Original: English
October-November 2020

REPORT OF THE VIRTUAL MEETING OF THE OIE AD HOC GROUP ON THE EVALUATION OF FOOT AND MOUTH DISEASE STATUS AND ENDORSEMENT OF OFFICIAL CONTROL PROGRAMMES OF MEMBERS 12 October to 4 November 2020

A virtual meeting of the OIE *ad hoc* Group on the Evaluation of Foot and Mouth Disease (FMD) Status and endorsement of official control programmes of Members (hereafter the Group) was held from 12 October to 4 November 2020.

1. Opening

Dr Matthew Stone, Deputy Director General for International Standards and Science of the OIE, welcomed and thanked the Group for its commitment and the extensive support towards the OIE mandates. He highlighted that the official recognition of disease status was an important activity for the OIE and acknowledged the amount of work before, during and after the *ad hoc* Group meeting and the efforts required in reviewing the dossiers, particularly considering the high number of dossiers received each year with regard to FMD.

Dr Stone reminded the Group of the confidentiality of the dossiers received for official recognition and thanked the experts for abiding by the undertaking of confidentiality. He underlined the OIE procedures for protecting the confidentiality of information and for declaring potential conflicts of interest; the experts would withdraw themselves from the discussion and conclusion in case of a potential conflict of interest.

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

The Group was chaired by Dr David Paton, and Dr Alf-Eckbert Füssel 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 <u>Appendices I, II</u> and <u>III</u>, respectively.

3. Evaluation of a request from a Member for official recognition of an FMD free status where vaccination is not practised

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

4. Evaluation of requests from Members for official recognition of FMD free zones where vaccination is not practised

a) Brazil

In August 2020, Brazil submitted an application for the recognition of three zones, namely the zone of the State of Paraná; zone of the State of Rio Grande do Sul and a zone (Block 1) including the States of Acre and Rondônia and 14 municipalities in the States of Amazonas and five municipalities in the State of Mato Grosso, as free from FMD where vaccination is not practised. All three zones have an official FMD-free status where vaccination is practised and are transitioning to become officially recognised FMD-free without vaccination. The Group requested additional information and received clarification from Brazil.

In accordance with the established procedures, the participating expert from Pan-American Centre for Footand-Mouth Disease (PANAFTOSA) expressed a possible conflict of interest and withdrew from the decision making on Brazil's dossiers.

The following report combines the observations for the three zones and only differentiates them when necessary.

i) Animal disease reporting

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

ii) Veterinary Services

The Group acknowledged that the Veterinary Authority had current knowledge of, and authority over, FMD susceptible animals in the proposed zones.

iii) Situation of FMD in the past 12 months

The Group noted that all three proposed zones consisted of areas having officially recognised FMD free status with vaccination, and the last FMD outbreaks in the three proposed zones occurred as follows: in February 2006 in the State of Parana, in 2001 in the State of Rio Grande do Sul and in 1999 in the zone of Block 1.

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

The Group noted that the last vaccinations in the proposed zones were carried out as follows: May 2019 in the State of Parana, April 2020 in the State of Rio Grande do Sul and in November 2019 in the zone of Block 1. In accordance with Article 8.8.3. of the *Terrestrial Code*, Brazil informed the OIE in advance about the intended cessation of vaccination in the proposed zones.

The Group acknowledged that vaccination was prohibited by law in the proposed zones as of 31 October 2019 in the State of Parana, and as of 29 April 2020 in both the State of Rio Grande do Sul and the zone of Block 1. The Group agreed that the zone of Block 1 and the State of Rio Grande do Sul would meet the provisions of Article 8.8.2. by December 2020 and May 2021, respectively, provided that Brazil certifies and submits documented evidence that during the past 12 months "no vaccination against FMD has been carried out" and "no vaccinated animal has been introduced except in accordance with Articles 8.8.8. and 8.8.9." (Article 8.8.2. Points 2.b and 4.e of the Terrestrial Code). This documentation should be provided to the OIE by the end of December 2020 and April 2021 for the respective zones.

