

***Ad hoc* Group on the Evaluation of Foot and Mouth Disease (FMD) Status and endorsement of official control programmes of Members**

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A virtual meeting of the *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 on 2 to 4, 7, and 9 November 2022.

1. Opening

Dr Montserrat Arroyo, Deputy Director General for International Standards and Science, welcomed and thanked the Group for its commitment and extensive support towards WOAHA mandates. She highlighted that the official recognition of animal health status was an important activity for WOAHA and acknowledged the amount of work before, during and after the meeting and the efforts required in reviewing the dossiers, particularly considering the high number of dossiers received each year for FMD.

Dr Arroyo reminded the Group of the confidentiality of the dossiers for official recognition and thanked the experts for abiding by the undertaking of confidentiality. She 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 Park briefed the Group on the state of play of the revision of Chapter 8.8 'infection with FMD virus' of the *Terrestrial Animal Health Code (Terrestrial Code)*, which included provisions for the introduction of animals from countries or zones free from FMD where vaccination is practised into countries or zones free from FMD where vaccination is not practised, recommendations for the importation of fresh meat of small ruminants from FMD-infected countries/zones, etc. She also mentioned the recommendation of the Scientific Commission for Animal Diseases (Scientific Commission) to develop FMD surveillance guidelines following these latest draft revisions of the Chapter.

The experts and WOAHA welcomed Dr Livio Heath as new member of the Group.

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

Dr Manuel Sanchez chaired the Group, and Dr Wilna Vosloo acted as rapporteur, with the support of the WOAHA Secretariat. The Group endorsed the proposed agenda.

The terms of reference, agenda and list of participants are presented as Appendices 1, 2 and 3, respectively.

3. Evaluation of an application from a Member for the official recognition of an FMD-free status where vaccination is practised

Republic of Korea

The Republic of Korea (hereafter referred to as Korea) had an 'FMD-free where vaccination is practised' status officially recognised by WOAHA in May 2014. This status was suspended due to an outbreak in July of the same year. In September 2022, Korea applied for official recognition of an FMD-free status where vaccination is practised. The Group requested additional information and received clarifications from Korea during the evaluation of the dossier.

i. Animal disease reporting

The Group considered that Korea had a record of regular and prompt animal disease reporting in accordance with Chapter 1.1. of the *Terrestrial Code*.

ii. Veterinary Services

The Group noted that the Veterinary Service system of Korea is layered composed of central and local governments. The Ministry of Agricultural, Food and Rural Affairs (MAFRA) and the Animal and Plant Quarantine Agency (APQA) are the central government bodies responsible for imports and exports of animals, livestock products and plants, animal disease control, testing, diagnosis, surveillance and research of domestic and foreign animal diseases. The system also counts on the participation of private veterinarians in

the identification, reporting, and control of FMD. The Group noted that the Korean Veterinary Services are supported by solid legislation, orders, and standard operating procedures. The Group agreed that the Veterinary Services has knowledge of and authority over FMD susceptible animals.

iii. The situation of FMD in the past two years

The last outbreak was in January 2019, involving three premises, two cases in Anseong, Gyeonggi-Do and one case in Chungju, Chungcheongbuk-Do. Two dairy cattle farms and one Korean native cattle farm were infected, and the outbreak was swiftly responded to and controlled at that time. Stamping-out, movement restriction, and emergency vaccination were implemented to prevent the spread of the FMD virus. The FMD virus that caused this last outbreak in 2019 was reported to be different from previous isolates indicating a new introduction.

iv. Routine vaccination and vaccines

Korea described that scheduled national FMD vaccination campaigns had been carried out, targeting all cattle and goats twice a year (in the months of April-May and October-November) since 2017. Korea explained that pigs are vaccinated every six months after the prime and boost dose at every breeding stage. The Group noted that non-compliance with the vaccination campaigns leads to severe economic penalties, and that there had not been any violations of the system in the past 24 months.

The Group agreed that the FMD vaccine used by Korea complies with the requirements of the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual)* and noted that the vaccination and vaccine costs are heavily subsidised.

The vaccination coverage was estimated to be close to 100%, and based on the results of post-vaccination monitoring studies carried out four weeks after vaccination, the Group concluded that the susceptible vaccinated animals (cattle, goats, and pigs) had adequate levels of population immunity to FMDV serotypes O and A. The Group also noted that regulations were in place giving the authority to the Korean government to order nationwide vaccination of cloven-hoofed animals against FMD during an outbreak.

v. Surveillance in accordance with Articles 8.8.40. to 8.8.42.

The Group commended Korea for the comprehensive details provided on the active and passive surveillance in place to document freedom from infection and substantiate the absence of viral transmission. The Group noted a complex system of random and targeted post-vaccination NSP and SP serological surveillance, with different designs depending on species and farm size, which were well-documented, including the follow-up procedures in case NSP antibodies are detected. The Group noted a strong central laboratory (WOAH Reference Laboratory for FMD) supported by regional centres and documented evidence on continuous activities for controlling and maintaining good test quality.

