targeted approaches. The dossier mentioned that there had been no clinical suspicions of FMD for the past two years in Kinmen County. The Lieyu Island was included in the regular surveys and no FMD infection had ever been detected. The Group noted sufficient regulatory measures in place for the early detection, prevention and control of FMD, as implemented in the other zone already officially recognised as free from FMD.

The Group noted that there was not a specific NSP survey design for the zone of Kinmen, but it was included as part of the nationwide general surveillance strategy. NSP sero-surveys to detect virus transmission had been designed for the whole of Chinese Taipei using 95% confidence and 1% between herd prevalence and a within herd prevalence of 20%. The dossier provided additional targeted approaches for surveillance in Kinmen, where samples were additionally obtained from: i) 'outlying island surveillance for pigs' where three pig farms are randomly selected every three months and 15 pigs from each farm are sampled for NSP antibody testing; ii) surveillance for cattle and pig farms intending to ship products to Taiwan ('Taiwan oriented farms'), and iii) surveillance for cattle and pigs entering slaughterhouses for local consumption in Kinmen.

The Group emphasised that a 20% within herd prevalence was too high in vaccinated animals, particularly in ruminants, when designing a sero-survey. The Group strongly recommended that Chinese Taipei consider this for any future design of serological surveys in demonstrating absence of virus transmission, as well as the fact that the design should be specific for each zone.

NSP sero-survey results were provided for 2015-2017. The Group noted that several NSP sero-reactors were reported each year, and were followed-up according to a specific protocol called, 'Standard operating procedure for confirmation of FMD NSP antibody positive reaction and infection case of cloven-hoofed animals,' where the reactors were bled again as well as several in-contact animals in addition to clinical investigations. Furthermore, probangs (cattle) and swabs (pigs) would also be taken for virological investigations using PCR and virus isolation. A large proportion of these sero-positive animals remained positive on follow-up, but with no positive virological results and were slaughtered. The additional information provided by Chinese Taipei showed that most of the animals were old and had received many doses of vaccines.

The design of the general (random) NSP sero-survey, which was not applied to Kinmen specifically but for the whole country, made it harder for the Group to judge whether or not the overall surveillance was adequate. Nevertheless, with the additional components of targeted surveillance over the last two years, the Group was of the opinion that the information provided was sufficient to demonstrate absence of FMDV transmission.

The Group suggested that Chinese Taipei could consider testing for structural protein for antibodies to other serotypes – than serotype O that is included in the vaccine strain – to rule out FMDV infection by other serotypes. However, animals vaccinated against serotype O several times may cross-react to other serotypes, and therefore only young animals should be tested. This testing would not rule out infection with serotype O, but could be considered as an additional tool for investigation of NSP reactors. Chinese Taipei indicated that it was not allowed to work with live FMDV serotype A, which would prevent virus neutralisation tests being performed. The Group suggested that Chinese Taipei consider implementing an ELISA that is based on inactivated reagents.

vi. Regulatory measures for the early detection, prevention and control of FMD

The Group noted sufficient regulatory measures described in the dossier for the early detection, prevention and control of FMD, as implemented in the other zone already officially recognised as free from FMD with vaccination.

vii. Description of the boundaries of the proposed free zones

The Group noted that the proposed free zone covers Kinmen County. Chinese Taipei clarified that Kinmen County was comprised with 14 islands varying in size, including the main Kinmen Island, Lieyu Island (also known as lesser Kinmen) and Wuqiu Township, which were the only ones that had FMD susceptible animals. No cloven-hoofed animals were raised on other small islands forming part of Kinmen.

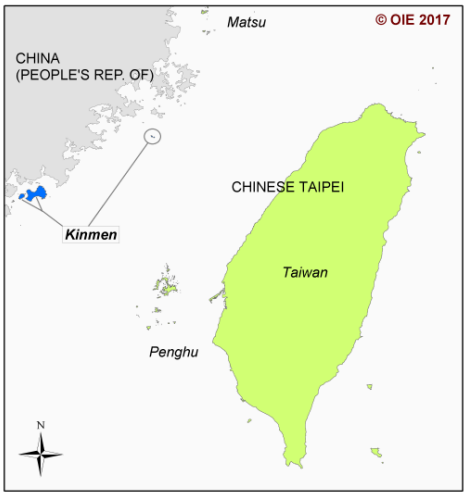

Figure 3. Kinmen County with the three islands – having FMD susceptible animals – of main Kinmen Island, Lieyu Island and Wuqiu Township.

viii. Description of the boundaries and measures of a protection zone, if applicable

Not applicable.

ix. Description of the system for preventing the entry of the virus

The Group noted that Kinmen County is composed of islands, sharing no land borders with other countries. Importation of susceptible animals and products thereof from FMD infected countries or zones were prohibited, except for dry animal products, which have been heat-treated or sterilised by other methods.