The Group noted that animals vaccinated against FMD are allowed to enter the proposed zones in some exceptional cases – directly to a slaughterhouse or to the establishment for the pre-shipment inspections prior to export – based on Articles 8.8.8. and 8.8.9. of the *Terrestrial Code* and consultations with the OIE. Upon the Group's request, Brazil further clarified the procedures in place and supported by official regulations to ensure that the animals are transported under the supervision of the Veterinary Authority in a sealed vehicle, directly from the establishment of origin to the slaughterhouse or the preshipment establishment without coming into contact with other susceptible animals and that the vaccinated animals transiting for export have not remained in the proposed zone. Brazil also provided details on the procedures carried out at the slaughterhouses to ensure the control of vaccinated animals and their carcasses and to inactivate the virus from the heads of ruminants (tongue, pharynx and associated lymph nodes).

v) Surveillance in accordance with Articles 8.8.40 to 8.8.42.

The Group acknowledged the rigorous passive surveillance schemes in place involving the participation of private veterinarians and farmers at state and district levels. Brazil described its surveillance system based on a combination of serological surveillance and systematic clinical surveillance at agricultural and livestock events, at slaughterhouses and during animal movement inspections.

Brazil provided information in its dossiers and annexes on the risk-based serological surveys conducted in the three proposed zones. In each of the three proposed zones, municipalities were classified as either at high-risk or at low-risk, based on livestock density, outward and inward movements and vaccination coverage. Farms and cattle in high-risk municipalities constituted the target population. A two-stage random sampling was used to select the farms and the cattle within selected farms. The Group considered that the design of these surveys achieved an adequate level of confidence to demonstrate no evidence of virus transmission during the last 12 months. Brazil also described the enhanced surveillance activities at the international borders of the proposed zones, one of which was a border surveillance programme in the State of Rio Grande do Sul.

The Group commended Brazil for the strong public-private partnership achieved that involves the availability of funds from the private sector for indemnities in case of FMD occurrence.

Overall, the Group concluded that the combined strategy for surveillance in Brazil was sufficient to demonstrate absence of infection with FMDV in unvaccinated animals and of FMDV transmission in previously vaccinated animals in all three proposed free zones. The Group also commended Brazil for its efforts in continuously evaluating its FMD surveillance programmes.

vi) Regulatory measures for the prevention and early detection of FMD

Brazil described and provided references to the legal framework for import conditions of FMD susceptible animals and animal products. The Group noted that between 2018 and the first semester of 2020, Brazil imported live susceptible animals into the proposed zones only from countries officially recognised free from FMD. Animal products were also imported only from free countries except for the importation of casings from an infected country. Upon request from the Group, Brazil explained the conditions for the importation of offal and casings from infected countries, and the Group agreed that they are in compliance with the provisions of Articles 8.8.31. and 8.8.38. of the *Terrestrial Code*.

The Group noted coordinated FMD prevention activities with neighbouring countries, in the framework of the Permanent Veterinary Committee (CVP).

Considering the information provided in the dossiers as well as the fact that the proposed zones are already officially recognised free from FMD (where vaccination is practised), the Group concluded that sufficient regulatory measures were described in the dossiers for the early detection, prevention and control of FMD.

vii) Description of the boundaries of the proposed free zone

Two of the proposed free zones cover the State of Paraná and the State of Rio Grande do Sul, and the zone of Block 1 includes the States of Acre and Rondônia and 14 municipalities in the States of Amazonas and five municipalities in the State of Mato Grosso. The Group acknowledged that the boundaries of the three proposed zones were based on natural barriers and administrative divisions. All proposed zones also border countries and zones officially recognised free from FMD.



Fig. 2. The three proposed FMD-free zones where vaccination is not practised (highlighted with red boundaries): zone of Block I in light blue, State of Paraná in pink and the State of Río Grande do Sul in light green for potential recognition in May 2021, and already officially recognised FMD-free zones with and without vaccination (in yellow and green colour).