Korea described that regular clinical surveillance is performed by veterinarians, civil servants of the cities/counties, or an honorary animal health monitoring agent; they visit farms and inspect animals for signs of FMD. Korea also reported having two types of active NSP serological surveillance (purposive and statistical), resulting in a large number of samples tested to substantiate the absence of FMD virus transmission. The Group noted that during the surveillance activities, one farm had a large proportion of NSP reactors and requested further information on follow-up investigations to rule out the possibility of undetected outbreaks in farms around the premises with NSP reactors. After reviewing the additional information, the Group commended Korea for the extensive follow-up actions taken including testing of all animals within the holding where NSP reactors were found as well as the regular examination of all farms with potential epidemiological links with the farm with NSP reactors, to rule out potential FMD virus transmission.

Overall, the Group agreed that surveillance results demonstrate no case of FMD during the past two years and no evidence of FMD virus transmission in Korea for at least the past 12 months in accordance with Article 8.8.3. of the *Terrestrial Code*.

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

Korea described in detail its regulatory, laboratory, surveillance, and preventive system to monitor, detect and respond to FMD outbreaks. The Group agreed that Korea's reporting systems and surveillance work well, and the vaccination programme is robust. The Group agreed that all efforts towards early detection, prevention and control of FMD are supported by i) an efficient system of animal identification and tracking which requires notification of births, deaths, and transfers of susceptible animals, also associated with monetary penalties to violators; and ii) by a clear chain of command within the Veterinary Services substantiated by official regulations and guidelines.

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 Korea had been actively working with other countries in the Asia and the Pacific Region and is an active member of the Global FMD Research Alliance. The laboratory operations were well funded, allowing training to be conducted in Korea with participation of six other countries.

Based on the control efforts against African swine fever, the Group acknowledged that the control of animal and food waste feeding practices have been strengthened in recent years.

The Group acknowledged strict importation protocols of susceptible animals and their products, as well as frequent detection of illegally imported forbidden products at entry ports. The Group commended Korea's efforts to address the illicit entry of agricultural products. Considering that illegal activities were reported by Korea as the cause of past recurrence of FMD outbreaks and still identified as a route of high potential for re-introducing the disease, the Group strongly encouraged Korea to continue to be vigilant in identifying potential routes of disease introduction, as well as to continue its efforts in adapting and strengthening its regulatory measures for the prevention of FMD virus introduction.

ix. Compliance with the questionnaire in Article 1.11.2.

The Group agreed that the format of the dossier was compliant with the questionnaire in Article 1.11.2.

Conclusion

Considering the points mentioned above, the Group concluded that Korea's application was compliant with the requirements of Chapter 8.8. and with the questionnaire in Article 1.11.2. of the *Terrestrial Code*. Therefore, the Group recommended the recognition of Korea as an FMD-free country where vaccination is practised.

4. Evaluation of an application from a Member for the official recognition of an FMD-free zonal status where vaccination is not practised

Bolivia

Bolivia has three FMD-free zones (one with and two without vaccination) covering the country's whole territory. In September 2022, Bolivia submitted a dossier for recognition of a new zone (currently part of the FMD-free zone where vaccination is practised) as an FMD-free zone where vaccination is not practised. Bolivia confirmed that the application is for the official recognition of the proposed zone as free without vaccination and merge with the adjacent zone consisting of the Department of Pando, which is officially recognised as free from FMD without vaccination.

The Group requested additional information and received clarifications from Bolivia during the evaluation of the dossier.

i. Animal disease reporting

The Group considered that Bolivia 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, the FMD susceptible animals in the proposed zone and the country and was compliant with the requirements for a country having officially recognised FMD-free zones.

iii. Situation of FMD in the past 12 months

The Group noted that the last outbreak of FMD in the proposed zone was in March 2003, while the last FMD outbreak in Bolivia occurred in March 2007.

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

The Group noted that the last vaccination in the proposed zone was carried out between 15 May to 16 June 2019 in the Department of Beni and between 24 April to 12 June 2019 in the Department of La Paz (dates established by Administrative Resolution No. 093/2019). In accordance with Article 8.8.3. of the *Terrestrial Code*, Bolivia informed WOAHP in advance about the intended cessation of vaccination in the proposed zone. During the transition from a zone free with vaccination to a zone free without vaccination, Bolivia provided evidence demonstrating continuous compliance with Article 8.8.3., which was approved by the Scientific Commission at that time, for the maintenance of the FMD-free zone with vaccination status.

The Group acknowledged that vaccination was no longer being implemented in the proposed zone, according to Administrative Resolution No. 186/2019 (issued in October 2019). Although there was no actual ban on vaccination in the zone; each campaign is authorised by an administrative resolution, and there was no resolution to conduct further vaccination in the proposed zone. In addition, marketing and sales of the FMD vaccines are only carried out during the vaccination cycles and with prior authorisation from the Veterinary Authorities-SENASAG (Servicio Nacional de Sanidad Animal e Inocuidad Alimentaria).

The Group noted that SENASAG had implemented Administrative Resolution No. 408/21 as of 30 December 2021, stating that from 1 January 2022, movement of vaccinated cattle to the proposed free zone is restricted and that only vaccinated cattle destined for slaughter may enter into the proposed zone or to FMD-free zones without vaccination. The Group agreed that the proposed zone would meet the provisions of Article 8.8.2. by 1 January 2023, provided that Bolivia certifies and submits documented evidence that during the past 12 months “no vaccinated animal has been introduced except in accordance with Articles 8.8.8. and 8.8.9.” (Article 8.8.2. Point 4.e of the *Terrestrial Code*). This documentation should be provided to WOAHP by the end of January 2023.

