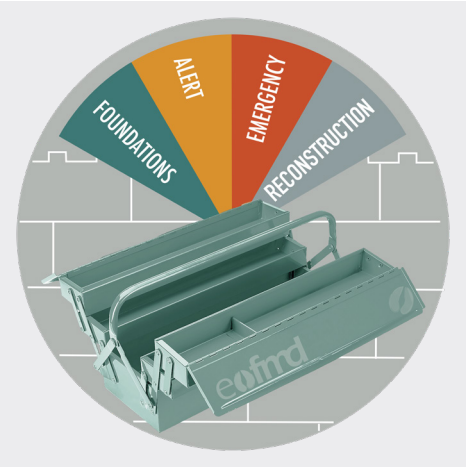
Food and Agriculture Organization of the United Nations

eufmd
european commission for the control of foot-and-mouth disease

VIRTUAL MEETING 21–22–23 APRIL 2021



Report

44TH GENERAL SESSION OF THE EUROPEAN COMMISSION FOR THE CONTROL OF FOOT-AND-MOUTH DISEASE (EuFMD)

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FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
European Commission for the control of Foot-and-Mouth disease (EuFMD)
Rome, 2021

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Preamble

The 44th General Session of the EuFMD Commission was held on the 21-22 and 23 April 2021 in virtual settings, due to travel restrictions. Rules of procedure concerning in-person sessions of the Commission were suspended, in order to allow the virtual format.

Delegates from all of the 39 Member Nations of the Commission, official Observers from the European Commission (EC), the Food and Agriculture Organization (FAO), the World Organisation for Animal Health (OIE), and civil society organizations participated in the three-day meeting.

Recommendations

Considering

1. The enormous economic consequences of even a single foot-and-mouth disease (FMD) outbreaks in FMD free countries;
2. The repeated FMD incursions into the direct European neighbourhood over the past years and the concern raised by long-distance movements of FMD virus (FMDV) lineages causing outbreaks in unexpected locations;
3. The importance of South Asia as a source of FMDV strains that have caused recent outbreaks in South East Asia, West Eurasia, and in the Indian Ocean islands;
4. The risk of introduction of FMDV from West, Central or East Africa to North Africa and the Middle East, associated with trans-Saharan animal movements and the related threat for Europe;
5. The scale of animal movements into countries neighbouring Europe, with the connected increased risk of FMD and similar transboundary animal (FAST) diseases introduction and spread in Europe and its neighbourhood, and the potential of risk mapping to better target surveillance and control;
6. The significant progress made by the EuFMD Member Nations Turkey, Georgia, and Israel in the surveillance and control of FAST diseases;
7. The important role of the FAO World Reference Laboratory for FMD (WRL-FMD) in leading the network of reference centers that provide global laboratory surveillance, that enables tracking and assessment of changes in risk, as well as informs vaccine recommendations;
8. The impact of the COVID-19 pandemic on surveillance activities of the FAO/OIE FMD Laboratory Network due to the repurposing of laboratories and staff for SARS-CoV-2 testing, local shortages in laboratory reagents and PPE, logistical challenges to arrange shipments to international Reference Laboratories that has led to a dramatic reduction in the number of samples submitted;
9. The difficulties encountered by some neighbouring countries in performing surveillance and outbreak investigation for the identification of the FMDV strain circulating, with particular reference to the serotype A detected in North Africa;
10. The progress made by the GF-TADs in the implementation of the FMD Global Control Strategy and the importance of continued support to the eighty countries that have embarked on the Progressive Control Pathway for FMD (PCP-FMD) to develop national FMD control strategies;
11. The importance of collaboration, coordination and synergy between regional organizations and programs for successful global control or eradication of FMD and other priority transboundary animal diseases (TADs);
12. The good outcomes of the collaboration between EuFMD, FAO and the OIE in specific training programmes and in the assistance provided to countries to improve FAST control;
13. The time elapsed since the last serotype C outbreak was detected (in Kenya and Brazil in 2004) and the importance of reducing the possibility of re-introduction through inadvertent escape;
14. The need to improve the monitoring of FMDV vaccine quality and performance and the importance of selection of vaccines appropriate to the antigenic threats in each region;
15. The length of time required for procurement procedures for quality FMDV vaccines that affects the application of vaccination in emergency management;
16. The main constraints identified in the operational capacity of EuFMD Member Nations to rapidly implement an emergency vaccination plan, the difficulties connected to the recovery of free status after vaccination and the opportunity to use the pan European FMD spread model (EuFMDis) to evaluate control options;

17. The increased demand for support to national training programmes to better equip national trainers with courses to update and train their staff, and the increased demand for virtual learning training and delivery of virtual events;
18. The benefit recognized by Member Nations of field-based training courses held in endemic settings and the opportunity to extend these to other FAST diseases;
19. The relevance of the application of the Minimum Standards for laboratory containment of FMDV, for prevention of escape of FMDV from laboratories responsible for diagnosis and vaccine production;
20. The opportunity for European Union (EU) Member Countries to adopt the Minimum BioRisk Standards without conflicting with any EU legislation in place, being the Directive 2003/85/EC replaced by Regulation 2016/429;
21. The outcomes of the Open Session organized in a virtual setting, with the involvement of a larger number of more geographically diverse scientists and participants and the quality of the research results shared;
22. The opportunity to update the EuFMD work plan for the next biennium to ensure the achievements of the objectives defined under the Phase V work programme, considering the results obtained and activities implemented in the current biennium;
23. The suspension by the majority of two third of Members of the rules of procedure that presuppose in-person session of the commission and set for elections of officer of the commission (Rule II.2.b, Rule IX, Rule XIV).

Acknowledges

1. The support of the European Commission (DG-SANTE) through the four-year Phase V of the work programme of the Strategic Plan agreed in 2019, and the excellent working arrangements that have resulted in efficient and timely emergency responses to situations arising in the European neighbourhood.

Recognizes

1. Progress with the implementation of the current Strategic Plan and the positive development of collaboration with the World Organisation for Animal Health (OIE) and with the Food and Agriculture Organization of the United Nations (FAO) on matters relating to the programme of the EuFMD in countries which are not Members of the Commission, and in regard to EuFMD support of the GF-TADs Global FMD Control Strategy.

Agrees

1. Upon the updating of the work programme for 2021-23, with the inclusion of the changes proposed in the paper presented under Item 6 of the agenda of the 44th General Session;
2. That relating to Pillar I, special attention should be given to the further development of tools and networks to assist the improvement of emergency preparedness, focusing on the specific issues identified by Member Nations during the first biennium such as the implementation of emergency vaccination and recovery of free status after vaccination;
3. That relating to Pillar I, special attention should be given to continue to improve and further develop the training programme, including the Real Time Training, and the Training Management System for the development of individuals' and Veterinary Services' capacities;
4. That relating to the work programme for Pillar II, special attention be given to further improve capacities for the identification of FAST disease risk hubs, for the implementation of risk-based early-warning surveillance and the assessment of surveillance systems' sensitivity, and the development of systems to facilitate the timely risk information sharing, risk analysis and forecasting;

5. That relating to the work program for Pillar III, special attention be given to South Asia and East, West and Central Africa, supporting capacity building through the virtual training programme and enhancing risk-based surveillance, working with the members of the FAO/OIE Laboratory Network and supporting the sustainable expansion of the PCP-FMD Support Officer (PSO) system;
6. Upon the further development of capacity building opportunities, working with GF-TADs partners for further developing virtual learning training courses for FAST diseases and virtual learning hubs;
7. Upon the implementation of the operation phase of the prequalification system for FAST disease vaccines aimed at improving quality, safety and efficacy of FAST disease vaccines procured and the identification of mechanism for ensuring its financial sustainability;
8. Upon the proposal to establish a Standing Committee on Prequalification of Vaccines, as presented under Item 8 of the agenda of the 44th General Session, that works within a specific budget framework and with procedures to avoid conflict of interest;
9. Upon the membership of the Standing Technical Committee (STC), the Special Committee for BioRisk Management (SCBRM) and the Special Committee for Surveillance and Applied Research (SCSAR), and the programme proposed by the committees for the next biennium, as presented at the 44th General Session;
10. Upon the adoption of the Minimum BioRisk Management Standards as presented at the 44th General Session;
11. Upon the contributions of the Member Nations for the biennium 2022-2023, as proposed in item 11, on the basis of the mid-point CPI (Eurozone and EU28_2019 &EU27_2020) of 2% for the two full calendar years;
12. Upon the proposal for the budget of the MTF/INT/011/MUL (Administrative Fund) for the forthcoming biennium;
13. Upon the proposal for the budget for Emergency and Training Fund (MUL004) for the next biennium and the extension of the not-to extend (NTE) date to 31st December 2023
14. Upon the need to review at the next Session held in presence, the ranking and categories in which countries are placed for contribution;
15. Upon the need of Members to revise the constitution and rules of procedures in light of the transboundary animal disease situation, the related risk for Europe and upon the opportunity of convening a special session in presence to cover this specific item.
16. Upon the Executive to continue ad interim function until elections will be carried out at the next physical session.

Recommends

1. The EuFMD further explores the possibility of using training materials and expertise already developed and available in order to assist GF-TADs partners in capacity building in FAST diseases prevention and control;
2. The EuFMD and the EU Reference Laboratory for FMD scrutinize the opportunity and possibility to establish an EU diagnostic bank of reagents for FMD;
3. The EuFMD continues to promote scientific research and networking in Europe, the European neighbourhood and globally through its action plan, the Applied Research programme and with the use the virtual means developed;
4. The EuFMD collaborates with the FAO/OIE Reference Laboratory Network to identify priority areas for improved FMD virological surveillance in endemic pools;
5. The EuFMD, works with the FAO/OIE Reference Laboratory Network to continue to promote post vaccination monitoring and studies to inform vaccine selection, in the European neighbourhood and globally;
6. The EuFMD to promote actions aimed at assessing the risk of introduction and spread of FMD and other FAST diseases in Europe and neighbouring region associated with livestock mobility;
7. The Member Nations promote the use PRAGMATIST to assist European vaccine bank managers and risk assessor to determine the most important strains to maintain in the national vaccine banks according to the risk;
8. The STC continues to monitor the impact of the risk reduction programme delivered in the European neighbourhood and continues identifying issues affecting FAST management that need be brought to the attention of the Commission;
9. The STC and the SCBRM finalize the joint opinion on the use of inactivated lateral flow devices for the international shipment of genomic material of FMDV;
10. The STC identifies options to assess the effect of the COVID-19 pandemic on the capacities for molecular testing globally and the possibility that its increased availability could decrease costs and increase efficiency of laboratory diagnosis of FMD and other FAST diseases.
11. The Member Nations to continue provide evidence of the application of Minimum Biorisk management standards through national and international inspections of FMD national laboratories and the EUFMD to identify possible actions to assist.

Urges

1. The GF-TADs to implements actions aimed at providing evidence of the global eradication of FMDV serotype C and avoiding reintroduction through inadvertent escape from laboratories or bio-terrorism;

Calls upon

1. The international community to recognize the importance of co-ordinated actions in emergency preparedness and progressive control of FMD and similar transboundary animal diseases, under the One Health framework, where improved biosecurity and epidemic preparedness will make a valuable contribution towards the achievement of the Sustainable Development Goals.

Day One

Key Messages

1. Welcome to the 44th General Session.
2. Scope, activities and role of the European Commission for the Control of Foot-and-Mouth disease.
3. Structure of the agenda and ground rules of the event.

Summary

Etienne Chevanne greeted participants to the 44th General Session as moderator, handing over to Martin Blake, Chief Veterinary Officer of Ireland. Mr. Blake welcomed all participants, outlining the scope of activities, the importance and the crucial role of the European Commission for the Control of Foot-and-Mouth disease.

Mr. Blake outlined the items in the agenda for the day and then handed over to Keith Sumption, Chief Veterinary Officer at FAO and Executive Secretary of the EuFMD. Mr. Sumption mentioned the characteristics of the Commission, its' partners, including OIE and EC, and welcomed the innovative drive of the EuFMD.