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 (into the proposed FMD free zone)

In the dossier, Brazil explained that importation of animals, their products, by-products, and genetic material are always preceded by a risk analysis by the Ministry of Agriculture, Livestock and Supply (MAPA), which defines the requirements to be met for the goods to enter the country. Specific measures to mitigate risk may be applied both in the country of origin and after their arrival in Brazil, including quarantine and diagnostic testing of live animals. Specific rules were established and substantiated by legislation regarding the movement of FMD susceptible animals and animal products, including transport within the country between zones with different health status. In addition, Brazil described the control posts and police checkpoints at the borders and within the proposed zones, which appeared comprehensive and strategically located to control the movements. The Group recommended maintaining active surveillance, especially at international borders where there are no natural barriers. The Group commended the joint activities carried out by MAPA with the Veterinary Services of bordering countries on surveillance and biosecurity for FMD prevention and early detection.

The Group took note that non-compliant imports of animals would return to the place of origin or euthanised, depending on the risk factors identified by the Veterinary Service. The Group appreciated that contingency plans are in place as well as a well-defined supportive legal framework. Brazil also provided information on the simulation exercises conducted in the past two years involving various stakeholders.

The Group considered the described measures including awareness campaigns, regular simulation exercises and legislation, to be adequate to prevent the entry of FMDV into the proposed zones.

x) Compliance with the questionnaire in Article 1.11.3.

The Group appreciated the well-structured and good quality dossiers provided by Brazil. The format of Brazil's three dossiers was compliant with the questionnaire in Article 1.11.3.

Conclusion

Considering the information submitted in the dossiers and to the questions raised, the Group agreed that the applications were compliant with the requirements of Chapter 8.8. and with the questionnaire in Article 1.11.3. of the *Terrestrial Code*. The Group, therefore, recommended that the three proposed zones of Brazil be recognised as FMD free zones where vaccination is not practised.

b) Other requests

The Group assessed two other requests from Members for the official recognition of FMD free zones where vaccination is not practised. The Group concluded that the applications did not meet the requirements of the *Terrestrial Code*. The dossiers were referred back to the respective applicant Members.

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

a) Colombia - former high surveillance zone

In August 2020, Colombia submitted an application for official recognition of a new zone free from FMD with vaccination. This zone is the former high surveillance zone (15-km strip along the border with Venezuela) consisting of parts of the Departments of Arauca, Boyacá and Vichada. Colombia confirmed that the application was for the official recognition of the former high surveillance zone (hereafter referred to as the proposed zone) and merge with Zone II (Eastern border) which is officially recognised free from FMD with vaccination.

The Group took into account the report of the OIE mission of November 2019 when assessing Colombia's application. The Group requested additional information and received answers from Colombia.

In accordance with the established procedures, the participating expert from the Pan-American Centre for Foot-and-Mouth Disease (PANAFTOSA) expressed a possible conflict of interest and withdrew from the decision making on Colombia's dossier.

i) Animal disease reporting

The Group considered that Colombia generally had a record of regular and prompt animal disease reporting. However, some concerns were noted in relation to delay in notification to the OIE. The Group reemphasised the recommendation of the OIE mission of November 2019 that notification to the OIE should be done immediately after the detection of a case defined in accordance with Article 8.8.1. of the *Terrestrial Code*, including illegally introduced animals regardless of the place of detection.

ii) Veterinary Services

The Group noted that the Veterinary Services were compliant with the requirements for a country having officially recognised FMD-free zones.

Colombia reported that in order to address the illegal entry of animals and agricultural products into Colombia, an Integrated Centre (CIIIP) was created, consisting of the Colombian Agriculture and Livestock Institute (ICA), the National Institute for Medicine and Food Surveillance (INVIMA), the Fiscal and Customs Police (POLFA) and the National Tax and Customs Office (DIAN). The CIIIP functions 24-hours a day and through the collaborative capacities of the agencies, the CIIIP Integrated Centre aims to counteract smuggling of goods from neighbouring countries by using the information systems available to detect irregularities in the movement of livestock.

iii) Situation of FMD in the past two years

According to the dossier, the last outbreaks in the proposed zone were in 1993. The Group agreed that the proposed zone complied with the requirements of Article 8.8.3. point 2 of the *Terrestrial Code*.

iv) Routine vaccination and vaccines

According to the dossier, cattle and buffalo are vaccinated against FMD twice a year, in May-June and November-December. An additional round of vaccination was carried out in January-February 2019 in eight departments at the border with a neighbouring country with undetermined FMD status. Colombia mentioned its plan to continue conducting an additional cycle of vaccination in young stock (cattle and buffaloes under 18 months of age) in the departments of the proposed zone following the recommendations of the OIE mission of November 2019. However, the Group noted that the additional cycle of vaccination that was initially planned to take place in the first quarter of 2020 was postponed to January-March 2021 due to the COVID-19 pandemic. The Group strongly recommended this additional cycle of vaccination to be conducted as soon as possible in all departments of the proposed zone for better mitigation of the risk of FMDV infection and spread.