Bolivia reported that the introduction of animals from the FMD-free zone with vaccination into the proposed zone for reproduction purposes is only allowed from 15 approved compartments where vaccination is not applied, as per Instruction 054/2022. Bolivia also described the transhumance movement of animals from the proposed zone into Santa Cruz Department (within the FMD-free zone with vaccination) during the rainy season, and the legislation in force (instruction 100/2021, replaced by Instruction No. 163 of 3 November 2022) which requires: i) the individual identification of these animals; ii) movement of these animals be supervised under SENASAG only to the authorised transhumance fields; iii) these animals in transhumance are separated from vaccinated populations through effective biosecurity measures; and iv) they are not vaccinated against FMD at their transitory destination (supervised by SENASAG during vaccination of populations destined for vaccination). The Group concluded that transhumant herds, and the 13 authorised shelter establishments where they may be kept during the rainy season, comply with the principles of compartments (animal subpopulations) as recommended in Article 8.8.4. of the *Terrestrial Code*.

In addition, the Group agreed that the Animal Movement Authorisation (GMA) system in place contributes to the prevention of any illegal movements; animal movement authorisations are generated from the local SENASAG offices, accredited by SENASAG, valid for seven calendar days, transit is carried out through fixed control posts and arrival at destination is controlled. Upon request, Bolivia provided records of checks carried out at the transhumance fields and compartments.

Based on the detailed measures described and records provided by Bolivia, the Group concluded that there was no evidence of introduction of vaccinated cattle into the proposed zone, and non-compliances had been rare and dealt with appropriately.

v. *Surveillance in accordance with Articles 8.8.40 to 8.8.42.*

Bolivia described its passive surveillance system as founded on reporting suspicions based on communal participation (epidemiological sensors). Epidemiological sensors are trained by SENASAG, and they have weekly communications with official veterinarians. The dossier provided the number of reported suspicions of vesicular disease from 2018 to 2022 (until the time of submission of the dossier) and described how they were followed up to rule out FMD and reach a final diagnosis.

The Group commended Bolivia on the serological survey performed in 2022 in the proposed zone of animals 6 to 18 months old on farms of all sizes. This study revealed no evidence of FMDV infection and transmission, which used a between-farm design prevalence of 1% and a within-farm prevalence of 10%.

Bolivia also participated in interlaboratory proficiency schemes in 2021 and 2022 for **serological and PCR diagnostic tests** with satisfactory results.

Overall, the Group concluded that the Bolivia's combined strategy for surveillance, including passive and serological surveillance, as well as surveillance at the abattoirs, was sufficient to demonstrate the absence of infection with FMDV in unvaccinated animals and FMDV transmission in previously vaccinated animals.

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

The Group noted that awareness-raising among producers is mainly carried out through a network of local leaders. The dossier described a strong network of epidemiological sensors and a comprehensive passive surveillance system. Information on awareness campaigns for farmers and other stakeholders was provided.

The Group also took note of the procedures established by law in case of detection of illegal imports which would lead to confiscation and destruction, as well as of the notifications of illegal imports of live cattle and animal products which were limited.

vii. *Description of the boundaries of the proposed free zone*

The Group was informed that the proposed zone has borders with countries or zones free from FMD with and without vaccination. The Group acknowledged that the proposed zone was clearly delimited by political, administrative and natural (rivers and mountains) national and international borders. Border controls on the zone's borders and two internal, fixed control points are staffed by SENASAG veterinarians and technicians, who control the movements of live animals and animal products. In addition, there are mobile control points carried out by SENASAG veterinarians in at least three strategic points.

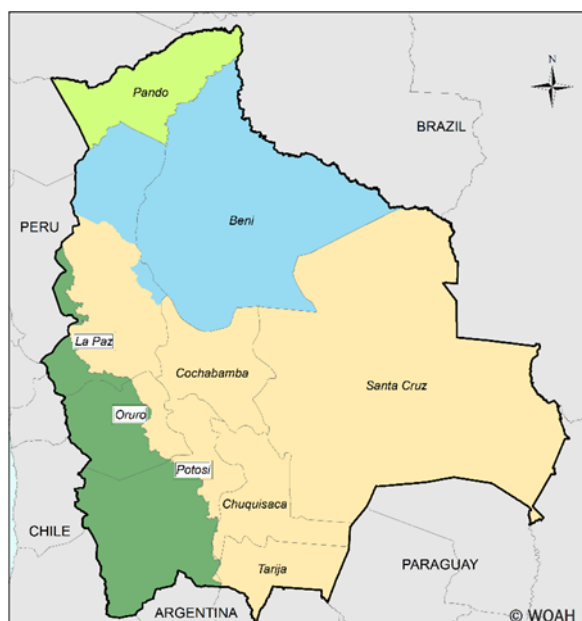


Fig. 1. Proposed zone (light blue) for potential recognition in May 2023 as FMD-free without vaccination and merge with the adjacent zone consisting of the Department of Pando (light green) already officially recognised as FMD-free without vaccination. Rest of the country officially recognised FMD-free zones with vaccination (in beige and dark green).