The dossier mentioned that the three international seaports had inspection stations, managed by the Bureau of Animal and Plant Health Inspection and Quarantine with close collaboration with the Coast Guard Administration and the Customs Administration, to detect illegal movement of animals and animal products. Passenger luggage and cargo were checked with regulations in place for confiscation and destruction or return of illegal imports. The Group took note that there was no international airport in Kinmen.

The dossier and additional information described the protocol when animals were moved from Chinese Taipei into Kinmen and the quarantine procedures applied. The Group strongly reminded Chinese Taipei that, as the proposed zone was requested as a separate zone from the zone already officially recognised as free from FMD since May 2017, all movement of FMD susceptible animals and their products between the two zones should continuously comply with Articles 8.8.11., 8.8.15., 8.8.19., 8.8.21., 8.8.24. and 8.8.29. of the *Terrestrial Code*; Chinese Taipei should control such movements between the two zones of the same status in accordance with Chapter 4.3. and Article 8.8.3. of the *Terrestrial Code*, as long as the two zones are kept separated.

x. Compliance with the questionnaire in Article 1.6.6.

The Group agreed that the format of the dossier was compliant with the questionnaire in Article 1.6.6.

Conclusion

Considering the information submitted in the dossier and the answers from Chinese Taipei to the questions raised, the Group considered that the application was compliant with the requirements of Chapter 8.8. and with the questionnaire in Article 1.6.6. of the *Terrestrial Code*. The Group therefore recommended that the proposed zone of Chinese Taipei be recognised as a FMD free zone where vaccination is practised.

4.3 Other request

The Group assessed the request of another Member for the recognition of a zone free from FMD where vaccination is practised and considered that the dossier did not meet the requirements of the *Terrestrial Code*. The dossier was referred back to the applicant Member.

5. Evaluation of a request from a Member for the endorsement of its national official control programme for FMD

The Group assessed the request of a Member for the endorsement of its national official control programme for FMD and considered that the dossier did not meet the requirements of the *Terrestrial Code*. The dossier was referred back to the applicant Member.

6. Review of the report of the *ad hoc* Group on Alternatives for surveillance for demonstration of freedom from FMD and recovery periods and consideration of the option document

The Group considered the report of the *ad hoc* Group on alternatives for surveillance for demonstration of freedom from FMD and recovery periods (hereafter the Group on FMD surveillance), as well as an option document linking the conclusion of the *ad hoc* Group meeting and its impact on the FMD Chapter of the *Terrestrial Code*.

The Group explored and discussed the pros and cons of the different options related to: i) the provisions on the waiting time requirements; ii) the provisions for the level of confidence; and iii) the method to be used for the assessment of the level of the confidence. The Group also consulted the chair of the Group on FMD surveillance by teleconference.

The Group agreed with the preferred options indicated by the Group on FMD surveillance: To maintain the current timing requirements of Article 8.8.7. but to add a sentence at the end of the article, clarifying that the waiting period should be respected unless there is evidence that the appropriate level of confidence has been reached earlier by implementing additional surveillance or other measures (T1, with reference to the option document in Annex IV); to provide qualitative guidance on the methods to assess the level of confidence (M2); to reach a qualitatively appropriate level of confidence (C1) (*cf* Report of the meeting of the Scientific Commission for Animal Diseases, September 2017). Furthermore, the Group discussed some examples of the "enhanced" surveillance that would be needed for shortening of the recovery period.

- Post-vaccination monitoring system
- Census surveys
- Risk-based surveillance

With reference to "Table 4. Requirements for a possible shorter recovery period" in the report of the Group on FMD surveillance, the Group proposed additional measures of "enhanced" surveillance as below (in bold text).