The Group noted that the characteristics of the vaccine and the standards for its production are laid down by ICA, following the provisions of the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual)*. The vaccine authorised for use in Colombia is an inactivated, bivalent vaccine containing viral strains A24 Cruzeiro and O1 Campos. Colombia explained that the viral strains contained in the vaccine were matched with the field virus isolated from the outbreaks in 2017 and 2018; these analyses were performed by PANAFTOSA.

The Group concluded that the results of post-vaccination monitoring studies carried out in 2019 showed adequate levels of population immunity, even if only eleven farms were sampled from the proposed zone.

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

The Group was given details of the active and passive surveillance in place. Colombia provided information on the number of suspected vesicular disease cases and investigations carried out in the last two years to exclude FMD. Furthermore, the dossier provided details on a serological survey conducted in November-December 2019, with a representative sample of farms in the proposed zone, demonstrating absence of FMDV transmission. The Group acknowledged that appropriate follow-up procedures were performed on holdings where seropositive animals were detected during the primary sampling. However, the Group recommended that probang tests should also be performed at least on newly detected NSP-reactor animals in the second sampling.

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

Colombia described its network of epidemiological sensors made up of professionals (i.e. veterinarians, veterinary zootechnicians with certified graduate or postgraduate degrees) and para-professionals (i.e. people who have completed one or two years of technical courses in livestock-related studies) in support of the early warning system. The sensors receive annual training provided by ICA on all diseases of national importance including FMD.

The Group commended Colombia's efforts to address the illegal entry of animals and agricultural products into Colombia with the establishment of an Integrated Centre (CIIIP) (see point ii on *Veterinary Services*). The report of the OIE mission confirmed the enhanced surveillance at the international borders of the proposed zone, as well as the timely intervention of security forces.

The dossier mentioned the measures in place to prevent FMDV introduction from neighbouring countries. Information was provided on the permanent and mobile coordinated control posts established at the border with the neighbouring country to prevent illegal movements, the number of inspections of vehicles, and quantities of seized animals and animal products from 2018 to 2020. The dossier also mentioned the use of drones in areas with difficult access and implementation of new mobile control posts supported by the Colombian Army and National Police along the frontiers.

Colombia made reference to different regulations to restrict the feeding of food waste to pigs, but in contrary, explained in the additional information that swill feeding was known to occur for social and cultural reasons in backyard pigs kept for local slaughter and consumption. Considering the low number of pig farms in the proposed zone the Group was of the opinion that the risk from swill feeding was low. Nevertheless, if the prohibition of swill feeding was not a plausible option, the Group strongly recommended implementation of regulations for the treatment of swill taking into account Article 8.8.31. of the *Terrestrial Code*.

vii) Description of the boundaries of the proposed free zone

The proposed zone is the former high surveillance zone (15-km strip along the border with Venezuela) consisting of parts of the Departments of Arauca, Boyacá and Vichada, namely the municipalities of Arauca, Arauquita, Cravo Norte and Saravena in the Department of Arauca; the municipality of Cubará in the Department of Boyacá; and the municipalities of La Primavera and Puerto Carreño in the Department of Vichada. Colombia confirmed that the application was for the official recognition of the proposed zone merged with Zone II (Eastern border), which is officially recognised free from FMD with vaccination. The Group noted that this proposed merger was in line with the recommendations of the OIE mission of November 2019 and agreed with the described logic of the merger for control purposes.





Fig. 4 (**left**) – Proposed FMD free zone (outlined in red) which is part of an area with undetermined FMD status (in stripe) and already officially recognised FMD-free zones with and without vaccination (in colours).

Fig. 5 (**right**) – The final proposal after the merge with Zone II (Eastern border zone; blue) for potential recognition in May 2021.