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 the zone was bordered by countries or zones free from FMD and the risk of entry of affected animals was minimal. Regulatory measures were in place to prevent importation from FMD-infected countries, and legal importation of animals and animal products follows strict protocols.

The Group also noted a regulation in place prohibiting feeding pigs with human food waste of any origin. In addition, the regulations framing slaughterhouse operations require animal waste management preventing potential access by pigs.

x. Compliance with the questionnaire in Article 1.11.3.

The Group agreed that the format of the dossier was compliant with the questionnaire in Article 1.11.3.

Conclusion

Considering the points mentioned above, the Group concluded that Bolivia's application complied with the requirements of Chapter 8.8. and with the questionnaire in 1.11.3. of the *Terrestrial Code*. Therefore, the Group recommended that the proposed zone of Bolivia be recognised as free from FMD without vaccination.

5. Evaluation of applications from Members for the official recognition of an FMD-free zonal status where vaccination is practised

Colombia – Protection Zone 1 (PZ1)

In September 2022, Colombia submitted an application for official recognition of a new zone free from FMD with vaccination: Protection Zone I (PZ I) covering 29 municipalities of the Department of Norte de Santander. Apart from

the proposed free zone, the rest of the country is officially recognised as free from FMD, consisting of two FMD-free zones where vaccination is not practised and four FMD-free zones where vaccination is practised.

i. Animal disease reporting

The Group considered that Colombia generally had a record of regular and prompt animal disease reporting. The Group emphasised the importance of prompt reporting to WOA. H.

ii. Veterinary Services

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

In order to address the illegal entry of animals and agricultural products into the country, Colombia established an Integrated Centre (CIIP) in 2018. The CIIP consist 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 CIIP functions 24 hours a day. Through the collaborative capacities of the agencies, the CIIP aims to counteract the smuggling of goods from neighbouring countries by cooperatively using the information systems available to detect irregularities in the movement of livestock. Colombia reported the operational results of the CIIP activities of 2019-2022.

iii. Situation of FMD in the past two years

According to the dossier, the last outbreaks in the proposed zone were in July 2017 in the municipality of Cucuta. The incursion was attributed to the smuggling of animals from a neighbouring country. Colombia reported that a stamping-out policy and emergency vaccination were implemented in all outbreaks.

iv. Routine vaccination and vaccines

Colombia reported that vaccination against FMD is compulsory for cattle and buffaloes. Regular vaccination cycles are implemented twice a year (May-June and November-December). Following the recommendations of the WOA. H field mission in November 2019, an additional round of vaccination was implemented in the proposed zone in January-February 2022 (Resolution 110726) for cattle and buffalos under 24 months of age.

According to the dossier, high vaccination coverage in cattle was achieved in 2021 and 2022 in the proposed free zone. The information provided on the serological survey conducted in 2022 showed that adequate population immunity had been achieved in the proposed zone whereby the proportion of "protected" bovines was reported to be higher than 90% in approximately 75% of herds.

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 *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.

v. Surveillance 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 four years to exclude FMD.

The Group noted that Colombia applies a two-stage design for the NSP serological survey. The Group considered the number of farms and animals sampled were sufficient to estimate with a high level of confidence that FMD virus transmission had not occurred in the last 12 months or that its prevalence was not higher than the design prevalence established (between and within farms). The Group noted that the target population for the NSP serological survey was cattle of 6-18 months old, but in farms where there were not enough cattle of the targeted age, the required number of animals was completed with animals of 18 to 24

months of age. All NSP reactors were properly followed up, and further tests of the in-contact animals and complementary tests of NSP-positive animals were conducted (ELISA 3ABC/EITB and probang) to demonstrate the absence of FMD virus transmission.

Upon request, Colombia presented detailed information and results of investigations carried out to rule out geographical clusters and clusters of NSP reactors within farms. The Group encouraged conducting further studies to rule out other potential types of epidemiological associations (i.e., business or commercial groups, families, etc.) in future investigations.

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

Colombia described its network of epidemiological sensors of professionals (i.e., veterinarians, veterinary zootechnicians with certified graduate or postgraduate degrees) and paraprofessionals (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 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, demonstrated by the operational results of the CIIP activities of 2019-2022 (see point ii on *Veterinary Services*).

The dossier mentioned the measures in place to prevent FMD virus introduction from neighbouring countries. Information was provided on the permanent and mobile coordinated control posts established at the border with the neighbouring country or in strategic locations in the proposed zone to prevent illegal movements of animals and animal products, as well as the number of inspections of vehicles and quantities of seized animals and animal products from 2019 to 2022. The dossier also stated the use of drones in areas with difficult access and the implementation of new mobile control posts supported by the Colombian Army and National Police along the frontiers.

Upholding legislation on swill feeding in backyard farms dispersed in mountainous countryside is difficult. Nevertheless, Colombia established different regulations to restrict feeding food waste to backyard pigs, involving health inspections and safety authorisation of all farms sending animals for slaughter destined for human consumption. Good practices for animal feeding, including the prohibition of swill feeding, are required to obtain authorisation to send pigs to abattoirs. In parallel, the Group noted that ICA regularly carries out awareness-raising campaigns to farmers regarding the risks of swill feeding.