Mr. Sumption handed over to Fabrizio Rosso, Deputy Executive Secretary of the EuFMD, who commented that transboundary animal diseases continue to circulate regardless of the Covid-19 crisis. Even though the difficulties in implementing surveillance strategies have increased due to the pandemic, EuFMD has continued to implement actions to improve risk-based control strategies for Member Nations, neighbouring countries and beyond. Mr. Rosso indicated the crucial role of the General Session in identifying further actions within the EuFMD workplan to address better the need to ensure reduced risk, better preparedness and better control. He introduced the structure and logistics of the event, the virtual environment made available for the session and the activities of the Commission, as well as the side events with presentation of the Training Management System and virtual simulation exercises using a crises simulation software.

Global Foot-and-mouth disease situation

Presenter: Don King, TPI on behalf of the FAO/OIE FMD Laboratory Network (**Appendix 1**)

Key Messages

1. A biennial agreement with the EuFMD supports the global GF-TADS Strategy via international FMD surveillance activities of the WRLFMD and coordination with sixteen partner laboratories of the OIE/FAO FMD Laboratory Network (www.foot-and-mouth.org).
2. The COVID-19 pandemic has impacted the depth of global FMD surveillance and targeted surveillance (with support from international donors) is urgently required to cover gaps in disease intelligence.
3. There continues to be a large proportion of samples leading to no-virus detected (NVD).
4. Risks of long-distance movements of different FMD virus lineages to cause outbreaks in unexpected locations. Sequence data continues to highlight the importance of South Asia as a source of new FMD viruses that have caused recent field outbreaks in Southeast Asia and West EurAsia.
5. The WRLFMD is working with international partners to improve systems to assess the performance of FMD vaccines to address gaps and challenges for vaccine selection for endemic pools.
6. WRLFMD works to improve the diagnostic capacity in FMD endemic countries through proficiency-testing schemes, training missions and delivery of eLearning courses.

Summary

The OIE/FAO FMD Laboratory Network (https://www.foot-and-mouth.org/) was established in 2004 as a forum to exchange laboratory and epidemiological data, as well as harmonize and improve the quality of diagnostic testing carried out by international and national FMD laboratories. A key role of the Network is to understand the spread of viral lineages across the world, and review constantly the risks posed to countries that are free of FMD (with or without vaccination).

In 2020-21, the surveillance activities of the Network have been impacted by the on-going COVID-19 pandemic through (i) the repurposing of laboratories and staff for SARS-CoV-2 testing, (ii) local shortages in laboratory reagents and PPE as well as (iii) the logistical challenges to arrange shipments to international reference laboratories. A large proportion of the samples received by the WRLFMD in the past biennium led to no-virus detected (NVD), highlighting major challenges affecting optimization of sampling, cold chain maintenance, and correct shipment of samples to Reference Laboratories.

The Network has continued to monitor the emergence of new FMDV lineages from South Asian countries (India, Nepal and Bangladesh) and tracked the new spread of different FMD viruses from central/eastern/western Africa into novel locations including the Gulf States of the Middle East (Bahrain), Islands of the Comoros (in the Indian Ocean) and to countries in North Africa, that pose a direct risk to Europe (individual and summary reports can be retrieved from www.wrlfmd.org). Together, these events highlight the ease by which new FMDV lineages can emerge and cross international boundaries. They emphasize the importance of the work undertaken by the Network to monitor continuously FMD risks for EuFMD Member Nations. Ongoing trans-pool movements since 2015: O/ME-SA/Ind-2001 sub-lineages “d” and “e”, O/EA-3 and A/AFRICA/G-IV into North Africa and O/EA-2 in Southern Africa.

There is evidence that serotype C has no longer been circulating in susceptible hosts as over sixteen years have passed since the last serotype C outbreak (in Kenya and Brazil in 2004). The Network partners have recently co-authored a study to highlight the importance of reducing the possibility that this serotype be reintroduced into the field.

FMD vaccines need to cover the different serotypes and field strains. Vaccine-matching data shows that these strains often exhibit considerable antigenic heterogenicity. The WRLFMD is working with international partners (including the Pan African Veterinary Vaccine Center of the African Union, AU-PANVAC) in order to improve the systems used to assess the performance of FMD vaccines (including those applied in FMD endemic countries).

Discussion

Different questions were addressed during the discussion particularly referred to the following points.

The impact of COVID-19 on FMD surveillance activities: compared to data from the past 15-20 years, the reduction in sample tests seen in 2020 was dramatic but there seem to be early signs of recovery during the first quarter of 2021.

The antigenic difference between O/Ind/2001e and O/Ind/2001d strains: there is no evidence of difference, based on vaccine-matching data that the same vaccines that work for one sub-lineage should also work for the other one (*in-vivo* potency test in cattle was performed for O-Manisa – data published).

The influence of vaccination pressure to facilitate sub-lineages emergence of O/ME-SA/Ind-2001: there is not a full understanding of the processes that drive the emergence of these sub-lineages. However, it is recognized that FMD virus genomes are changing constantly (due to the error-prone processes of viral genome replication). It is believed that this continuous evolutionary process can explain the emergence of the “d” and “e” lineages - rather than positive vaccine pressure and host vaccine immunity.

The general performance of laboratories about the Proficiency Testing and follow-up activities: data supports the idea that diagnostic performance is slowly improving, but can only assess the performance of those labs that participate in the schemes. When labs participate in a PTS, they always receive personalized feedback and suggestions for improvement, followed-up with specific guidance (via SOPs, improved reagents etc.).

The solutions to improving samples submissions for the field: sample quality is still a common challenge, continued training of people in the field is needed, and cold chains have to be maintained during sample transport. Lateral Flow Devices (LFD) and other alternative sampling approaches (e.g. environmental sampling) can also play a role. However, further work is required to ensure consistency of results. Recent sampling from sample shipment to the EURL-FMD from Burkina Faso and Niger demonstrated the viability of inactivated LFDs. Unfortunately, the most widely used LFD supplied by a commercial company is no longer available.

The specific plans to address the current surveillance gaps: more targeted surveillance is needed. The WRLFMD and EuFMD are currently working on a tool to identify priority countries and regions to collect samples and possibly to increase the focus on the countries that are connecting between pools.

Conclusions

The COVID-19 pandemic has affected global FMD surveillance. Targeted surveillance is urgently required to cover gaps in disease intelligence by identifying priority countries and regions, possibly with increased focus on the countries connecting between viral pools. LFDs and other alternative sampling approaches (e.g. environmental sampling) can also play a role and further work is required to address the current limitations.

Trans-pool movements of FMDV remain a key concern as the epidemiology of FMD is very dynamic and new unpredictable patterns in Asia and North Africa are threats to FMD-free countries in Europe.

Sixteen years have passed since the last serotype C outbreak (in Kenya and Brazil in 2004) and actions should be promoted to provide evidence of the global eradication of FMDV serotype C and avoiding reintroduction through inadvertent escape from laboratories or bio-terrorism. A new paper from the Network provides recommendations to reduce the possibility that this serotype is reintroduced into the field.

Overview of activities conducted by the EU reference laboratory

Presenter: Labib Bakkali Kassimi, ANSES on behalf of the EURL for FMD (**Appendix 2**)

Key Messages

1. The new EURL was appointed on the 1st of January 2019 as a consortium between Anses and Sciensano.
2. The EURL provides technical assistance to MS and works to improve and maintain diagnostic capacity through organisation of annual proficiency test (PT) and sharing relevant information on FMD with the network during its annual workshop. PT 2021 is ongoing, with a face-to-face workshop currently planned for November 2021
3. The EURL contributes to the global monitoring and control of FMD through collaboration with OIE, FAO and EuFMD by providing diagnostic services, training and expertise missions.
4. Survey on the needs and perspectives for the EU Reference laboratory network was conducted. The Covid-19 pandemic has highlighted the need to set up a bank of FMD diagnostic reagents and kits at national and/or European level.
   Collaborative research project proposal on assessment of efficacy of A vaccines against A/Africa/G-IV was submitted to the Standing Technical Committee (STC).

Summary

The new EURL was appointed on the 1st January 2019 as a consortium between ANSES in France and Sciensano in Belgium.

The EURL has set up a website (http://eurl-fmd.anses.fr) to share information with its network of 40 European laboratories. The EURL organizes an annual proficiency test (PT) based on outbreak scenarios to improve and maintain diagnostic capacity of the European laboratories. In 2019 and 2020, 38 countries participated in the PT including 31 countries supported by the EURL and seven countries supported by the EuFMD via a Letter of Agreement signed with ANSES. For the 2021 PT, 40 laboratories from 38 countries registered for participation. The panels will be shipped to participants by the end of May.

The EURL organized its first annual scientific workshop in October 2019 at ANSES in France. Fifty-six participants from 35 countries attended the meeting. Due to the Covid-19 pandemic, the 2020 workshop was organized on line and this allowed more participants (70) to attend the meeting. However, although participants evaluated the WS as excellent or very good, they expressed the need of face-to-face meeting that would improve communication and allow having more presentations. During the workshop, outcomes of a survey conducted by EURL on the needs and perspectives for the EU Reference laboratory network were presented and discussed. Participants have expressed interest in setting up a national bank (73%) and/or EU bank (85.8%) of FMD diagnostic reagents and kits.

The efficacy of available A vaccines against A/Africa/G-IV strains was also discussed given the poor in-vitro vaccine-matching data performed by the WRL for recent virus strains from Egypt and East Africa and the lack of in-vivo vaccine protection data. In order to clarify this issue, a collaborative research project proposal on assessment of vaccines against A/Africa/G-IV was submitted to the Standing Technical Committee (STC), to perform additional in-vitro vaccine matching and to carry out an in-vivo vaccine protection study.

The EURL contributes to the global monitoring and control of FMD through collaboration with OIE, FAO and EuFMD and by providing diagnostic services to countries in case of an outbreak. The EURL recently assisted Rodrigues Island for detection and typing FMDV following a new outbreak that occurred at the beginning of March 2021. In collaboration with the WRL, the FMDV strain was identified as belonging to the same lineage as the one in Rodrigues and Mauritius in 2016, i.e. O/ME-SA/Ind-2001e lineage, however the two lineages shared only 96.4% identity. In collaboration with EuFMD, the EURL received citric acid inactivated LFDs collected in 2020 from Burkina Faso and in 2019-2020 from Niger. FMDV SAT2/VIILib-12 virus was detected in Burkina Faso and in Niger, SAT2/VII and A/Africa/G-IV were detected.

The EURL contributes to the improvement of diagnostic capacity by training. In collaboration with EuFMD, the EURL conducted two surveys on the capacities and expertise of laboratories for the diagnosis of FAST diseases. Following these studies, two online training on FMD diagnostic were provided by the EURL. One training session was provided to REMESA country members on emergency diagnosis and post-vaccination monitoring. The second training session was provided to South Eastern European countries on FMDV detection and typing using molecular tools.

The GF-TADS Global Strategy: progress of the FMD control strategy and action plan of the FMD Working Group

Presenter: Neo Mapitse, OIE on behalf of the GF-TADS FMD Working Group (**Appendix 3**)

Key Messages

1. The need for support from development and technical partners is increasing as countries engage and advance in FMD control and the Global Strategy enters its final phase of implementation.
2. Eighty endemic countries in Asia, Africa and Middle East are engaged and closely monitored, with noticeable evidence of advancement.
3. Collaboration, coordination and synergy with regional organizations/programs are essential for successful global control and eradication of FMD and other priority transboundary animal diseases (TADs).

Summary

The Global FMD Control Strategy was launched in 2012 with the aim of contributing to poverty alleviation, improving the livelihoods in developing countries and to protect the global and regional trade in animals and animal products. Its goal is also to ease the impacts of the FMD worldwide and maintain the status of free countries. The Strategy consists of three components: 1. Improving global FMD control; 2. Strengthening Veterinary services and 3. Prevention and control of other major diseases of livestock.