Status of animal population	Current *Terrestrial Code* requirements Article 8.8.7. Point 1.c)	Objective	Additional measures	Benefit
Vaccinated population in the control area*	Demonstration of absence of infection through serological surveillance in vaccinated population in accordance with Articles 8.8.40. to 8.8.42.	Demonstration of absence of virus transmission through serological surveillance in vaccinated population in accordance with Articles 8.8.40. to 8.8.42.	**- Census surveys (all herds in the area and all animals within those herds)** **- Herd census surveys (all herds in the area and a sample of animals within those herds)** **- Risk-based census survey (all herds in the stratum of higher risk and a sample of animals within those herds)** **- Risk-based survey (a sample of herds in the stratum of higher risk and a sample of animals within those herds)** - Assessment of immunity of the vaccinated population in accordance with Article 8.8.40. Point 6. **This is based on the level of target immunity and the precision with which it is estimated. It can be based on good records of vaccination coverage combined with serosurveillance of vaccinated animals.** **- Heterologous potency tests may be useful to demonstrate the effectiveness of the vaccine and to calculate immune protection with precision.** - Active clinical surveillance	**- Census surveys increase the confidence in demonstrating absence of virus transmission** **- Risk-based surveillance could enhance survey sensitivity** - Population immunity above a defined threshold will increase the confidence of the absence of virus transmission - Increase detection of clinical cases
Unvaccinated population in control area*	Demonstration of absence of infection in the sub-population through serological surveillance in accordance with Articles 8.8.40. to 8.8.42.		- Enhanced abattoir surveillance - Active clinical surveillance **- Both abattoir and clinical surveillance should be quantified (number of animals and herds inspected, and the sensitivity of the system estimated) with good records of detected suspicions** **- Serological surveillance in species where subclinical infection is common**	Increase detection of clinical cases **and infection**
Remaining area where vaccination is not applied	Demonstration of absence of infection in the area through serological surveillance in accordance with Articles 8.8.40. to 8.8.42.		- Enhanced passive surveillance - If already in place, syndromic surveillance could contribute to the confidence of demonstrating freedom	Increase detection of clinical cases

* Control area: area designated by the Veterinary Authority in response to the occurrence of FMD outbreaks, in order to control and prevent its spread to uninfected areas. These measures may include, but are not limited to, vaccination, movement control and an intensified degree of surveillance. The control area could be comprised of two separate areas where movement control is in place and in which measures of different intensity are conducted.

In addition to surveillance activities, the Group also considered the possible contribution of monitoring other control measures (efficiency of tracing and response, movement restrictions, etc.) for reaching the appropriate level of confidence for demonstrating freedom. Finally, the Group considered that differences between outbreaks (such as density of animals and types of production systems, capacity of Veterinary Services) influencing the levels of residual risk for continuing FMDV transmission, should be taken into account for reaching the appropriate level of confidence. However, the Group noted the difficulties to consider and quantify all these parameters.

In conclusion, the Group was in favour of developing a qualitative approach, to describe in detail the additional measures needed to provide a high level of confidence in a short period, along with the procedure for monitoring and evaluating the implementation of these measures. This could be created through a separate questionnaire or a checklist in the recovery section of the FMD questionnaire in Article 1.6.6. of the *Terrestrial Code*.

This framework could then be used for developing more quantitative assessment approaches. In the first instance, a semi-quantitative methodology might be developed by the two *ad hoc* Groups in consultation. Later on, if considered relevant, the possibility of a fully integrated model could be the subject for a future research project.

7. Update on Chapter 8.8. on FMD of the *Terrestrial Animal Health Code*

The Group was informed that comments received from Members on the amended chapter, that included new concepts related to FMD control, were addressed by the Scientific Commission in September 2017. These new concepts included i) a broader concept of containment zone, ii) compartmentalisation with vaccination and iii) implementation of emergency preventive vaccination in response to an increased risk of FMDV incursion. The Group was informed that some of the new concepts were considered in the discussions of the horizontal chapter (Chapter 4.3.) on zoning and compartmentalisation of the *Terrestrial Code*, which was circulated in October 2017 for Members' comments, prior to further application in the FMD Chapter.

The Group was also informed of the state of play of the revision of the questionnaires – for the official recognition of disease status and for the endorsement of national official control programmes – primarily aimed at the scientific relevance of each questionnaire and harmonising the questionnaires between the different diseases.

8. Adoption of report

The Group reviewed the draft report provided by the rapporteur and agreed to circulate the draft report electronically for comments before the final adoption. Upon circulation, the Group agreed that the report captured the discussions.

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…/Appendices

Appendix I

MEETING OF THE OIE AD HOC GROUP ON THE EVALUATION OF FOOT AND MOUTH DISEASE STATUS OF MEMBERS

Paris, 6 – 9 November 2017

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Terms of Reference

The OIE *ad hoc* group on foot and mouth disease (FMD) status of Members (the Group) is expected to evaluate the applications for official recognition of FMD free status and for endorsement of control official programme of FMD received from five Members.

This implies that the experts, members of this Group are expected to:

1. Sign off the OIE Undertaking on Confidentiality of information, if not done before.

2. Complete the Declaration of Interests Form in advance of the meeting of the Group and forward it to the OIE at the earliest convenience and at least two weeks before the meeting.