The Group noted the procedures in case of detection of illegal imports established by law which would lead to confiscation and destruction of animals and animal products. The Group concluded that adequate regulatory measures were described in the dossier for the prevention, early detection, and control of FMD, while also recognising the persistent risk of introduction of FMD from neighboring countries

vii. *Description of the boundaries of the proposed free zone*

A clear description of the boundaries of the proposed zone was provided in the dossier based on natural barriers and administrative divisions. The proposed zone includes 29 municipalities of the Department of Norte de Santander.



Fig. 2. Proposed FMD-free zone where vaccination is not practised (outlined in red) for potential recognition in May 2023. Rest of the country officially recognised FMD-free zones with and without vaccination.

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)

Colombia established in November 2018 an inter-institutional coordination organisation called CIIP (see point ii on *Veterinary Services*). In this regard, and based on driving anti-smuggling strategies, these coordinated state entities fulfil a cooperating operation action in prevention, criminal investigation, illegal cross-border movements, control and intelligence. This improved surveillance of the country's borders and the timely intervention of security forces.

The Group noted that there were limited movements of live animals from and into the proposed zone and most movements occurred within the zone. The dossier described Resolution 60865 of 2020, establishing the sanitary requirements for moving FMD-susceptible animals and their products from the proposed zone to a FMD-free zone where vaccination is practised.

The dossier described that all susceptible animals leaving the proposed zone are clinically inspected and an official authority seals the transport vehicle before it leaves the establishment of origin. The Group also acknowledged the information provided on the four coordinated control posts (Zulia, Los Acacios, Guayabales and Pedregales), manned by the Colombian National army, navy, police and air force, and strategically located within the proposed zone.

Regarding animal identification, Colombia estimated that 64% of the total cattle and buffalo population was individually identified in the proposed zone so far and explained that this is an ongoing process. Colombia explained that this individual identification of cattle and buffalo was delayed due to external factors associated with some public order and climatic problems that have affected this territory. Colombia clarified that all animals that are moved out of the proposed zone must have individual identification prior to transport and using hot-iron brand identification of cattle and buffalo at the herd level was mandatory.

Colombia mentioned that there is no official identification for small ruminants, but producers may voluntarily identify their animals with commercially available devices. Nonetheless, the identification of small ruminants is required prior to movement. The Group noted a relatively small population of sheep and goat in the proposed free zone. Pigs were identified using a colour-coded ear tag differentiating pigs by the zone of origin in relation to classical swine fever (CSF) status; zones with or without an officially recognised CSF-free status by WOA. The identification records are entered into the Information System for Animal Movement Permits (SIGMA) and represent an essential requirement for issuing pigs movement permits.

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 points mentioned above, the Group concluded that the currently submitted application of Colombia was compliant with the requirements of Chapter 8.8. and with the questionnaire in 1.11.4. of the *Terrestrial Code*. Therefore, the Group recommended that the proposed zone of Colombia be recognised as free from FMD with vaccination.

Russia – Zone V Far East

In September 2022, Russia submitted an application for the recognition of Zone V ‘Far East’ consisting of five Subjects: Amur Oblast, Jewish Autonomous Oblast, Primorsky Krai, Khabarovsk Krai, Zabaykalsky Krai. The Group requested additional information and received clarifications from Russia during the evaluation of the dossier.

i. Animal disease reporting

The Group considered that Russia had a record of regular and prompt animal disease reporting. The Group noted that Russia’s definition of an FMD case described in ‘25 of Order of the Ministry of Agriculture of the Russian Federation No. 157 of 24 March 2021’ does not include reference to serological detections and requested that Russia should revise its case definition to be fully in line with Article 8.8.1. point 3.c. of the *Terrestrial Code*.

ii. Veterinary Services

The Group acknowledged the description of the organisation of Veterinary Services in Russia and a comprehensive set of legislation related to FMD activities that is periodically updated. The Group agreed that the Veterinary Authority had current knowledge of and authority over FMD susceptible animals in the proposed zone.

iii. Situation of FMD in the past two years

The Group noted that FMD outbreaks were reported in Khabarovsk and Primorsky Krai in 2019, and the last outbreak in the proposed zone was reported in January 2020 in Priargunsky Raion of Zabaykalsky Krai. Russia reported that the outbreaks were related to illegal movements of animals or infected animal products from FMD-infected countries.

iv. Routine vaccination and vaccines

Russia indicated that the viral strains in the vaccine are selected based on the circulating field viruses in Russia and in neighbouring countries, as recommended by ARRIAH (WOAH Reference Laboratory for FMD). The vaccines are produced by Russia and provided to producers for free, and the vaccination is overseen by the Veterinary Services. The Group noted that the vaccine complies with the provisions of the *Terrestrial Manual*.

The Group noted that cattle, sheep, goats, buffaloes, yaks, and camels are vaccinated, but not pigs according to the Russian vaccination programme. Cattle are vaccinated from four months of age onwards, then every three months until they reach the age of 18 months, and after 18 months, vaccination is maintained twice a year. Vaccinated animals are identified (each animal is assigned an individual number shown on its ear tag, brand or tattoo), and animal breeding and production performance records are kept on each farm. The Group

acknowledged that Russia submitted tables with the numbers of animals per species and the number of FMD vaccine doses administered per region, however, it was not possible to accurately estimate the vaccination coverage.