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 (into the proposed FMD free zone)

The dossier described Resolution 60865 of 2020 establishing the sanitary requirements for the movement of FMD susceptible animals and their products from the proposed zone to an FMD-free zone where vaccination is practised.

Regarding animal identification, Colombia stated that individual identification of cattle and buffalo was mandatory in the proposed zone since 2010 by resolution and provided an estimation of 75% of the total cattle and buffalo population that have been individually identified. Colombia also clarified that all animals that are moved out of the proposed zone must have individual identification prior to transport. Colombia also mentioned that identification of cattle and buffalo at herd level using hot-iron brand was mandatory. Whilst the Group commended Colombia's progress made, it emphasised the importance and urgency to achieve 100% of individual identification of cattle and buffalo in the proposed zone considering the high potential of FMDV introduction due to illegal entry of infected animals or animal products from a neighbouring country with undetermined FMD status.

The dossier described the import requirements of susceptible animals and their products. The Group acknowledged that the imported FMD susceptible animals and animal products from 2017 to 2019 were only from countries or zones recognised by the OIE as free from FMD.

The Group acknowledged the significant efforts in implementing control measures to prevent the introduction of FMDV. The Group encouraged Colombia to continue strengthening its early warning system and surveillance activities, as well as to fully implement the individual animal identification system in the proposed zone.

x) Compliance with the questionnaire in Article 1.11.4.

The Group agreed that the format of the dossier was compliant with the questionnaire in Article 1.11.4.

Conclusion

Considering the information submitted in the dossier and to the questions raised, the Group agreed that the application was compliant with the requirements of Chapter 8.8. and with the questionnaire in Article 1.11.4. of the *Terrestrial Code*. The Group, therefore, recommended that the proposed zone of Colombia be recognised and merged with Zone II (Eastern border) which already has an official FMD-free status, as one enlarged zone free from FMD where vaccination is practised.

b) Russia - Zone-South and Zone-Sakhalin

Russia was recognised as having a zone free from FMD where vaccination is not practised in May 2016. In August 2020, Russia submitted applications for the recognition of additional zones free from FMD where vaccination is practised as follows:

Zone-South: zone including Southern and North Caucasian Federal Districts, consisting of 13 Subjects: Rostov Oblast, Stavropol Krai, Krasnodar Krai, Volgograd Oblast, Astrakhan Oblast, Republic of Kalmykia, Chechen Republic, Republic of Ingushetia, Republic of Dagestan, Kabardino-Balkarian Republic, Karachay-Cherkess Republic, Republic of North Ossetia-Alania, Republic of Adygea; and

Zone-Sakhalin: consisting of the Island of Sakhalin and the Kurile islands.

The Group requested additional information and received answers from Russia. Furthermore, as part of the evaluation, the Group had a teleconference with technical experts from Russia.

The following report combines the observations for the two zones and only differentiates them when necessary.

i) Animal disease reporting

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

ii) Veterinary Services

The Group acknowledged the provision of the comprehensive set of legislation related to FMD activities and the organisation of the Veterinary Service in Russia. The Group agreed that the Veterinary Authority had current knowledge of, and authority over, FMD susceptible animals in the proposed zones.

iii) Situation of FMD in the past two years

According to the information submitted in the dossiers, the last outbreaks in the proposed zones were in 2013 in the Zone-South and in 1956 in the Zone-Sakhalin. In the Zone-South, the last outbreaks of FMD serotype A occurred in Krasnodar Krai, Republic of Kabardino-Balkarian and Republic of Karachay-Cherkess in 2013. The dossier stated that no clinical suspicions in wildlife nor in domestic animals were detected. The Group agreed with the rationale to maintain vaccination in the proposed zone as it borders countries not recognised as free from FMD.

iv) Routine vaccination and vaccines

The Group agreed that the vaccine complies with the provisions of the *Terrestrial Manual*. Russia explained that the viral strains in the vaccine were selected based on the circulating field viruses in Russia and in neighbouring countries. Russia explained that the vaccines are purchased using federal budget and vaccinations are overseen by the Veterinary Service and provided to producers free of charge. Cattle, sheep and goats are vaccinated, but not pigs.