The GF-TADs FMD Working Group supports the implementation of the Global Strategy through coordination and collaboration. In the last two years, regional roadmap meetings on the FMD Progressive Control Pathway (PCP-FMD) were held in West Eurasia, West Africa and Southern Africa to assess progress and provide guidance to countries to progress along the PCP-FMD. Further meetings were held with the Regional Advisory Groups (RAGs). Due to COVID-19, some of the meetings were held virtually with the technical support of Virtual Learning Centres and EuFMD.

The FMD WG reviews and provides feedback to countries regarding their national control plans and risk based strategic plans to move along the PCP for FMD; eleven countries submitted their plans and received feedback in the last 24 months. The feedback was reviewed by the Regional Advisory Groups (RAGs) and two countries progressed from PCP-FMD Stage 0 to Stage 1 (Guinea and Burkina Faso) and one country, Kenya, progressed from Stage 1 to Stage 2. Additionally, Kyrgyzstan received OIE endorsement of its Official Control Programme in May 2020.

There has been continued application, improvement, and development of tools to support the PCP-FMD, such as the PCP-FMD guidelines, self-assessment tool, templates for control strategies, the post-vaccination monitoring guidelines and the PCP TRAC (tool for review and communication). The PCP Support Officer (PSO) program, implemented in collaboration with EuFMD, provides technical support to apply these and other tools, and helps countries keep momentum and progress in between Roadmap meetings.

Looking to 2021-2022, the FMD Working Group will continue activities to coordinate the implementation of the Global Strategy. The PCP-FMD toolkit will be improved by the strengthening of the PSO network, the development of technical guidelines and training in key areas. An external evaluation of the strategy will be implemented as it is almost ten years since the Strategy was launched in 2012. Furthermore, a Global Coordination Committee for FMD control (GCC-FMD) will be convened to enhance regional cooperation and

facilitate alignment of regional programs with the global strategy. The input of the GCC-FMD, together with the results of the evaluation will be used to develop a harmonized five-year action plan for the final phase of the Global Strategy.

Discussion

During the discussion, PCP Support Officers (PSO) support examples was addressed and their instrumental role was outlined, in assisting countries to develop plans and risk-based control strategies, particularly in West, Central and East Africa, and progress along the PCP-FMD. The possibility of engaging more countries within the PCP-FMD was also discussed, particularly for countries in North Africa that are not currently involved in a FMD Roadmap.

The support provided by EuFMD to the FMD WG was welcomed as an opportunity to continue to strengthen the connections with countries through the Regional Advisory Groups (RAGs) and further improvements and expansion of the PSO network.

Participants discussed the clear reinforced synergies with complementary activities and initiatives undertaken by other stakeholders and/or related to other FAST diseases, and these were indicated as an opportunity to improve the efficiency of actions implemented.

Finally, the need to engage more countries in the Progressive Control Pathway for FMD control, such as countries in North Africa that are not currently in the FMD Roadmap, was highlighted.

Report of the Executive Committee on the actions since the 43rd General Session

The EuFMD team gave a short presentation on the activities implemented in Europe, the neighbourhood and sustaining the global FMD control strategy (**Appendix 4**).

Summary

The biennium was characterized by the adaptation to Covid-19 restriction measures, with the conversion of face-to-face planned workshops and trainings to a virtual format. The new online courses developed and delivered through an upgraded EuFMD virtual platform allowed the implementation of a large part of the training program, achieving most of the planned learning objectives. However, some of the programmed events with a strong field component, such as the Real Time Training courses and the laboratory courses organized in collaboration with the Pirbright Institute, have been postponed to 2022.

Good progress has been made on the development of tools such as GET Prepared (toolbox for emergency preparedness), EuFMDiS (pan European FMD spread model) and TOM (Training Management System), to assist countries in capacity development, simulation exercises with the use of crisis simulation software, and other initiatives implemented to ensure continuity of actions to better prepare EuFMD Member Nations to respond to an incursion of FMD or similar TADs.

The risk reduction programme in the European neighbourhood made good progress with the risk mapping, risk information sharing system and quarterly FAST reports. Constant assistance has been provided to neighbouring countries in the implementation of surveillance and improved control in risk areas, in order to minimize risks and related costs and losses.

The support to the FMD Global Control Strategy was maintained through regular participation in the GF-TADs FDM Working Group activities, with a collaboration for the development of the FMD-PCP Toolkit and the PCP Support officer system (PSO), as well as via the partnership with the WRL to monitor the global evolution of FMD virus dynamics.

Discussion

For Pillar I, Fabrizio Rosso (EuFMD) highlighted the importance of the Pragmatist tool in providing risk information to Member Nations and non-members. He also stressed the importance of the work on the pre-qualification of vaccines.

For Pillar II, Neo Mapitse (OIE) commended the work done and underlined the importance of risk-based approaches to surveillance and disease control, which continue to be promoted and developed by the EuFMD. Mr. Rosso thanked the FAO and OIE regional offices in the European neighbourhood for their support in the delivery of the EuFMD's programme. The Pillar II programme aims to reduce risk for Member Nations and the deputy executive secretary outlined both the need to continue to monitor this risk in the European neighbourhood and the impact of the risk reduction programme, with the involvement of the Standing Technical Committee.

Regarding the overall programme of activities conducted in the 2019-2021 period, Keith Sumption commented that EuFMD's move to virtual training had helped in its adaptation to the COVID-19 crisis. He highlighted the importance of EuFMD's influence in stimulating applied research in Pillars II and III and in the promotion of technical field studies by partners. Martin Blake commented on the excellent delivery of activities across the three pillars and congratulated EuFMD staff on their resilience, and ability to adapt and innovate. He concluded by congratulating Keith Sumption on his appointment as CVO of FAO. Fabrizio Rosso thanked the dedicated logistical, financial and administrative staff of EuFMD for their ability to respond quickly to the COVID-19 crisis.

Keith Sumption considered the unique value of the Real Time Training courses and the considerable investment in time and money made by the EuFMD. He requested comments from Member Nations on the value of reinstating these courses once travel becomes possible again. In response, Fabrizio Rosso mentioned the current development of virtual Real Time training including virtual reality and mobile-first virtual learning solutions.

Conclusions

EuFMD has delivered a wide range of activities and shown innovation and rapid evolution to virtual modalities in response to the COVID-19 pandemic.

The EuFMD Secretariat and its research committees should reflect upon the degree to which the FAST disease risk from the European Neighbourhood has been reduced and how this might be assessed regularly.

The EuFMD Secretariat and Member Nations should reflect on the value of virtual versus face-to-face training, with particular reference to the Real Time Training programme.

Report on the status of FMD antigen and vaccine banks in Europe

Presented by Kiril Krstevski and Charlotte Rendina, EuFMD (**Appendix 5**)

Key Messages:

1. The output of the PRAGMATIST tool helps vaccine bank managers to determine the most important strains to maintain in the banks. It is recommended that vaccine bank managers explore the use of the tool to quantify the extent of coverage and gaps in their holdings.
2. Approximately 31,466,000 doses across five serotypes and 13 antigens are being held (excluding the central EU bank). Most of the antigen strains indicated by PRAGMATIST as having high coverage scores are well represented across the national banks. Notable exceptions are A-Malaysia 97 strain, which covers a specific part of the risk and is held in only one national antigen bank, and A-G VII, hold in two national banks.
3. Contingency plans and operational capacity to implement emergency vaccination are a critical component of FMD emergency preparedness. EuFMD MNs would benefit from continued participation and collaboration through the FMD emergency preparedness network; 85% of the countries responding to the survey indicated an interest in continued participation in or joining the FMD emergency preparedness network.
4. Eleven countries hold stocks of vaccine for other TADS. The extent to which this could be an issue depends on the capacity of the suppliers to provide suitable quality and quantity of stocks in an emergency rapidly.

Summary of replies to the Vaccine Bank Questionnaire

Following two EuFMD surveys that were conducted in 2017 and 2019, an online survey was issued in February 2021 with a questionnaire sent to the 39 EuFMD Member Nations.

The results showed that approximately 31,466, 000 doses across five serotypes and 13 antigens are held by MNs in their national vaccine and antigen banks, excluding the EU antigen bank. This showed a reduction from earlier surveys that showed 38 and 39 Million doses in 2017 and 2019 respectively. The survey demonstrated that eight EuFMD MN hold these vaccines and antigens (or have other arrangements such as commercial contracts with a third party) for the supply of FMD antigen for emergency use, comprising four EU member nations and four non-EU member nations. It was also noted that 78% of all antigen doses are held by two countries. Compared to the previous report from 2019, this is a reduction of one country (one EU MN responded that has no longer a vaccine bank).

Seven out of eight countries estimated that time needed for formulation and delivery of the vaccines is a week or less; one country estimated up to ten days would be needed.

Antigens in relation to risks

The output of the PRAGMATIST tool (chart below) provides recommendations of FMDV vaccines to be included in antigen banks. It is based on an analysis of the latest epidemiological data collected by the OIE/FAO FMD Laboratory Network regarding FMDV lineages present in different source regions, as well as available data to score the ability of vaccines to protect against these FMDV lineages.

Most of the antigen strains with high scores for risk coverage are well-represented across the national antigen banks. An important exception is the A-Malaysia 97 strain which covers a specific part of the risk and is held in only one national antigen bank. Another notable exception is A-G VII strain, which still represents a risk for Europe and is held in two national banks. Additionally, antigen strains A-22 and A-Iran-05 cover the same part of the risk and keeping only one would be sufficient.

Contingency plans and use of emergency vaccination

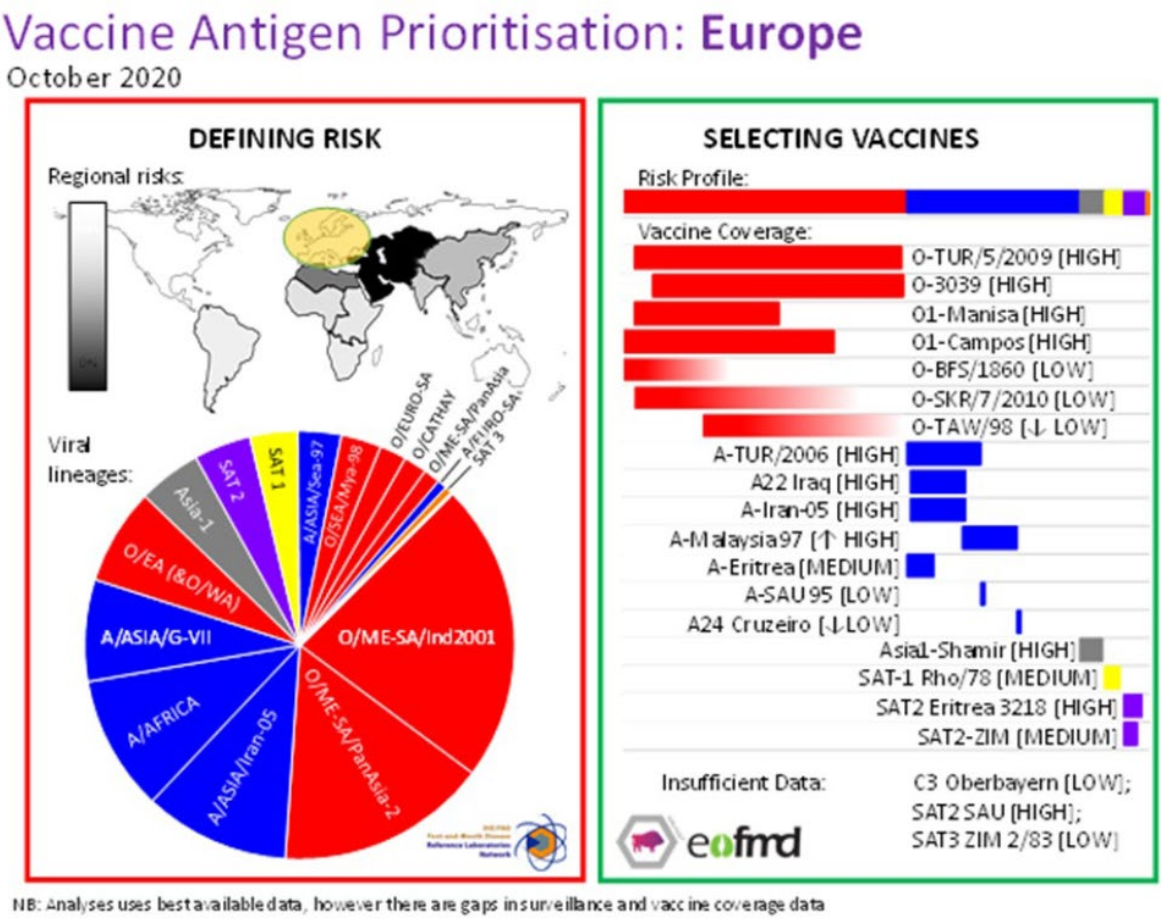
All responding countries (100%) indicated emergency vaccination is included as a potential control in their current contingency plans for FMD. The majority (80%) indicated that subject matter expert committees would support decision making in relation to: i) a decision to proceed with vaccination and, ii) the vaccination strategy to be employed. Forty three percent of respondent countries indicated that models are used to inform contingency planning and preparedness for emergency vaccination. A similar number (40%) of countries indicated that models might be used to support decision-making during an actual FMD emergency response.