3. Evaluate the applications from Members for official recognition of FMD free status

   a) Before the meeting:

      - read and study in detail all dossiers provided by the OIE;
      - take into account any other information available in the public domain that is considered pertinent for the evaluation of dossiers;
      - summarise the dossiers according to the *Terrestrial Animal Health Code* requirements, using the form provided by the OIE;
      - draft the questions whenever the analysis of the dossier raises questions which need to be clarified or completed with additional details by the applicant Member;
      - send the completed form and the possible questions to the OIE, at least one week before the meeting.

   b) During the meeting:

      - contribute to the discussion with their expertise;
      - withdraw from the discussions and decision making when possible conflict of interest;
      - provide a detailed report in order to recommend, to the Scientific Commission for Animal Diseases, the country(ies) or zone(s) to be recognised (or not) as FMD free and to indicate any information gaps or specific areas that should be addressed in the future by the applicant Member.

   c) After the meeting:

      - contribute electronically to the finalisation of the report if not achieved during the meeting.

In addition at this meeting, the experts, members of this Group are expected to:

4. Review the report of the *ad hoc* Group on alternatives for surveillance for demonstration of freedom from FMD and recovery periods, consider the option document and discuss them during the meeting. Based on their experience in the evaluation of applications, provide an opinion on the different options presented and propose, if relevant, potential amendments in the FMD Chapter of the *Terrestrial Code*.

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Appendix II

MEETING OF THE OIE AD HOC GROUP ON THE EVALUATION OF FOOT AND MOUTH DISEASE (FMD) STATUS OF MEMBERS

Paris, 6 – 9 November 2017

Agenda

1. Opening
2. Adoption of the agenda and appointment of chairperson and rapporteur
3. Evaluation of requests from Members for the status recognition of FMD free countries where vaccination is not practised
    - Peru
    - Suriname
4. Evaluation of requests from Members for the status recognition of FMD free zones where vaccination is practised
    - Brazil
    - Chinese Taipei
5. Evaluation of a request from a Member for the endorsement of its official control programme for FMD
6. Review of the report of the *ad hoc* Group on *Alternatives for surveillance for demonstration of freedom from FMD and recovery periods* and consideration of the option document
7. Update on Chapter 8.8. on FMD of the *Terrestrial Animal Health Code*
8. Adoption of report

Appendix III

MEETING OF THE OIE AD HOC GROUP ON THE EVALUATION OF FOOT AND MOUTH DISEASE STATUS OF MEMBERS

Paris, 6 – 9 November 2017

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Appendix IV

OPTION DOCUMENT

MEETING OF THE OIE AD HOC GROUP ON

ALTERNATIVES FOR SURVEILLANCE FOR DEMONSTRATION OF FREEDOM

FROM FOOT AND MOUTH DISEASE (FMD) AND RECOVERY PERIODS

LINKING THE CONCLUSION OF THE AD HOC GROUP MEETING AND

ITS IMPACT ON THE FMD CHAPTER OF THE *TERRESTRIAL CODE*

1. Objective of the surveillance

In Article 8.8.7. Point 1.c) the Group recommended modifying the surveillance objective, for recovery of FMD free status in a country or zone where vaccination is not practised, to reflect the surveillance objectives to demonstrate the absence of infection in the unvaccinated population and the absence of transmission of FMDV in the vaccinated population.

It would be amended as follows: "*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, surveillance in accordance with Articles 8.8.40. to 8.8.42, are applied. However, this requires a serological survey based on the detection of antibodies to nonstructural proteins of FMDV to demonstrate no evidence of ~~infection~~ transmission in the remaining vaccinated population."*

2. Timing requirements

There are 3 options to consider the recommendation of the Group:

Option T1: The current timing requirements of Article 8.8.7. are maintained AND a sentence is added at the end of the article clarifying that the waiting period should be respected unless there is evidence that the appropriate level of confidence has been reached earlier by implementing additional surveillance or other measures.

NB: for the 'appropriate' level of confidence, please see sections 3 and 4 of this document.

Pros:

- This option would enable countries which have the means to achieve the appropriate level of confidence in demonstrating freedom from FMD earlier than 6 months to recover their status quicker.
- This does not pose an impediment for countries with less resource. Countries not capable of implementing additional surveillance and other measures to reach this level in a shorter time could still regain their status after 6 months by respecting the current requirements of Article 8.8.7.