The Group noted that cattle are vaccinated every three months until they reach the age of 18 months, aiming at building a good level of immunity in early stages, and after 18 months, vaccination is maintained every six months. Small ruminants, yaks and buffaloes are also vaccinated.

According to the data provided by Russia on the population immunity levels for the past two years, stratified by Subject and by age, the target population immunity level of 75% set by Russia was barely achieved in both zones using an average figure of the immunity levels of all Subjects in each zone. The Group also found the rationale for the sampling design of the population immunity survey unclear. Upon the Group's request, Russia explained that the expected population immunity was not reached due to the difficulties to vaccinate animals in some remote areas. In the Zone-South, the results were particularly dragged down by the rather low results in three Regions (i.e., Republic of Kalmykia, Republic of North Ossetia-Alania and Karachay-Cherkess Republic).

Whilst the Group considered the overall level of population immunity acceptable for both zones; it strongly urged Russia to investigate and address the causes of the low immunity levels, taking into account that these surveys included samples taken from older animals that had been vaccinated many times.

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

Russia described its passive surveillance based on investigations of FMD suspicions and clinical examinations during routine disease prevention activities on commercial farms on a quarterly basis and at least three times a year on family-operated farms and backyards. The Group also noted that regular serological surveillance was performed in the proposed free zones with structural protein and non-structural protein (NSP) tests and follow-up field investigations and testing in case of suspicious or inconclusive results.

The Group noted that a randomised sampling approach was taken for the NSP surveys. This approach is based on an infinite animal population, assuming a 0.5% design prevalence and aiming to achieve a 95% confidence level. In the additional information provided, Russia explained that the survey targets all types of holdings (i.e. backyard, family-operated farm, and commercial farm). This was shown by the descriptive statistics for herd size provided for all sampled holdings.

The results of the surveys conducted in 2019 and 2020 in the proposed free zones showed zero NSP reactors in the second paired sampling, ruling out presence of FMDV transmission. The Group was concerned by the absence of new NSP-reactors in the second rounds of sampling of farms that had NSP-reactor animals during the first sampling. This sustained absence of potential false positives in the second sampling appeared unexplainable and precludes further investigations to be carried out on possible causes for the initial NSP-positive results.

Although the procedure of the survey followed a two-stage sampling (selecting the settlements and then the animals), this two-stage approach was not followed in the study design nor in the sample size calculation. A two-stage sampling design is recommended to account for clustering in the design of surveillance activities and in the statistical analysis of surveillance data (as described in Article 1.4.3., point 1.e. of the *Terrestrial Code*).

The Group recommended Russia to review the survey design to adjust the sample size calculation to a two-stage sampling approach with an epidemiological focus to the whole proposed zone. Thus, the sample size calculation should first determine the number of epidemiological units (e.g. settlements, herds, etc.) and number of animals per epidemiological unit to include in the survey, accounting for sensitivity and specificity of the test. Then, the epidemiological units should be sampled following a random process or other strategy (e.g. stratified, risk based, etc.) based on justified criteria; the same method should be used for the selection of animals within each epidemiological unit.

With regard to the Zone-South, the Group noted the number of herds sampled in the NSP surveys for 2019 (N=319) and in 2020 (N=299). These figures were close to the number of herds expected to be sampled under a two-stage design recommended above to rule out the presence of FMDV transmission with a between-herd design prevalence of 1% and 95% confidence level. Additionally, the number of samples per herd was adjusted to the herd size. Thus, the Group considered that the sample size and sampling strategy followed by Russia in the Zone-South was sufficient to rule out the presence of FMDV transmission in the zone.

In the Zone-Sakhalin, the Group observed that the passive surveillance would be an important contributor to early detection and to demonstrate absence of FMD. This is mainly due to the relatively high proportion of animals that are species not vaccinated against FMD (48,075 pigs *vs* 26,635 cattle and 4,451 small ruminants) wherein the level of detection of clinical presentation of FMD, if present, is expected to be greater than in vaccinated animals.

The Group noted that the sample size for the number of holdings included in the surveys in 2019 and 2020 was, in general terms, low (20 in 2019 and 16 in 2020). However, the Group also considered the relatively low number of cattle in the proposed free zone, resulting in a relatively high proportion of cattle sampled in relation to the total population (approximately 2.5%).