Respondent countries indicated that the most important constraints on their operational capacity to implement an emergency vaccination plan rapidly are: i) sourcing a suitable human resource pool to conduct vaccination (59% vs 69% in 2019), ii) vaccine delivery system, including cold chain management (44% vs 58% in 2019) and, iii) management of vaccinated animals, including post-vaccination monitoring and surveillance (44% vs 15% in 2019); iv) biosecurity protocol and property-level risk assessment, including pre-vaccination surveillance (22% vs 50% in 2019); v) appropriate training and where required, legislative appointment of vaccinators (9% vs 15% in 2019).

Deciding if, when and how to implement emergency vaccination during an outbreak remains the most important topic for discussion in the FMD emergency preparedness network, followed by operational planning for emergency vaccination, including human resource, information systems and laboratory capacity estimates and capability (agreed by 79% and 41% of the responding countries, respectively).

Vaccine reserves for other Transboundary Animal Diseases

Twelve respondent countries (8 EU MS and 4 non-EU MS) indicated **t**hat they have national vaccine banks (n=4) or other arrangement (e.g., commercial contract) with a third party (n=8) for supply of vaccine for emergency use for other transboundary animal diseases. Nine of these eleven countries (82%) reported to have/hold vaccines for rabies (7,348,950 doses in total), and four (36%) for lumpy skin disease (3,151,000 doses in total). Vaccine reserves were also reported for classical swine fever (three countries) bluetongue (one country), Peste des Petits Ruminants (one country) and Rift Valley Fever (one country).



NB: Analyses uses best available data, however there are gaps in surveillance and vaccine coverage data

Conclusions

Outputs of the PRAGMATIST tool can help vaccine bank managers to determine the most important strains to maintain in the vaccine banks.

Significant strategic vaccine reserves for FMD (5 serotypes and 13 antigens) are held in Europe in addition to the EU-vaccine bank, but primarily by two countries. Most of the antigen strains with high coverage scores are well represented across the national banks, exceptions are A-Malaysia 97 and A/ASIA/G VII.

Contingency plans and operational capacity to implement emergency vaccinations is a critical component of FMD emergency preparedness in EuFMD Member Nations.

Current FMD and similar transboundary diseases situation Turkey, Israel and Georgia

Presenters: Tengiz Chaligava (Georgia), Michel Bellaiche (Israel), Naci Bulut (Turkey) (**Appendix 6**)

Key Messages

1. In the past two years, outbreaks of FAST diseases, except RVF, have been reported from Turkey and Israel.

2. Georgia, Turkey and Israel have conducted risk-based surveillance and control for FAST diseases.

3. Georgia and Turkey are leading countries in the FMD PCP of the West Eurasian Roadmap; both countries aim to progress to PCP stage 3 in the near future.

4. The reduced resources for FAST surveillance and control in some of the countries neighbouring Turkey and Israel combined with conflicts in some areas can increase the risk of disease introduction in both countries.

Summary

Turkey and Georgia are currently in PCP stage 2. Georgia has submitted its Official Control Programme to progress to PCP stage 3 to the GF-TADs FMD Working Group. Turkey has increased its control and surveillance measures to comply with PCP stage 3 requirements.

No outbreaks of Peste des Petits Ruminants (PPR), Sheep and Goat Pox (SGP) Lumpy Skin Disease (LSD) Rift Valley fever (RVF) and Bovine ephemeral fever (BEF) have been reported in Georgia in the past two years. Vaccinations are conducted against FMD, PPR and LSD. Georgia follows a risk-based FMD control strategy and has been implementing risk-based vaccination since 2017. The entire population of cattle and small ruminants of eastern Georgia is considered at high risk of FMD and therefore regularly vaccinated. In western Georgia, vaccination is targeted to FMD risk hotspots, i.e. proximity to live animal markets, migrating herds and flocks, and borders with Turkey and conflict territories.

Outbreaks of FMD, PPR, SGP, and LSD were reported in the Anatolian part of Turkey and in Israel in the past biennium, while RVF and BEF have not been reported in Turkey. BEF was frequently diagnosed in Israel, while LSD was last reported in 2019. None of the FAST diseases were reported from Turkish Thrace in the past two years; here, FMD risk-based surveillance is supported by EuFMD.

Both Turkey and Israel conducted FAST diseases surveillance and vaccination programs, emergency vaccines against RVF are kept in stock by Israel.

The reduced resources for FAST surveillance and control in some of the countries neighbouring Turkey and Israel combined with conflicts in some areas is considered a risk of disease introduction for both countries.

Discussion

The three countries have FAST monitoring and control measures in place, but there are significant risks of FAST disease introduction into these countries.

EuFMD's support in monitoring and controlling FAST diseases as well as training is greatly appreciated.

Georgia has submitted its Official Control Programme in order to progress to PCP stage 3 before the EuFMD General Session, also thanks to the FMD PCP support from EuFMD. Turkey is currently working on its Official Control Programme and is implementing increasingly stringent FMD control measures.

Conclusion

There is a strong need to continue and further develop support for FAST risk reduction programme in EuFMD neighbouring countries (surveillance, control, and training) and the wider region.

OFFICIAL OPENING (day 2)

The official opening of the 44th General Session was held on day 2 as the agenda was covering items for decision, while day 1 was dedicated to items for information.

Martin Blake, Chairperson of the EuFMD, officially opened the biannual EuFMD General Session 2021, held in virtual format due to the COVID-19 pandemic and upon endorsement of the EuFMD Member Nations (suspension of Rules of Procedure for in-person sessions of the Commission). After having outlined the EuFMD's three pillar approach, Mr. Blake stressed that the EuFMD has established an internationally respected capacity for efficient delivery of training and in-country support to FMD progressive control programmes and in modeling of FMD control measures, guiding towards emergency planning. He remarked that, over the years, the EuFMD has leveraged its impact by working closely with all significant partners and in particular with FAO, OIE and the European Commission. Mr. Blake invited the representatives of these organizations to the podium.

Maria Elena Semedo, the FAO Deputy Director General, spoke about the EuFMD's early days, recent growth in membership and expansion in work programme, and stated that FAO has recently been investing resources to improve transboundary animal diseases (TADs) control in the European neighbourhood and globally. However, she emphasized that the repeated incursions of TADs and the potential economic impact on EuFMD Member Nations are a reminder that preparedness, capacity to respond, and the continuous monitoring of risk, must remain a priority. The capacity to increase diagnostics in animal health laboratories, to scale-up critical veterinary and animal health human resources during crises, to ensure the rapid availability of quality and safe vaccines and to guarantee continuous capacity development and networking can ensure proper preparedness and response. Ms. Semedo mentioned that the EuFMD Hold-FAST strategy adopted in 2019, builds on good principles for FMD preparedness, prevention and control and extends them to similar TADs, which pose an immediate threat to the EuFMD Member Nations. The EuFMD strategy aims to promote and facilitate the best use of resources, expertise, tools and coordination mechanisms developed for FMD and apply them for similar TADs. She remarked that EuFMD initiatives, such as systems to facilitate availability and access to diagnostics for emergency response, to enhance procurement processes for an improved security of quality vaccines, or the training programme, learning management tools and virtual learning hubs established to develop national and individual capacities, are just a few examples of the benefits that the EuFMD workplan can provide to its Member Nations, and to assist FAO in its actions towards an increased resilience of livelihood to threats and crises. She added that the EuFMD support complements actions agreed under the GF-TADs coordination system between FAO and OIE, making the best use of the different capacities developed by the Commission to better equip and prepare Veterinary Services to control priority diseases. She acknowledged that the decision on the revision of the Constitution is for the Member Nations to make, but reminded that FAO will support the Member Nations' decision and will continue to welcome the contribution of the Commission, in the joint efforts to achieve FAO's Strategic Development Goals.

Monique Eloit, Director General of the OIE, appreciated the EuFMD development that has taken place over the past years. The OIE commended the EuFMD for the relevance of its programme and the EuFMD team for the high level of achievement in Europe and other countries, without forgetting its engagement at global level. Ms. Eloit emphasized that the OIE and EuFMD have strengthened their collaboration significantly over recent years. To illustrate her point, she first mentioned the bilateral collaborations, including delivery of capacity building programmes to the OIE Members. This included a jointly-conducted training on 'Public Private Partnership in the Veterinary Domain', core for the recognition of the value of the private sector as a means to support the capacities of national Veterinary Services in building robust and sustainable animal health systems, and the course on 'Safe trade and FMD control'. Ms. Eloit informed that the OIE will aim to continue developing training courses and in particular e-learning modules to support the capacity building of its Members, and therefore

looks forward to strengthening its collaboration with EuFMD in developing well-structured and customized training courses, and to better respond to its Members' needs. The OIE recognized the EuFMD contribution in the control of FAST diseases and risk reduction programme delivered in the European neighborhood, through strong partnership and networks, and more globally through the assistance in the implementation of GF-TADs partners' strategies. . The OIE has supported the extension of the scope of the Commission to similar TADs, which pose an immediate threat to the OIE Members, and to adapt current tools and training for FMD to other FAST diseases, as the Global FMD Control Strategy states that the control of FMD should benefit to the control of other TADs. Ms. Eloit concluded saying that over the recent years, the broadening of EuFMD domains of engagement and interventions call for new synergies and mechanisms of collaboration between the EuFMD and OIE.

Bernard Van Goethem, Director for Crisis preparedness in food, animals and plants (SANTE/G), DG Health and Food Safety of the European Commission acknowledged FAO support provided to EuFMD and its activity, the OIE for constant collaboration and support, the EuFMD Executive Committee for the dedicated work, and the EuFMD Secretariat for the successful guidance of the team in this challenging times. Mr. Van Goethem stated that coordination and cooperation are essential elements to the success of EuFMD. He highlighted that the EuFMD is the perfect example of the motto 'Prevention is better than cure', which is at the heart of the new animal health law (21st of April 2021), and which has allowed the European Union to remain free of FMD for the last ten years. He reminded participants that the 44th General Session will examine the proposed changes to the EuFMD Constitution, although no decision on this issue will be taken. In particular, he emphasized the importance of defining criteria for the FAST diseases focusing on synergies with FMD (such as the existence of vaccines, or similar pathway of disease spread), and affected species (with focus on ruminants, considering the risk they represent in terms of spread of FMD). He stressed that the extended mandate to FAST diseases is useful as practical benefits can arise from synergies in animal disease preparedness and surveillance efforts. However, Mr. Van Goethem highlighted the need to clarify which are FAST diseases, requiring the establishment of criteria in the Constitution, as well as a concrete list of diseases. He also stressed the important role of EuFMD in maintaining a first-hand experience for field veterinarians from EuFMD Member Nations who have never experienced FMD, and that this should be extended to other FAST diseases. The EC appreciates the efforts of the Secretariat to carry out activities despite the current COVID-19 crises, and the initiatives to continue delivering online training and organizing online meetings according to the EuFMD programme. The EC welcomed the discussions on the first day regarding the continuous work in monitoring the global FMD situation, so that preparedness can be updated and vaccine banks tailored to the current situation. In order to continue the success story of the EuFMD, the EC called for the EuFMD to continue supporting its Member Nations efforts to prevent or eradicate FMD, highlighting the benefit to build on activities to improve o FMD surveillance and preparedness and extend them to similar Transboundary animal diseases.