Cons: Even if the recovery period can be shortened when additional surveillance measures are applied, documenting the effectiveness of surveillance remains tricky. There might be a need for an objective method of assessment of the supplementary surveillance measures applied to substantiate a shorter recovery period. In that case, a measureable/quantitative approach (e.g. scenario tree model) for the analysis and evaluation of surveillance system components could be considered as suggested by the Group. Should an objective method be needed, another technical *ad hoc* Group may be required to come up with suitable approach to be used (see point 4 below).

Option T2: The current timing for recovery of FMD freedom without vaccination after emergency vaccination to live (Point 1c) of Article 8.8.7.) is adjusted to 3 months with a description of a supplementary set of measures to be implemented.

In this case, Point 1c) of Article 8.8.7. would be amended as follows: "~~six~~ *three 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, surveillance in accordance with Articles 8.8.40. to 8.8.42, and additional surveillance and other measures in accordance with….are applied. ~~However,~~ This requires a serological survey based on the detection of antibodies to nonstructural proteins of FMDV to demonstrate no evidence of ~~infection~~ transmission in the remaining vaccinated population."*

Pros: Countries capable of implementing additional measures to demonstrate freedom from FMD would have the opportunity to regain their free status earlier than 6 months.

Cons:

- Same as for T1
- The countries that could demonstrate freedom from FMD even earlier than the specified period would still be limited by the waiting period.
- For countries with limited resources, the implementation of a supplementary set of measures might not be feasible and only proposing this option (3 months with additional measures) could become an unjustified trade barrier.
- The *Code* would have to provide guidance on the expected "*additional surveillance and other measures"* and make sure that it is feasible to all Members.

Option T3: The time requirements for the recovery periods all along Article 8.8.7. are removed and replaced by a requirement to achieve a certain level of confidence.

NB: for the 'certain' level of confidence, please see sections 3 and 4 of this document.

Pros: As suggested by Members, in this case the recovery period would be completely detached from time requirements and would only be based on the quality and intensity of the surveillance conducted. Countries could regain their free status once they have reached the specified level of confidence without having to wait for a specific time period to elapse.

Cons:

- Same as for T1
- This would most likely require that the expected level of confidence be quantified (see point 3 below).
- Members may need some guidance to evaluate the reached level of confidence of freedom (see point 4).

The ad hoc Group's preference:

The Group was of the opinion that a country's assessment to regain its status should be based on the quality of surveillance, not the time that has elapsed since the last case, although the time elapse could also contribute as one of the factors in increasing the confidence of demonstrating freedom from FMD. As a consequence, the Group was not in favour of specifying the recovery period. Among the 3 options for time requirements, the Group was mostly in favour of T1.

3. Qualitative or quantitative requirement for the level of confidence

Option C1: We only ask that a 'high' level of confidence is achieved.

Pros:

- 'High' level of confidence would provide more assurance in the credibility of a countries' recovered free status.
- Flexibility

Cons:

- Not fully objective.

Option C2: We quantify the requested level of confidence.

Pros: Transparency, clarity

Cons:

- Scientific rationale should be given to justify the selected level of confidence.
- It wouldn't leave any flexibility to the countries.

The ad hoc Group's preference:

The Group expressed its preference for option C1.

4. Method for the assessment of the level of the confidence

Option M1: We just indicate the required level of confidence, without providing any additional guidance on the way to evaluate it.

Pros:

- Simple, easy, flexible and not prescriptive
- Most of the countries able to shorten the recovery period would have the capacity to evaluate the level of confidence reached thanks to the surveillance and control measures in place.

Cons:

- Some countries may want some more guidance

Option M2: We provide qualitative guidance on the methods to assess the level of confidence.

Pros:

- Same as for M1
- Can be developed in the horizontal chapter (Chapter 1.4. on surveillance)

Cons:

- Some countries may want some more guidance.
- This may require another technical ad hoc Group to come up with suitable approach to be used.

Option M3: We develop a model.

Pros:

- Improvement of the transparency and objectivity in the evaluation of the surveillance information in applications for recovery of free status.
- Harmonisation and simplification of the assessment.

Cons:

- This could be a significant impediment for some countries which may encounter difficulties not only implementing but even interpreting such a model (the BSE example and the current exit-strategy should be considered).
- This would also require another technical ad hoc Group to come up with suitable approach to be used.
- In addition, FMD has a complex epidemiology that varies significantly depending on the serotypes, among different geographical regions and evolves through time. Therefore, a model may not be globally applicable or adapted to different situations to reflect these differences.

The ad hoc Group's preference:

The Group expressed its preference either for option M1 or M2. Although the Group was of the opinion that the possibility of a model could be explored, it stressed that quantitative models, while useful, can be misleading if they are not appropriately carried out with good quality data.