Based on the post-vaccination monitoring (PVM) surveys of the past two years, the Group acknowledged that the immunity levels in cattle continued to improve. However, the Group still noted that the immunity levels were generally lower than expected considering the age of the animals tested and the number of vaccinations received. In this regard, the Group encouraged Russia to continue monitoring and improving the population immunity.

v. *Surveillance in accordance with Articles 8.8.40. to 8.8.42.*

The Group acknowledged that the early detection system for FMD in the proposed zone is based on passive and serological surveillance. Russia described its passive surveillance based on investigations of FMD suspicions and clinical examinations during routine disease prevention activities, which are carried out at least three to five times a year. Russia also reported results from testing pathological material from wildlife (i.e., harvested dzerens) with no evidence of FMDV infection. The Group expressed concerns about the low number of FMD suspicions detected despite the large number of inspections carried out in farms and abattoirs.

The Group noted that the results of the serological survey (SP and NSP) conducted over 12 months, 50-70 days after vaccination in the proposed free zone, showed zero NSP reactors in the second paired sampling, leading to the rule out of the possibility of FMD virus transmission. Most of the blood samples were collected from cattle over 24 months old. The Group found the number of NSP reactors in the first test (screening) surprisingly low, considering the expected percentage of false positive reactors in serosurveys with a large number of samples. In this regard, Russia mentioned that the sensitivity and specificity of the test used are 100%. However, no explanation was provided on how such sensitivity and specificity could be established for the test.

Regarding the serological survey (SP and NSP), Russia explained that the sampling scheme was randomised but with additional criteria for selecting a representative sample of farms taking into account geographic location, animal population density and economic activities. Russia also explained the aim to select an even distribution of holdings (sampling points) within the territory of each Subject. However, the Group found it difficult to understand how the criteria for the selection of the herds was applied for a random survey. Moreover, the sample size estimation – for the number of herds and animals within herds – was unclear based on the formula and the parameters provided by Russia. The Group also emphasised that younger animals should be targeted for SP and NSP studies, when possible.

Although the procedure of the survey included two-stages of sampling (selecting the settlements and then the animals), a two-stage approach was not followed in the study design nor in the sample size calculation. In addition, the criteria used for the selection of epidemiological units was not clearly explained. Upon request, Russia explained that the sampling scheme was randomised and described the main criteria for selecting the farms taking into account the representativeness. The distribution of sampling points were selected considering animal population density in Raions of the Subject; the geographical location; the even distribution of holdings (sampling points) within the Subject territory; the type of farm based on economic activity (i.e., backyard, commercial, etc.), and the holding size.

The Group agreed that there was no evidence of FMD virus transmission in the proposed zone based on the surveillance information and results provided by Russia.

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

The Group noted that reporting 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 training conducted for farmers and veterinarians to promote the reporting of FMD suspicions.

Russia provided documented evidence on the regulatory measures for the movement of animals and animal products between Zone V and other zones with different animal health status. Russia also provided the numbers of non-compliant activities detected and amounts of confiscated animal products between zones of different animal health status. Russia described the specific activities in place to control and monitor transhumance using mobile and stationary control posts to prevent the movement of animals from infected zones into the rest of the country. Additionally, following a request from the Group, Russia provided a clear description regarding the control of animal movements including those of transhumance between Subjects. Russia also provided a set of measures implemented to prevent the introduction of the FMD virus across the borders with neighbouring countries with undetermined FMD status, including indoor housing of FMD susceptible animals.

The Group noted that legislation was in place for the treatment of swill and that its compliance is enforced by the implementation of monitoring and control of swill and production waste handling carried out by local authorities and the Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing.

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 zone

The proposed zone comprises five Subjects: Amur Oblast, Jewish Autonomous Oblast, Primorsky Krai, Khabarovsk Krai and Zabaykalsky Krai. The Group agreed that the boundaries of the proposed zone were well defined and appropriately displayed in maps.



Fig. 3. Proposed FMD-free zone where vaccination is practised (outlined in olive green) Zone Far-East for potential recognition in May 2023. Zones already having an FMD-free status where vaccination is not practised (in light green), FMD-free status where vaccination is practised (Zone-South in orange, Zone Sakhalin in blue, Zone Eastern Siberia in turquoise). Zone with an undetermined FMD status (striped area).

viii. Description of the system for preventing the entry of the virus (into the proposed FMD-free zone)

The Group acknowledged the comprehensive legal framework provided by Russia on the identification and registration of animals and 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 zone 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 acknowledged that in 2020-2021, Russia undertook a large-scale reconstruction of the BIPs in the Zabaykalsky, Khabarovsk and Primorsky Krai. Furthermore, Russia mentioned that the BIPs in the Jewish Autonomous Oblast have remained closed after the outbreak in the neighbouring Russian Subjects.

The Group also acknowledged that Russia established a plan with measures to prevent the potential introduction of FMDV from wild animals migrating to Zabaykalsky Krai.

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

ix. 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 in response 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 Russia be recognised as free from FMD where vaccination is practised.

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

No applications were received for evaluation during this cycle.