The President of the EuFMD, Martin Blake, welcomed the representatives of the EuFMD Member Nations and asked to adopt the Agenda (**Appendix 7**), which was done without change.

Highlights and proposed updating to the work programme for the biennium

Key Messages

1. The EuFMD has successfully adapted the delivery of most training courses to an online format and will resume face-to-face activities as soon as possible.
2. Adaptation of face-to face training to remote delivery have brought benefits such as increasing the number of participants enrolled in activities. Remote delivery should be further encouraged, even after (and when) Covid restrictions are lifted.
3. The EuFMD will continue to support Member Nations and countries in the European neighbourhood by delivering training, enhance networking, developing tools to improve preparedness, monitoring and mitigate risk related to FAST diseases.
4. The EuFMD will continue the programme to sustain the FMD Global control strategy through the support to the GF-TADs FMD working group, training, global laboratory support and actions aimed at improve FMD vaccine security supply.

The proposed updating to the workprogramme for the three Strategic Goals was presented by the EuFMD Secretariat:

Pillar I. Improved preparedness for management of FMD and similar TADS (FAST disease) crises by Members and across Europe as a whole.

Pillar II. Reduced risk to Members from the FAST disease (FMD and similar TADS) situation in the European neighbourhood.

Pillar III. Sustained progress of the GF-TADS Global Strategy against FMD and the improved security of supply of effective vaccines

Each presentation included a summary of the expected outcomes and success stories, proposed updates and the plan on how they could be implemented.

Summary

Pillar I. Improved preparedness (presented by Maria de la Puente, Erica Chenais, Etienne Chevanne, and Melissa Mclaws) (**Appendix 8**).

- Each EuFMD MN is to allocate 8/10 training credits to any course offered in the training menu, while 2/10 training credits are reserved for online courses.
- Following the outcomes of the TQMS evaluation visit, further consolidation of the Training Quality Management System (TQMS).
- Support MNs veterinary services to monitor the training progress of their veterinary staff by implementing TOM, the EuFMD Training Management System.

Emergency preparedness

- Continue development of the EuFMDis modelling environment to include post-outbreak management, passive surveillance and rendering capacity.
- Prioritize additional disease(s) to be included in EuFMDis.

Synchronize Public Private Partnership related activities between different components (i.e. emergency preparedness and emergency vaccination).

Emergency vaccination

- Based on the scoping work, some aspects of emergency vaccination can move proceed from discussions to more robust recommendations, e.g. criteria for implementing emergency vaccination and prioritization of vaccine doses.
- Starting of operation of Prequalification (PQv) is deferred. Work in 2021 will be focused on detailed design with a view to starting implementation in the fourth quarter.

Work on AESOP has been deferred to the second biennium and will start with clarification of how PQv fits within the overall framework for procurement of FMD vaccines with EuFMD/FAO.

South East Europe

- Reduce the delivery of simulation exercises, in order to prioritize the provision of additional assistance to countries to address gaps in emergency preparedness.
- Continue strengthening the networks between policy makers and research institutions (second call for proposals and expansion of diagnostic bank).

Applied research

- Increase the visibility of the outputs from EuFMD funded scientific research.
- Further encourage networking between research institutions.

Proficiency test services

- No changes. All activities organized under this component will continue in the new phase

Disease risk assessment and forecasting

- Continue to produce joint FMD Quarterly reports with WRL which will be made available through an online dashboard.
- Develop a Risk Monitoring tool using information for Pillar II to assess and monitor the risk of FAST disease incursions into Member Nations.

- Improve guidance documentation and accessibility of the Prioritization of Antigen Management with International Surveillance Tool (PRAGMATIST), encouraging its users to share relevant data.
- Shift activities under this component (Research studies to generate information necessary to understand FAST disease risks - submission of samples) to other components of the workplan.

Pillar II. Reduced risk to Members (presented by Nick Lyons) (**Appendix 9**)

Co-ordination and FAST control framework

- Establish a review system for FAST disease control strategies and encourage integrated plans for priority FAST diseases.
- Review and modify the delivery of FAST reports, following consultation with users and risk assessors at national and international level.

Improved early warning for FAST diseases

- Ensure all countries meet a defined standard for the creation and regular update of risk maps.
- Define ecoregions in the European neighborhood, adopting a data-driven spatial clustering approach and using recent and detailed spatial data on climatic and environmental factors.
- Support mobility studies and expansion of training on entomological surveillance to inform risk maps.
- Further develop risk-based surveillance strategies for FAST diseases and provide support to the evaluation of passive surveillance systems.
- Expansion of the Statement of Intention (SOI) to include more information on FAST diseases risk and expand it by including other regions of the European Neighbourhood.

Capacity development for surveillance and improved control programmes

- A Group for Vaccination Advice Guidance and consultation (GVA) workplan will be created and implemented.
- Develop new virtual training courses based on requests from countries in the European Neighborhood
- Provide new training on quality assurance and biosecurity to laboratory networks.

Pillar III. Sustained progress of the GF-TADS Global FMD control Strategy (presented by Paolo Motta) (**Appendix 10**).

Global Strategy Implementation

- Focus on the improved roll-out and application of the existing PCP-FMD Toolkit and supporting resources.
- Increased focus on the sustainability of the PSO network and in the decentralization of technical support and monitoring of PCP progress, including in training/event delivery and governance of the FMD control strategies.
- Implementation of the Support Unit and optimization of the coordination with GF-TADs FMD Working Group partners.
- Increased focus on optimization of collaborations for collection and analysis of risk information on FMD surveillance and control and PCP-FMD progression.

Improved Global Laboratory Support

- Develop a new FLITC course in French and consider the development of a Biorisk Management course.
- Establish a new mechanism supporting more targeted virological surveillance and better characterizing the technical, logistical, capacity hurdles limiting the surveillance and diagnostics capacities.
- Develop an interoperable digital repository and online dashboard for virological and risk information.
- Establish advisory groups for vaccination and technical guidance for Eastern and Southern Africa, taking into account current developments in these regions.
- Continue support to vaccine matching tests and VNTs and the development and validation of new tests for vaccine matching and measures of protection.

Better Training for Progressive Control

- Improvement of quality assurance processes following evaluation and strengthening of training impact assessment.
- Progressive transition to long-term sustainability for the three VLCs established with EuFMD support and liaison with other VLCs established with FAO funding, to explore potential for improved delivery mechanisms for EuFMD courses and FMD-PCP activities.
- Integrate the “Sustainable Business through Training for Veterinary Paraprofessionals” extra-budgetary initiative in the PII and PIII workprogramme.
- Refine the Training Management System (TOM) tool, following a pilot phase to ensure that it best meets the needs of countries and partners.

Improved security in FMD vaccine supply

- Continue and strengthen the consultative and research work to quantify the un-met demand and predicted growth for FAST vaccines, including the development of an interactive interface for model application.
- Increase the emphasis on characterizing technical and regulatory challenges and opportunities for novel vaccine platforms and distribution mechanism, particularly in East and Southern Africa.

Discussion

Martin Blake thanked the speakers and opened the floor for discussion on the topics presented after each pillar presentations.

Pillar I. Labib Kassimi Bakkali congratulated the EuFMD for the work carried out and recommended that that reagent bank should also consider storing and distributing diagnostic kits to laboratories, in addition to the reagents, as many facilities do not keep them routinely. He also asked if there were plans to extend the diagnostic bank to other MNs in Europe and how these would be delivered.

Fabrizio Rosso replied that the possibility of extending the model for the diagnostic bank to other MNs has been included in the updated workplan. There is a need to identify how to implement this mechanism and its sustainability. In addition, the diagnostic bank, originally created for FMD, is being expanded to store reagents for other FAST diseases. Currently, the regents are stored in two places: the Institute in Brescia (Italy) and The Republic of North Macedonia, the latter due to the potential difficulty in transporting reagents from Italy to the Balkans in case of an outbreak.

Francesco Berlingieri (EC) asked to have a clarification regarding who is entering the data in the Thrace Surveillance System, how this data is used and especially how the outcome is displayed. Maria De la Puente explained that the three countries involved in the Thrace Surveillance System (Greece, Bulgaria and Turkey) regularly collect data, which is then uploaded by the competent authorities. The data is analysed every three months using the Cameron model (analysis show the confidence of freedom). The system has now been extended to include PPR and sheep and goat pox. There are plans to integrate the Cameron model with the database so that countries are able to download the analysis directly.

Richard Irvine (UK) thanked all the colleagues working on Pillar I activities and asked, regarding component 1.3, is there had been consideration for exit strategies from vaccination scenarios. Mr Rosso replied that this was an issue raised by the contingency planning network. The difficulties in implementing post- vaccination surveys to regain a free status have also been considered. Currently, the main issues for each country's contingency plans have been identified. There are plans to prioritize post-outbreak monitoring modules within the EuFMDis model, to estimate the time and resources needed for post vaccination surveillance.

Hendrik Jan Roest (NL), supported by Mr. Irvine, asked about the continuity of field training and observed that although the EuFMD has successfully implemented virtual training in the last year, the value of field training is hard to replace. Fabrizio Rosso agreed that Real Time Training cannot be replaced and there is a growing interest for these types of training from other continents as well (example of New Zealand, Australia and the USA). So far, they could not be implemented because of the Covid19 pandemic, but the intention is to resume the delivery when possible. In the meantime, other options, such as the use of virtual reality, are being explored. It is noted that there is also an interest to expand the RRT to other FAST diseases.

Pillar II. Fabrizio Rosso commented that a number of the activities carried out under Pillar II were delivered in partnership mainly with the French Agricultural Research Centre for International Development (CIRAD) and the French Agency for Food, Environmental and Occupational Health & Safety (ANSES). There is interest in further expanding partnerships in order to make use of the expertise from different groups. Martin Blake thanked MNs for supporting countries in the European Neighbourhood.

More details were requested on the functioning of the GVA and their role in the use of vaccines. Nick Lyons indicated that the aim is to improve regional capacities to evaluate the vaccines and vaccination programmes that are being used and implemented. The group will be an independent group assisted by international experts.

Neo Mapitse (OIE) commented on the perspective of the OIE for whom an early warning system is a critical component for countries with a free status and for those who have official control programs as it demonstrates the sensitivity and response of their early warning system. Nick Lyons agreed and confirmed the EuFMD is keen to promote the evaluation of passive surveillance systems.

Pillar III. Paolo Motta explained that the sustainability of the PSO system relates to the establishment of new partnerships at regional level and that emphasis should be on decentralizing support for the PCP. The PSO system has supported countries at international level and, in the upcoming biennium, this will be shifted to a regional level in collaborations with the OIE and FAO. This will reaching out to further experts depending on the specific needs of the countries. So far, the PSO system has been successful in providing support to countries.

Fabrizio Rosso mentioned the importance of focusing on surveillance and control in specific areas within the Pillar III countries such as the Sub-Saharan region, as well as West, Central and East Africa, as animal movement networks could represent a threat of FAST introduction into European neighbouring countries. This should be an area to focus on during the next biennium, for example by assessing FMD vaccines used in West Africa.

Sweden supported the proposed updates of the work programme. They see benefits in using the EuFMD expertise and experiences also for the control of other FAST-diseases. However, Sweden states focus should remain on FMD and the activities should only be broadened if it is cost-beneficial, within the budget frame and if it does not endanger the core activities against FMD. Fabrizio Rosso appreciated the support from Sweden and that the main focus should remain FMD, which should not be affected negatively if the activities are broadened also to other FAST diseases.

Martin Blake closed the session with a general support for the proposals outlined for the next biennium.

Conclusions

EuFMD should continue to deliver actions towards the objectives of better preparedness, better awareness and better control through the three pillars workplan. The proposed amendments to the EuFMD workprogramme were endorsed by Member Nations.