The Group acknowledged the Russian laboratory's participation and satisfactory results in interlaboratory proficiency testing schemes in 2018, as well as its participation in 2019.

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

The Group noted that reporting of FMD suspect cases is enforced by law and FMD is included in the list of priority diseases for immediate notification to the Veterinary Authority. Information was also provided on awareness campaigns and trainings conducted for farmers and veterinarians to promote the reporting of the FMD suspicions.

The dossier described the regulatory measures for movement of animals and animal products between zones of different animal health status. Russia provided the numbers of non-compliant movements detected and amounts of confiscated animal products. The Group also noted that the Veterinary Authorities were working together with the police and armed forces in preventing illegal movements and entry of FMD susceptible animals and their products.

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

vii) Description of the boundaries of the proposed free zones

The Group agreed that the boundaries of the proposed free zones were clearly defined based on administrative divisions and taking into account natural barriers.

The Group noted that the Zone-South borders to the south countries not officially recognised free from FMD, and to the north and north-east FMD-free zones where vaccination is not practised of Russia and Kazakhstan.

The dossier described that the Zone-Sakhalin has no land borders with the mainland of Russia or any other countries.



Fig. 6. Proposed FMD-free zones where vaccination is practised (Zone-South in orange and the Zone-Sakhalin in blue) for potential recognition in May 2021. Zone already having an FMD-free status where vaccination is not practised (in green) and a zone with an undetermined FMD status (striped area).

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 (into the proposed FMD free zones)

The Group considered that the Zone-Sakhalin was in a favourable location as it has no land borders with the mainland of Russia or any other countries.

The Group acknowledged the comprehensive legal framework provided by Russia on the identification and registration of animals, as well as for the traceability of animal movements using an electronic certification system. Each animal is assigned an individual number shown on its ear tag, brand or tattoo. The dossier stated that records of farms and animals are updated yearly at the end of the calendar year through a comprehensive census. Russia also explained that live animals imported into Russia or transported between the Customs Union member countries should also be identified either individually or as a group, by ear-tags, microchips, rings or tattoos.

The Group noted that live animals and animal products are subjected to inspections carried out at the border inspection posts (BIPs) prior to entry into the proposed zones and the country. Importation of live animals and animal products is permitted based on the results of a previous risk analysis conducted in accordance with the Customs Union Decisions and following the provisions of the *Terrestrial Code*. Russia also explained that the control of movements of live animals and animal products between the different zones is ensured by the regional departments of the Veterinary Service.

The Group considered the described measures adequate to prevent the entry of FMD virus into the proposed zones. Nevertheless, the Group emphasised the importance of continuous compliance with the provisions of the *Terrestrial Code* for importation of animals and their products from countries or zones with lesser animal health status, and for maintaining effective separation and control on movements of animals and their products between the zones of different animal health and vaccination status.

x) Compliance with the questionnaire in Article 1.11.4.

The Group agreed that the format of the dossiers was compliant with the questionnaire in Article 1.11.4.

Conclusion

Considering the information submitted in the dossiers and the answers from Russia to the questions raised, the Group considered that the applications for the two zones of Russia were compliant with the requirements of Chapter 8.8. and with the questionnaire in Article 1.11.4. of the *Terrestrial Code*. The Group therefore recommended the official recognition of the two proposed zones as free from FMD where vaccination is practised.

Nevertheless, the Group would draw the attention of Russia to the following recommendations and to provide updates when Russia reconfirms its FMD status (also detailed in the relevant sections above):

- to investigate and address the causes of the low immunity levels, particularly in older animals that had been vaccinated many times (e.g., more than 18 vaccinations for animals older than 8 years).
- to review the survey design to adjust the sample size calculation to a two-stage sampling approach with an epidemiological focus to the whole proposed zone. Thus, the sample size calculation should first determine the number of epidemiological units (e.g. settlements, herds, etc.) and number of animals per epidemiological unit to include in the survey, accounting for sensitivity and specificity of the test.
- NSP reactors found in surveys should be followed-up by further investigations in accordance with Article 8.8.42. point 1 of the *Terrestrial Code*, and by studies on clustering as described in Article 1.4.3., point 1.e. of the *Terrestrial Code*.

c) Other requests

The Group assessed two other requests from Members for the official recognition of FMD free zones where vaccination is practised. The Group concluded that the applications did not meet the requirements of the *Terrestrial Code*. The dossiers were referred back to the applicant Members.