7. Evaluation of applications for recovery of FMD-free status with change of vaccination status

The Group assessed applications for recovery of FMD-free status. The Group requested additional information and received clarifications from the applicant Member during the evaluation of the dossier. The Group also had a teleconference with technical experts from the applicant Member. The opinion of the Group was forwarded to the Scientific Commission.

8. Other matters

The Group noticed several recurring problems when Members present sero-surveillance results where the NSP ELISA is used to demonstrate that FMD virus is no longer present or circulating in the susceptible population. Their use and interpretation of serological test results not being consistent with the provisions of Article 8.8.42. of the *Terrestrial Code*, in which a screening NSP test with high sensitivity is recommended to ensure all possible reactors are detected, even if the test has lower specificity. Any positive results can be followed up in the laboratory with a second test with a sensitivity that approaches that of the screening test and with higher specificity. All herds with at least one laboratory confirmed reactor should be investigated following the provisions of Article 8.8.42.

One consistent problem noted by the Group is that the surveillance results presented in Members' dossiers do not agree with the stated specificity of the assays they use. Even with an algorithm with high specificity (e.g., 99%), one would expect some false positive results. However, Members often present results where several thousand animals are tested without any positive results, which is inconsistent with the stated specificity^{1,2}. In this regard, the Group strongly recommended that Members clearly present their testing algorithms and all the data in the dossiers, including the screening and confirmatory laboratory results, and describe in detail the follow-up actions and testing results; sero-surveillance results that do not agree with the stated specificity of the testing algorithm will not be accepted in future.

In addition, the Group recommended that validation data must be provided to support the claims for the sensitivity and specificity of the assays used for all serological testing (including test that are used for the detection of antibodies to structural and non-structural proteins).

The Group strongly encouraged all Members submitting dossiers to closely study all the recommendations in the *Terrestrial Code* and provide evidence of their implementation to ensure acceptance of their dossiers.

The Group would welcome a discussion on these items with the Scientific Commission.

.../Appendices

¹ Paton DJ, de Clercq K, Greiner M, Dekker A, Brocchi E, Bergmann I, Sammin DJ, Gubbins S, Parida S. Application of non-structural protein antibody tests in substantiating freedom from foot-and-mouth disease virus infection after emergency vaccination of cattle. *Vaccine*. 2006 Oct 30;24(42-43):6503-12. doi: 10.1016/j.vaccine.2006.06.032. Epub 2006 Jul 5. PMID: 16872727.

² Stevenson, M. A. (2021). Sample size estimation in veterinary epidemiologic research. *Frontiers in veterinary science*, 7, 539573.

Appendix 1 Terms of reference

VIRTUAL MEETING OF THE *AD HOC* GROUP ON THE EVALUATION OF FOOT AND MOUTH DISEASE STATUS AND ENDORSEMENT OF OFFICIAL CONTROL PROGRAMMES OF MEMBERS 2-4, 7 and 9 November 2022

Terms of reference

Purpose

The purpose of the ad hoc Group on the evaluation of foot and mouth disease (FMD) status and endorsement of official control programme of Members (the Group) is to evaluate applications for official recognition of FMD-free status and for endorsement of official FMD control programmes of Members.

Background

In accordance with the [procedure for official recognition of animal health status](#), Members can be officially recognised by WOAHA as having an FMD-free status or an official FMD control programme endorsed by the WOAHA through the adoption of a resolution by the World Assembly of Delegates (the Assembly) in May every year. A Member wishing to apply for the official recognition of its FMD-free status or its official FMD control programme endorsed by WOAHA should complete and submit the relevant [questionnaire](#) laid out in Chapter 1.11. of the *Terrestrial Animal Health Code (Terrestrial Code)* and comply with all requirements specified in the *Terrestrial Code*. The Scientific Commission for Animal Diseases ([Scientific Commission](#)) is responsible for undertaking, on behalf of the Assembly, the assessment of Members' applications for their compliance with WOAHA standards. The assessment carried out by the Scientific Commission is based on the recommendations formulated by a relevant *ad hoc* Group. *Ad hoc* groups are convened under the authority of and report to the Director General.

Specific issues to be addressed

The Group will evaluate Members' applications in detail on their compliance with the requirements specified in the *Terrestrial Code* for FMD. Based on the evaluations, the Group will provide its conclusions and recommendations to the Scientific Commission.

Pre-requisites

Group members should:

- Sign the Undertaking on Confidentiality of information (if not done already);
- Complete the Declaration of Interest form.
- Understand that the membership of the Group may be retained between its meetings to ensure continuity of the work.

Actions to deliver

Before the meeting

Upon reception of an application from a Member, the Status Department (SD) conducts a preliminary screening to check the conformity of the dossier (structure of the dossier in accordance with the SOP and with the questionnaire under Chapter 1.11. of the *Terrestrial Code*, main sections of the questionnaire, regular notification to WOAHA, payment of the fee, Performance of Veterinary Services (PVS) report, etc.). If an information gap is identified, the SD requests additional information from the Member.

As the PVS reports are bound by the rules on confidentiality of information of the WOAHA, the SD and experts will consider for the evaluation the available PVS report(s) if not obsolete (PVS reports from more than five years ago) or confidential.