EuFMD should consider the expansion of the diagnostic bank model to other European countries. This could be explored considering an assessment of feasibility and sustainability.

EuFMD should resume face-to-face training when possible, bearing in mind current restrictions posed by Covid19 pandemic. This is particularly relevant for practical training such real time training. In the meantime, other possibilities such as the application of virtual reality should be explored.

The proposed actions to further development of tools and networks to assist the improvement of emergency preparedness, focusing on the specific issues identified by Member Nations during the first biennium such as the recovery of free status after vaccination, are relevant.

Assessment tools should promote the evaluation of passive surveillance systems in the European neighbourhood as the latter are critical to the early detection of FAST diseases.

Continuity of actions aimed at assessing the risk of introduction and spread of FAST diseases in Europe and neighbouring region associated with livestock mobility, are relevant.

Within the Pillar III countries, it is important to focus on those regions which pose a greater risk to the European neighbourhood countries, for example by assisting post-vaccination monitoring initiatives. These include the Sub-Saharan region, as well as West, Central and East Africa.

Assuring the quality of vaccines through a Pre-Qualification system[1]

Presented by David Mackay, EuFMD (**Appendix 11**)

Key Messages

1. The EuFMD is committed to improving vaccine security by making sure that vaccines of appropriate, high quality are available when needed.
2. The pre-qualification vaccine system (PQv) is a procedure for independent peer review of information on vaccines against FAST diseases, to confirm compliance with the minimum internationally accepted standards for vaccines, as defined in the World Organisation for Animal Health (OIE) Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (OIE Terrestrial Manual).
3. The procedure is separate to, but dependent on, registration procedures by national competent authorities. Only products that have been approved by at least one national competent authority will be eligible for PQv and authorities play an essential role in monitoring of products on their markets.
4. PQv will form part of a wider framework for vaccine security by promoting the uptake of 'quality assured' vaccines (Assured Emergency Supply Options -AESOP).
5. The PQ procedure benefits manufacturers, purchasers and users of vaccines against FAST diseases as independent PQv reduces the time and amount of work required by procurement managers by removing the need to evaluate 'quality' as part of the procurement process.

Summary

The EuFMD is committed to improving vaccine security by making sure that vaccines of appropriate, high quality are available when needed. Establishing a Pre-Qualification vaccine (PQv) procedure aims to ensure that vaccines supplied to EUFMD meet minimal internationally accepted criteria for quality, safety and efficacy, and are produced and controlled consistently in manufacturing facilities that operate according to the principles of good manufacturing practice. The system includes a procedure for independent peer review against the standards for vaccines that are defined in the World Organisation for Animal Health (OIE) Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (OIE Terrestrial Manual), and contributes one important element of a future system for Assured Emergency Supply OPtion (AESOP) of FMD vaccines. It further provides vaccine security by promoting predictability for suppliers and assisting vaccine production planning, reducing the timescale required for procurement and the risks for countries to procure vaccines of inadequate quality as it confirms the quality of vaccines in advance of need. It separates assessment of quality from the tendering procedure. PQv is separate from, but relies upon, national and regional registration procedures. Only vaccines that have been approved by at least one national competent authority will be eligible for PQv, and national authorities play a key role in continued monitoring of vaccines on their markets.

The PQv procedure requires applicants to supply evidence of the 'quality' of a vaccine in terms of: pharmaceutical quality including evidence for consistency of production; safety with respect to target animals, users, consumers of products from vaccinated animals, and the environment; efficacy in terms of evidence to support the claims made for the product on the label; and, standards of manufacture (compliance with the principles of Good Manufacturing Practice). These aspects will be considered in the independent peer review performed by recognized experts and against internationally accepted standards. Vaccines that are approved will be published in a list of PQ vaccines, thus readily available to contingency planners and risk managers.

[1] Based on the same principles as the existing system for human vaccines operated by WHO.

The PQv procedure will benefit the manufacturers, purchasers and users of vaccines against FAST diseases. PQv ensures that the properties and claims for the vaccine are fully supported by the information submitted, but it is the responsibility of the risk/procurement manager to ensure that the vaccine is appropriate for use in a particular epidemiological situation (fitness-for-purpose).

The document 'A pre-qualification procedure for vaccines against FAST diseases' was published in the first quarter of 2021, having completed consultation with stakeholders. The inception phase (detailed planning for delivery) of the project is planned to take place during 2021, subject to endorsement at the 44th General Session. The implementation and operational phases of the project are planned from 2022 with an initial invitation to companies to submit applications for PQ on a volunteer basis. The procedure will be reviewed and optimized once sufficient applications have been evaluated to gain experience.

Discussion

The following issues were discussed

The possibility for the PQv to look at the relevance of vaccines for use against field strains: pre-qualification relates to evaluating the quality and performance of a vaccine in relation to the claims made in the product literature. PQv can only evaluate fitness for a particular epidemiological purpose (e.g. relevance of strains) if such a claim is made. In other cases, evaluating fitness-for-purpose must be carried out as part of procurement once the particular needs are known (e.g. strains, species, adjuvant, onset and duration of immunity).

Actions in case vaccines are found not to meet PQ standards: only products that meet the requirements for PQv will be included on the list published on the EuFMD website. Internal reports will be produced for all vaccines evaluated and supplied to manufacturers who will have the option to address any deficiencies or data gaps identified and resubmit an application.

The system is foreseen as cost recovery or funded activity: the business model has yet to be finalized but partial cost recovery is envisaged provided a way can be found to ensure this does not act as a disincentive to smaller manufactures, particularly those from LMIC[2].

Number of vaccines expected to be pre-qualified: more work is needed on this question. As part of the inception phase, the EuFMD will engage with stakeholders to estimate demand as part of building the business case.

Relation between PQv and Post Vaccination Monitoring: PQv focusses on evaluating evidence provided by applicants on quality, safety and efficacy. Post vaccination monitoring (PVM) is focussed on evaluating the use of vaccines in the field. It is difficult to conduct PVM studies to the standards of Good Clinical Practice that would be required for adoption of these studies by manufacturers as data supporting their products. Nevertheless, EuFMD will look at ways in which to use PVM data to inform the PQ system.

Relationship between licensing by national regulatory authorities and PQv by EuFMD: PQv is not a regulatory procedure. It is a peer review of information to assess compliance with OIE standards. PQ relies on products being approved and monitored by national regulatory authorities working the standards and requirements that apply in their country or region.

Conclusion

The General Session noted the presentation on PQv and supports the approach to its implementation and operation.

[2] Lower and Middle Income Countries

Standing Technical Committee Report

Presenter: Stephan Zientara, Chairperson Standing Technical Committee (**Appendix 12**)

Key Messages

1. The committee held six meetings – one of which was face-to-face in ANSES.
2. The main activity was the guidance for the Open Session 2020 with the theme "Livelihoods @risk in a FASTer world".
3. This event included four virtual sessions in December 2020, four virtual workshops in January/February 2021 and a closure meeting in mid-February, and was attended by over 3 000 participants.
4. Other items covered by the Committee during the biennium were: FAST diseases control and management; Call for applied research; Vaccine pre-qualification system; EuFMD as risk information provider; Sub-committees activities and situations (SCBRM, SCSAR); Gaps, Priorities and opportunities emerging from COVID 19 situation; Opinion on serotype C in EU bank.

Summary

Dr Zientara introduced the committee, which has six members from France, Spain, Italy, Denmark, Switzerland and the United Kingdom. Six committee meetings were held during the first biennium, on 18 June 2019, 7 November 2019, 27 February 2020, 3 June 2020, 9 September 2020 and 4 February 2021. The main activities of the Committee were focused on the below items.

FAST diseases control and management

FAST diseases was a major change in the activities of the EuFMD and the Standing Technical Committee (STC) has given guidance in balancing the efforts made. Considering that up to 2019 the EuFMD supported multiple disease surveillance only in the Thrace region, the STC has assisted the team in identifying gaps that needed to be addressed in accordance with the new strategic approach. Integrated Risk-Based surveillance seems to be an area to which all the members of the STC can contribute.

The STC has contributed to EuFMD modelling (looking into opportunities for its application for vector-borne diseases) as well as in establishing training priorities, anticipating whether such trainings should address specific diseases or rather address thematic items that can represent cross-cutting issues among different FAST diseases.

Preparation of the Open Session 2021

The Open Session of the Standing Technical Committee of the European Commission for the Control of Foot-and-Mouth Disease is held every two years and has become the largest technical and scientific meeting on Foot-and-mouth Disease to be convened on a regular basis. The EuFMD has organized these meetings since the early 1970s, alternating a Closed Session with an Open Session for scientific exchange.

Due to the travel restrictions related to Covid-19, the Open Session 2020 (OS20) was held in a virtual format and over four days in December (8, 10, 15, and 17). The online conferences were hosted in a virtual space (the EuFMD lighthouse) and the scope broadened to TADs similar to FMD, which remained the focus. Under the theme of "Livelihoods @ risk in a FASTer world", 45 Keynote and oral presentations were delivered during four sessions:

1) Measuring animal movements and drivers for FAST risk mapping; 2) From risk to actions, make them happen; 3) Vaccine security and critical resources for emergency management; 4) Resilience to long term FAST crisis.

Each session had a Chair and two facilitators. A question and answer roundtable was conducted at the end of each session to reply to all the questions sent in via a dedicated chat box in the virtual area. The virtual environment allowed participants to engage in a discussion forum concerning the talks and posters. A virtual poster area was set up, showing 76 studies and works, with podcasts by the authors summarizing their findings. Two gaming experiences related to diseases prevention and control were available, one of which is an interactive lesion ageing video and the other is the Get Prepared wall. Participants could access an information point and a live chat box connected to the EuFMD. Seven dedicated virtual rooms were available, to show the core activities and projects led by the EuFMD Team: Training, EUFMDis, Simulation Exercises, Pragmatist, Pre-qualification of Vaccines, Risk Forecasting and Global Strategy GFRA, GF-TADs, and PPR.

The virtual format of the Open Session resulted in a large number of participants: over 3000 users from all over the world accessed the website and virtual environment to watch the live and recorded sessions. In addition, the event was also broadcast live via Facebook™ and YouTube™, and available after the event for those in different time zones.

Call for applied research

The prioritization of applied research projects was outlined during the Bari (Italy, 2019) meeting. In particular (i) Penside test for FMD to differentiate serotypes; (ii) Penside test for FMD, PPR and SG-Pox; (iii) Non-invasive sampling; (iv) Studies to reduce PPR vaccine wastage; (v) development of simple tools to teach bio-security; (vi) studies on culling and disposal capacities in Member Nations with modelling, which is a bottleneck for EuFMDis.

The STC has agreed with the themes proposed with the exception of item (vi) which seemed to be more a logistic issue rather than a topic for a research proposal.

For **Pillar I**, the main priority is to improve policy support with the objective of identifying control options that could guarantee business continuity especially for those countries with significant export to other EU or third countries. Additional priorities could be the identification of guidance criteria on when to implement preventive vaccination against FMD, LSD, Sheep and Goat pox and PPR.

For **Pillar II** and **III**, a priority area could be the improvement of surveillance systems for FAST disease with a major output being new or adapted tools for managers. Another area of research could be the optimization of environmental sampling with a major output being its application to routine or early detection of FMD in settings like animal markets.

Recently, and following the FMD EURL workshop (organized in November 2020), a research project proposal to assess the efficacy of vaccines against A/Africa/GIV strain was also discussed among the STC members. The issue of the amount of funds requested for the proposal was further discussed in relation to the overall amount (200,000 Euro) allocated by the EuFMD for such activities. The STC members proposed that, in order not to deplenish the fund (and be detrimental for other potential proposals), two parallel options need to be explored: (i) request to explore the possibility of lowering the amount requested for the vaccine efficacy study; and (ii) explore the possibility of obtaining extra funds.

Three preliminarily potential new research themes were also identified: (i) Define criteria on when to implement emergency vaccination in disease free countries; (ii) Policy support tools for economic analysis of FAST control strategies; (iii) Operational optimization of environmental sampling.