6. Evaluation of requests from Members for the endorsement of official control programme for FMD

The Group assessed two requests from Members for the endorsement of their official control programme for FMD. The Group concluded that the applications did not meet the requirements of the *Terrestrial Code*. The dossiers were referred back to the applicant Members.

7. Adoption of the report

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

.../Appendices

Appendix I

VIRTUAL MEETING OF THE OIE AD HOC GROUP ON THE EVALUATION OF FOOT AND MOUTH DISEASE STATUS AND ENDORSEMENT OF OFFICIAL CONTROL PROGRAMMES OF MEMBERS 12 October to 4 November 2020

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 their official control programme of FMD received from Members in accordance with the Standard Operating Procedure for official recognition of disease status and for the endorsement of national official control programmes.

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 and for endorsement of their official control programmes for FMD.
 - 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, i) the country(ies) or zone(s) to be recognised (or not) as FMD free ii) country(ies) to have (or not) the OIE endorsement of national official control programme for FMD, 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.

Appendix II

VIRTUAL MEETING OF THE OIE AD HOC GROUP ON THE EVALUATION OF FOOT AND MOUTH DISEASE STATUS AND ENDORSEMENT OF OFFICIAL CONTROL PROGRAMMES OF MEMBERS

12 October to 4 November 2020

Agenda

- 1. Opening
- 2. Adoption of the agenda and appointment of chairperson and rapporteur
- 3. Evaluation of a request from a Member for official recognition of FMD free status where vaccination is not practised
- 4. Evaluation of a requests from Members for the official recognition of FMD free zones where vaccination is not practised
 - Brazil three zones (State of Parana; State of Rio Grande do Sul; States of Acre and Rondônia and 14 municipalities in the States of Amazonas and five municipalities in the State of Mato Grosso)
- 5. Evaluation of requests from Members for the official recognition of FMD free zones where vaccination is practised
 - Colombia –former high surveillance zone
 - Russia Zone-South and Zone-Sakhalin
- 6. Evaluation of requests from Members for the endorsement of official control programme for FMD
- 7. Adoption of the report

Appendix III

OIE AD HOC GROUP ON THE EVALUATION OF FOOT AND MOUTH DISEASE STATUS AND ENDORSEMENT OF OFFICIAL CONTROL PROGRAMMES OF MEMBERS

12 October to 4 November 2020

List of participants

MEMBERS

ARGENTINA

SOUTH AFRICA

Dr Sergio Duffy Consultant Arenales 2303 C1124AAK Ciudad Autónoma de Buenos Aires

Dr Ben Du Plessis (Invited but could not attend)
Deputy Director Animal Health,
Ehlanzeni South District

Acting Head of Unit, DG SANTE/G2 Rue Froissart 101-3/64 - B-1049 Brussels BELGIUM

Dr Alf-Eckbert Füssel

Dr Manuel J Sanchez Vazquez FMD Center/PAHO-WHO Centro Panamericano de Fiebre Aftosa Caixa Postal 589 - 20001-970 Rio de Janeiro BRAZIL **Dr David Paton**The Pirbright Institute
Ash Road, Woking
Surrey GU20 0NF
UNITED KINGDOM

Dr Wilna Vosloo Group Leader CSIRO Livestock Industries Australian Centre for Disease Preparedness Private Bag 24 Geelong, VIC 3220 AUSTRALIA

REPRESENTATIVE OF THE SCIENTIFIC COMMISSION

Dr Kris de Clercq Sciensano Department of Virology Section Epizootic Diseases Groeselenberg 99 B-1180 Ukkel BELGIUM

OIE HEADQUARTERS

Dr Matthew Stone
Deputy Director General
12 rue de Prony
75017 Paris
FRANCE
Tel: (33) 1 44 15 18 88
Fax: (33) 1 42 67 09 87

oie@oie.int

Dr Neo Mapitse Head of Status Department disease.status@oie.int

Dr Min Kyung ParkDeputy Head of Status Department

Dr Mauro MeskeDisease Status Officer
Status Department