The SD will send the working documents to the Group, including the dossiers received from applicant Members, at least one month before the Group meeting (i.e., 05 October 2022).

The experts can request support from the SD at any time.

The SD suggests the nomination of a Chair and Rapporteur for the Group's consideration.

The SD can suggest a preparatory meeting with the Chair, the Rapporteur or all experts to address specific points in advance, if needed.

The experts are expected to:

- Be familiar with Chapters [1.11](#), and [8.8](#), of the *Terrestrial Code*;
- Evaluate and study in detail all dossiers provided by WOA;H;
- Take into account any other information available in the public domain that is considered pertinent for the evaluation of the dossiers;
- Summarise the dossiers according to the *Terrestrial Code* requirements by completing the summary tables provided by the SD (the summary tables will be provided at a later stage along with the working documents for the meeting). Experts are expected to capture and summarise in each corresponding section of the summary table the main gaps as well as strengths identified during the assessment of the dossiers, using extracted texts or reference to pages/annexes from the application;
- Draft questions to the applicant Members whenever the analysis of the dossiers identifies incomplete or unclear information;
- Submit to the SD the completed summary tables for each application together with possible questions for the applicant Members at least 10 days before the teleconference and preferably by 21 October 2022;

The SD will compile the summary tables and the questions to be forwarded to the applicant Members before the teleconference. All subsequent information and material provided by a Member will be forwarded to the Group.

During the meeting

- Agree on the appointment of the Chair and Rapporteur of the meeting (the Chair will lead the discussion and the Rapporteur will ensure that the report reflects the discussion and captures the detailed assessment of the dossiers);
- Mention any potential conflict of interest and, if relevant, withdraw him/herself from the discussion;
- Contribute to the discussions;
- Provide a detailed report in order to recommend, to the Scientific Commission, the Member(s) and/or zone(s) to be recognised (or not) as free from FMD and the official control programme of Member(s) to be endorsed by WOA;H and to indicate any information gaps or specific areas that should be addressed in the future by the applicant Members.

If during the teleconference the Group decides that additional information should be requested from an applicant Member before an informed conclusion can be drawn, the SD can request it and forward the additional information to the Group at a later date. The Chair is responsible for coordinating the finalisation of the assessment and for ensuring that the views of all members of the Group are taken into consideration.

Should the Group not be able to complete its Terms of Reference during this meeting, experts' contributions will be solicited after the meeting, including by teleconference if needed.

After the meeting

The SD will circulate the draft report after the teleconference is over. Experts are expected to contribute to the finalisation of the report within approximately one week.

The SD will circulate the final version of the report to the Group once endorsed by the Scientific Commission and is published online.

Deliverables

A detailed report to recommend to the Scientific Commission whether an applicant Member(s) should be (or not) recognised with an official FMD-free status or an official FMD control programme endorsed by WOA;H. The report should indicate any information gaps or specific areas that should be addressed in the future by the Members.

Reporting / Timeline

WOAH will circulate the draft report no more than seven days after the teleconference (no later than 16 November 2022) and the Group will finalise its report within ten days (indicative deadline: 26 November 2022).

Appendix 2 Agenda

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

2-4, 7 and 9 November 2022

Agenda

1. Opening
2. Adoption of the agenda and appointment of chairperson and rapporteur
3. Evaluation of an application for the official recognition of an FMD-free country status where vaccination is practised
 - Republic of Korea
4. Evaluation of an application for the official recognition of an FMD-free zonal status where vaccination is not practised
 - Bolivia – Department of Beni and northern part of Department of La Paz
5. Evaluation of applications for the official recognition of FMD-free zonal status where vaccination is practised
 - a) Colombia – Protection Zone 1
 - b) Russia – Zone V
6. Evaluation of applications from Members for the endorsement of an official control programme for FMD
7. Evaluation of applications for recovery of free status
8. Other matters
9. Adoption of the report

Appendix 3 List of Participants

AD HOC GROUP ON EVALUATION OF FOOT AND MOUTH DISEASE STATUS

AND ENDORSEMENT OF OFFICIAL CONTROL PROGRAMMES OF MEMBERS

2-4, 7 and 9 November 2022

List of Participants

MEMBERS

Dr Sergio Duffy Consultant Buenos Aires ARGENTINA	Dr Arjan Stegeman <i>Invited but could not attend</i> Utrecht University Department of Population Health Services Utrecht THE NETHERLANDS	Dr David Paton The Pirbright Institute UNITED KINGDOM
Dr Livio Heath Agricultural Research Council Onderstepoort SOUTH AFRICA	Dr Manuel J Sanchez Vazquez FMD Center/PAHO-WHO Centro Panamericano de Fiebre Aftosa Rio de Janeiro BRAZIL	Dr Wilna Vosloo Group Leader CSIRO Livestock Industries Australian Centre for Disease Preparedness Geelong AUSTRALIA

REPRESENTATIVE OF THE SCIENTIFIC COMMISSION

Dr Kris de Clercq
BELGIUM

WOAH HEADQUARTERS

Dr Min Kyung Park Head Status Department disease.status@woah.org	Dr Manoel Tamassia Deputy Head Status Department	Dr Mauro Meske Disease Status Officer Status Department
	Dr Natalie Moyen Disease Status Officer Status Department	