Vaccine pre-qualification system

The STC has followed regularly and given advice on the progress with developing a procedure for prequalification (PQv) of vaccines against FAST diseases on several issues that have arisen in discussions of the Technical Advisory Group on PQ (PQTAG). The approach under development is based on the principle that PQv is not a new or additional regulatory procedure, but is a scientific peer-review of evidence of the quality, safety and efficacy of a vaccine that will include details of any previous registration/licensing/authorization that has been issued by a regulatory authority. The committee endorsed that the procedure for PQv should be simplified for those vaccines that have already been approved by recognized authorities such as the EMA or USDA. The procedure should not exclude those vaccines that have not been approved to the standards of advanced regulatory regions such as the EU or US. One of the objectives should be to provide a route to approval or recognition of quality for vaccines produced to adequate standards in other regions.

The STC supported the work done by David Mackay and the upcoming efforts through a working group to review thoroughly the results of the discussions held at the Rome meeting (Jan 2020) on (i) vaccine prequalification and (ii) vaccine demand for FAST diseases. The STC supported, in principle, the creation of a dedicated committee to oversee the operation of the procedure in order to provide appropriate scrutiny, input from OIE and other partners, and sustainability of operation.

EuFMD as risk information provider

The STC has supported the EuFMD by providing information on risks to Member Nations and informing on the changes of such risks. The FMD quarterly report is one of these tools and recently provided support to Member Nations to better assess their respective risks.

Moreover, the information at country level can be summarized in country cards or be represented through the outputs generated by the FMD Self-Assessment Tool that can be used for Risk Assessment purposes. There is also the possibility of further developing data-sharing in specific regions through Statement of Intention agreements (currently in place between South East European neighbouring countries).

The STC members believe that the information generated through these EUFMD initiatives complement those that, for example, the OIE provides. The OIE database is updated every six months by endemic countries, and the information generated through this initiatives can be at shorter intervals.

Sub-committees activities and situations (SCBRM, SCSAR)

These two committees met only once, in Bari (Italy) in 2019. The STC gave advice on their activities, which are very useful in assisting in fine-tuning the EuFMD program and may further assist in areas that still need support.

Gaps, Priorities and opportunities emerging from COVID 19 situation

The STC was concerned about the COVID-19 crisis which has caused a significant reduction of capacity to respond in the event of an outbreak. The STC has taken into consideration the COVID-19 impact survey for Risk assessment purposes, considering that a delay in the detection of FAST diseases may translate into an increased risk of introduction.

Serotype C in EU bank

The STC has suggested that a decision-making methodology should be defined and that it can be proposed to be developed by the WRL using the PRAGMATIST tool.

Discussion

Mr. Sumption congratulated Mr. Zientara and his team, and the secretariat, for their work, which was greatly appreciated.

The Chairman extended his thanks on behalf of the Executive Committee and Member Nations for the delivery of the Open Session 2020, which was extraordinary.

Conclusion

The composition of the STC, with same members of previous biennium was endorsed.

Special Committee for Surveillance and Applied Research (SCSAR)

Presenter: Phaedra Eblé, Member of SCSAR (**Appendix 13**)

Key Messages

1. The committee was established at the GS43 and replaced the Research Group of the Standing Technical Committee.
2. The membership is made up of representatives from centers of expertise for FAST diseases.
3. Terms of reference have been agreed by committee members.
4. A meeting of the committee was held on 22 January 2021 to discuss: surveillance indicators and data needed for risk assessment by EuFMD Member countries, assessment of diagnostic capacity of EuFMD Member countries during crises and implementation of integrated disease surveillance and control. Gaps and research priorities were identified.

Summary

Ms. Eblé explained the background to the committee, which was established at the 43rd General Session in April 2019, and which replaced the Special Committee for Applied Research. The remit of the committee was extended from FMD, to FMD and Similar Transboundary (FAST) diseases – in particular Category 1 (FMD, PPR, Capripoxviruses) and Category 2 diseases (RVF, Bovine Ephemeral Fever).

The members are from centers of expertise for FAST diseases. They provide expertise in epidemiology and laboratory diagnosis of Category 1 and 2 FAST diseases, (potential) vaccines and in specialized disciplines critical for FAST diseases (e.g. surveillance, wildlife control).

Ms. Eblé confirmed that terms of reference for the group have been agreed. She outlined some, and noted that they are set-out fully in the report of SCSAR which can be found on the EuFMD website.

The composition of the SCSAR has been revised with experts nominated to replace members who are no longer available. New members proposed are: David Lefebvre (Sciensano), Phaedra Eblé (Wageningen Bioveterinary Research), and Santina Grazioli (IZSLER).

Additional experts are proposed to be appointed in their personal capacity because of their competence in technical matters (according Art VII of Constitution): Emiliana Brocchi (Former Head, National FAO-OIE Reference laboratory for FMD- IZSLER Italy), and Kris De Clercq (Former Director of Virology & Head of the Unit Vesicular and Exotic Diseases, Sciensano Institute, Belgium)

Ms. Eblé detailed the SCSAR meeting on 22 January 2021. The committee was split into three working groups.

Group 1 (Defining surveillance indicators and data needed for risk assessment by EuFMD Member Nations) concluded that the use (with care) of indicators and metrics is needed, event-based surveillance systems might be useful, the importance of integrating laboratory and epidemiological expertise, wildlife surveillance and a database with information on movements / trade could be useful, and the need to adapt the Quarterly FAST disease report.

Group 2 (Assessing diagnostic capacity of EuFMD Member Nations during crises) identified the most important crisis-response indicators for labs (personnel, laboratory supplies, equipment/space, laboratory operation,

national and international networks), and discussed the applicability of a reagent bank, and improvement of laboratory preparedness.

Group 3 (Integrated disease surveillance and control) discussed syndromic and slaughterhouse surveillance, the integration of serological surveillance for multiple diseases, the use of milk for surveillance, entomological surveillance, proficiency testing and co-vaccination.

Each group identified gaps and research priorities, and overall conclusions were drawn.

Discussion

Mr. Rosso thanked the committee for their guidance and support and he underlined overall appreciation for their availability and quick responses.

Conclusion

The terms of reference and composition of SCSAR for the second biennium were endorsed.

Special Committee for Biorisk Management (SCBRM)

Presenter: Kirsten Tjørnehøj, Chairperson SCBRM (**Appendix 14**)

Key Messages

1. The committee has established three working groups on Minimum Biorisk Management Standards (MBRMS), training in biorisk management and accepted inactivation/disinfection methods.
2. Some changes to the MBRMS proposed by MN have been accepted with minor adjustments, with main issues to be discussed at an in-person meetings.
3. A summary of inactivation/disinfection methods from the MBRMS and practices of SCBRM members has been drafted, and the future needs identified.
4. A comprehensive learning matrix has been developed.
5. The committee is working with the STC on a joint opinion on shipment of inactivated FMDV in LFDs.

Summary

Ms. Tjørnehøj introduced the committee of nine members from Denmark, Italy, the Netherlands, Spain, United Kingdom, Germany, Ireland, Switzerland and Sweden. The committee has held three on-line meetings in the first biennium. Three working groups have been established: on the revision of the EuFMD Minimum Biorisk Management Standards (MBRMS) (chaired by M. Eschbaumer), training in biorisk management (chaired by R. O'Neill) and the Annex/database of accepted inactivation/disinfection methods (chaired by G. Harkess).

Continued development of the EuFMD Minimum Biorisk Management Standards (MBRMS), including Tiers A and B (Coordinator Michael Eschbaumer)

The list of comments from the 2019 revision of Tiers C and D was evaluated, and some changes proposed. The proposed document has been accepted by Member Nations (MN) and the OIE, and minor adjustments from the EU (DG SANTE) have been implemented.

There is still an outstanding list of more principal issues raised by the MN in both 2019 and 2021, which require more in-depth discussion and will necessitate a SCBRM in-person meeting to resolve. These include a re-evaluation of the risk associated with full-length FMDV RNA, a framework for the evaluation, adoption and dissemination of alternative virus inactivation procedures, the resolution of outstanding issues related to the concept of routine exclusion testing for FMDV in free areas, and a general reassessment of permitted Tier C activities and the Tier C/D division.

With regard to the drafting of standards for Tiers A and B, the SCBRM has requested the participation of biosafety representatives from endemic countries in the European region.

The SCBRM proposes new members Can Çokçalışkan, Turkey, and Sharon Karnieli, Israel. Stephan Karlen, Switzerland, will leave IVI and will be replaced by his successor.

Training in biorisk management (Coordinator Ronan O'Neill)

On-line training modules to support the EuFMD MBRMS should make it more accessible, and could focus target audiences on highly relevant sub-sections and will enable the basic text to be supported with more modern audio-visual explanation.

A comprehensive learning matrix has been developed, with content and intended learning outcomes defined over 14 modules, complementing the basic structure of the Biorisk standards. This is intended to guide the production of a set of professional digital materials which will co-host the strong messages found within the MBRMS itself, opening up that information and guidance to the widest possible FMD diagnostic and research communities.

Annex/database of accepted inactivation/disinfection methods (Coordinator Graeme Harkess)

The SCBRM has undertaken a review of existing information relating to FMDV inactivation/disinfection within the MBRMS and drafted a summary of this together with current practices collated from members of FMDV facilities. The group will now look at the evidence base for these protocols. The next steps have been discussed, including:

- defining what the SCBRM would see as sufficient validation of data for a protocol to be added to a central "accepted methods" database;

- how approval of submissions of new protocols to this database would work;

- how this database would be maintained and made available to facilities.

This annex should provide a database of current methods, as well as serve as a framework to allow for the formal assessment of novel methods of inactivation/disinfection. In addition to which, the SCBRM and the STC have discussed the shipment of FMDV in the form of inactivated LFDs.

The SCBRM and STC are working on a joint opinion on shipment of inactivated FMDV in LFDs. Based on data produced by ANSES (Romney et al., 2018), the committee has determined that FMD virus on the tested LFD is fully inactivated after minimum 15 minutes submerged in 0.2% citric acid. This means that with regard to FMDV, the inactivated LFDs fall under the exception in IATA Dangerous Goods Regulations (section 3.6.2.2.3.3). However the committee considered that these should not be sent in normal mail, and are considering additional conditions for shipment. Furthermore, the tested LFD is currently not available, and other LFD designs would need to be evaluated individually.

During the second biennium, work will continue on the ddevelopment of Tiers A and B, and outstanding issues raised by MN in 2019 and 2021 will be discussed at an in-person meeting. Support will be provided for the development of biorisk management training modules, the first version of the annex/database of accepted inactivation/disinfection methods will be finalized. The SCBRM and STC will finalize a joint opinion on the transportation of inactivated FMDV on LFDs.

Discussion

Mr. Füessel (European Commission) reminded EU Member Nations that the FMD Directive 2003/85/EC had been repealed and replaced by Regulation 2016/429 which obliges laboratories handling disease agents to follow relevant international standards and take appropriate measures to prevent the escape of these agents. He thanked the committee for its work. He stated that there was no legal obstacle to the adoption of the EuFMD standards or to the adherence to them. In future, parts of these could be translated into EU standards. However, this is not a priority, as the standards in Member Nations are known to be good. He saw no reason for MN not to support the adoption of the EuFMD MBRMS.

Mr. Sumption applauded the chairs of each of the committees for their work. He stressed the importance of biorisk standards for everyone and noted this is very detailed work and needs a lot of care and attention.

Conclusion

The committee will continue its work on revision of the MBRMS, training in biorisk management and the development of an Annex/database of accepted inactivation/disinfection methods. The SCBRM and STC will finalize a joint opinion on the transportation of inactivated FMDV on LFDs.

The EuFMD should reflect on the cost, partnerships and extent of the training on biorisk management and how this would be managed.

The committee proposal to the inclusion of two additional members from FMD endemic countries (Turkey and Israel) for its membership has been endorsed.

Proposal for the Establishment of a Standing Committee on Pre-Qualification of Vaccines against FAST diseases (SCPQv)

Presenter: David Mackay, EuFMD (**Appendix 15**)

Key Messages

1. The creation of a Standing Committee for Pre-Qualification of Vaccines (SCPQv) is proposed to oversee the operation of the prequalification system for vaccines against FAST animal diseases.
2. The Terms of Reference for the SCPQv and profile of members are proposed for endorsement
3. The committee will act as the decision-making body for the PQv procedure; decisions made by the committee will be enacted through the EuFMD Secretariat.
4. The committee will operate according to the rules for standing committees of EuFMD; in line with which the committee will nominate its own Chairperson. The committee will act by consensus and no voting is foreseen.

Summary

The creation of a Standing Committee for Pre-Qualification of Vaccines (SCPQv) is proposed to oversee the operation of the prequalification system for vaccines against FAST animal diseases, with the terms of reference indicated hereafter.

The committee will be required to come into operation in the third and fourth quarter of 2021 as the PQv project moves from the inception phase (2021) to the implementation (2022) and operational (2022 on) phases;

The following steps are therefore proposed:

- The establishment of the SCPQv, initially on an *ad interim* basis; The definition of membership profiles; That EuFMD will liaise with partner organizations (OIE, WHO, regulatory agencies) and Member countries to identify suitable experts that meet the profiles proposed; A proportion of the experts are recruited following a call for expression of interest from suitably qualified individuals; The composition of SCPQv is formally proposed at the next session for endorsement.

The **terms of reference** for the SCPQv have been proposed as follows:

- To adopt formally the guidance and documentation relating to the technical requirements and procedures applicable for operation of the PQv procedure. The technical standards applied for PQv will be those described in the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organisation for Animal Health (OIE);
- Review, and where appropriate formally approve, reports and recommendations from expert evaluation teams for inclusion of products onto the list of pre-qualified vaccines (the 'PQv list');
- Raise general or specific concerns and issues related to inclusion or exclusion of vaccines on the PQv list;
- Provide advice on request on topics referred by the EuFMD secretariat or expert evaluation teams;
- Act as an arbitration body in situations where expert evaluation teams are unable to reach a decision on listing or where manufacturers request an appeal in line with agreed procedures;
- Act as the coordination body between the nominating organizations represented on SCPQv on topics related to the quality of FAST vaccines and, where relevant, on wider issues of vaccine security;

- Discuss, and where appropriate consult, with other stakeholders, particularly the animal health industry, to ensure their full engagement with the process of PQ and with related issues of vaccine security.

The general skills and knowledge required include

- Experts should be at a senior level and have broad experience (a minimum of five years) in one or more of the following areas with respect to veterinary vaccines: Research and development; Manufacture under the principles of Good Manufacturing Practice (GMP); Registration (also termed licensing or marketing authorization); Monitoring and quality control Use of veterinary vaccines in a variety of settings. In the first phase of operation, experience with respect to FMD vaccines would be an advantage

Members and observers will be identified among Member Nations and partner organizations, according to the profile indicated above. A call for expressions of interest will be launched for individual experts with the general skills and knowledge required as indicated above. In addition, the following profiles will be considered as relevant for the composition of the committee: 1. Expert in the application of the principles of Good Manufacturing Practice for facilities manufacturing veterinary vaccines, particularly vaccines against FAST diseases; 2. Expert from a National Regulatory Authority in a region where FMD is endemic; 3. Expert from a country in which FAST disease vaccines are used routinely with knowledge of the particular requirements for their use in low to middle income countries (LMIC).

The committee will act as the decision-making body for the PQv procedure; decisions made by the committee will be enacted through the EuFMD Secretariat.

Meetings and operations of the SCPQv will be supported by the EUFMD Secretariat.

The committee will operate according to the rules for standing committees of EuFMD; in line with which the committee will nominate its own Chairperson.

Scheduled meetings will be held at least twice per year; one physical meeting (when possible) and one virtual.

Additional, ad hoc, meetings may be convened as required either physically or virtually.

The committee will act by consensus and is not a voting committee.

The committee may invite additional experts to meetings as observers or to provide specialist advice, subject to the agreement of the Chairperson.

The committee will consult with affected stakeholders in an open and transparent manner before adopting documents that will affect them (e.g. on technical requirements and procedures relating to PQv);

Documents adopted by the committee related to the PQv procedure will be published on the EuFMD website.

All information supplied to the committee by applicants in relation to specific PQv applications will be treated as commercially confidential information (CCI) and managed accordingly.

The secretariat, Members, observers and invited experts will operate according to an agreed code of conduct to ensure that CCI is respected.

Procedures will be put in place to ensure that members do not have conflicts of interest (COI) in relation to decisions on applications for PQv in which they are involved. Where a potential for COI is identified, the procedures will ensure that any risk arising is managed appropriately.

Discussion

Martin Blake thanked David Mackay for the presentation and reminded the attendees that the work conducted by David Mackay has been ongoing for some years and that and this would be a next stage of the process, with a standing committee to oversee the process and the involvement of governments.
Richard Irvine (UK) Thanked David and all the colleagues who worked on this project and asked, with regards to governance, how conflicts of interest would be managed. Emphasis was made on the need for a robust system in place to ensure that conflict of interest is clearly managed.

Conclusion

The General Session endorsed the creation of the Standing Committee on Pre-Qualification of Vaccines (SCPQv), initially on an *ad interim* basis.

The profile for Members and Observers to be invited to join the committee and the profile for additional experts to be appointed following a call for expressions of interest has been endorsed.

The step-wise, iterative approach to the creation and operation of SCPQv has been also endorsed.

Revision of the Constitution

Report

Martin Blake reminded participants that at the 43rd General Session in April 2019, Member Nations agreed to extend the scope of the EuFMD workplan to leverage the scope of preparedness and risk reduction activities developed for FMD to other similar TADs, which pose an immediate threat to Member Nations. Ahead of the 43rd General Session, FAO legal services had advised the policy changes on the work programme shall precede any efforts to deal with amendments on the Constitution. Following the amended work programme, the Executive Committee followed on from this change of policy, and initiated a review process of the Constitution (**Appendix 16**). Two issues were also considered: (i) the updating of rules of procedures with some amendments previously approved by Members Nations but not yet endorsed by the FAO (due to conflict with the RoP of the Organization e.g. the possibility for virtual attendance to meetings), and (ii) a recommendation from the 42nd GS regarding associate membership or additional membership of the Commission. A consultation process was launched in April 2021 on the draft amended text of Constitution proposed by the Executive Committee to the EuFMD Member Nations. After the 44th GS, there will be one month for the EuFMD Member Nations to provide written comments/suggestions on the proposed amendments. Then, the Constitution will be further revised and a legal process launched with FAO legal services. Fabrizio Rosso informed that the Secretariat assisted the Executive Committee in verifying the current proposed amendments with the FAO legal services. An in-presence EuFMD session is foreseen in autumn 2021 to finalize the update of the Constitution, and up to this meeting, additional comments or suggestion on the Constitution from the EuFMD Member Nations will be taken into account.

Fabrizio Rosso went through the proposed amendments to the Constitution as follows.

In the **PREAMBLE**, the proposed amendments explained the rationale of expanding the preparedness and risk-reduction actions of the Commissions to similar TADs (so-called FAST diseases), without affecting its core objective to promote national and international actions with respect to preventive and control measures against FMD. The amended text also states that the similar TADs are identified regularly according to the threat that they pose to territories of the Member Nations, and the criteria of selection and prioritization of similar TADs are indicated in Article IV.

ARTICLE I: there are no major changes proposed with the exception of the name of the OIE. At the 43rd GS, Member Nations recommended the Executive Committee to consider the benefit of EuFMD to review the Constitution, and include in the Constitution the benefits and conditions for associate or additional membership. Such amendment is not yet included in the proposed text, but considerations shall be made on opportunities to include other non-European Members such as the European neighboring countries in the membership of the Commission, and the possible benefits connected to the reduction of risk to Europe. Indeed, EuFMD Member Nations are bound to respect obligations regarding national policies and international cooperation for the control of FMD and with the proposed amendments of the Constitution, now bound to respect obligations with regards to other TADs similar to FMD. Therefore, expanding the membership to European neighboring countries would possibly improve control in the European neighborhood, reduce the risk to Europe and strengthen the support provided to GF-TADs partners in the European Union neighboring countries and regions, as part of the mandate of the Commission. The regional focus of the Commission would not be altered as its function and name would continue to refer to Europe, and membership could be extended to countries with geographical (sea or land) borders with Europe.

ARTICLE II: the obligations of Member Nations regarding national policies and international cooperation for the control of FMD are proposed to be applied also for the control of similar TADs, in line with the policy changes of

the work programme, the HOLD FAST Strategy and the extended mandate of the Commission. The extended obligations of the Member Nations to similar TADs are related to (i) availability of contingency plan, (ii) availability of arrangements for the typing of viruses from outbreaks, (iii) availability of arrangements for rapid dispatch of isolates to OIE/FAO Reference Laboratories and (iv) provision of immediate information to EuFMD on any outbreak detected. An additional obligation (point 7) is proposed to ensure that national laboratories for FMD operates as a minimum in accordance with the minimum biorisk management standards as adopted by the Commission at its regular Session.

ARTICLE IV: the proposed amendments reflect the extended mandate of the Commission, the Commission therefore expanding its General Functions to similar TADs (points 1 to 10). An additional point (point 11.) would ensure that maintaining the focus on FMD, with the extended General Functions to cover other TADs implemented according to priorities agreed at each General Session, and with considerations of the budget available. In other terms, this additional point would ensure that priority TADs similar to FMD are consistently defined at each Session. Elements of similarity to FMD and criteria for prioritization of diseases are proposed. These would allow more flexibility to the Commission to adapt the programme every two years but would also guarantee the continuity of actions in-between Sessions. The diseases defined at each Session, and included in the preparedness and risk reduction activities of the Commission, shall not imply any additional financial obligation to Member Nations.

ARTICLE V (Special Functions of the Commission): no amendments are proposed but it is implied that Special Functions of the Commission are also extended to prioritize TADs similar to FMD (points 2.1 to 2.4).

ARTICLE IX: a clarification was made on the term Associate Member, which refers to Associate Member of the FAO.

ARTICLE XVI: a typo in the text was fixed.

RULES OF PROCEDURES

RULE II: consider, in the agenda of each Session of the Commission, the need to update the prioritization of TADs similar to FMD to be targeted in the preparedness and risk reduction actions.

RULE VI: amendments are proposed to ensure clarity on the power and duties of the Chairperson and the Vice-Chairperson, and ensure consistency with the RULE V, by better defining the role of the Vice-Chairperson in the absence of the Chairperson during the Session.

RULE VII: the proposed amendments indicated that the Executive Committee meeting will be held in private unless otherwise determined by the Executive Committee (and no longer the Commission); this amendment to ensure that the Executive Committee meetings are open to observers when appropriate, upon decision of the Executive Committee itself, ensuring easier process and keeping the decision at the level of the Executive Committee guiding the activities of the Commission. The amendment, previously discussed by the Member Nations, on the possibility for virtual attendance is pending FAO legal services' position (expected in 2021).

RULE XIV: the proposed amendment consider the opportunity to include the gender balance criteria in the election of the officers of the Executive Committee. This criteria is added to that on geographical representation of the Members (included in ARTICLE X) and the latter criteria remains the priority one. FAO legal services has advised to include gender balance criteria in Rules of procedures rather than in the Constitution (Art X).

Discussion

ARTICLE I:

Alf Füessel (EC) asked which differences are foreseen between statutory members and associate members for the activities to be supported by the Commission (e.g. real time training). He also wondered if, with wider memberships, there would be mechanisms to ensure timely payment of dues. Martin Blake assured that both aspects would have to be considered more in-depth. Fabrizio Rosso reminded participants that the Executive Committee should also consider about the benefits of having new members to join the Commission. Almansa de Lara Valentin (Spain) supported Dr Füessel's comment.

Article IV:

Alf Füessel encouraged taking the experience of the Animal Health Law into account for the Constitution, in which a clear list of diseases is drawn, and later supplemented by tight criteria to review a provisional list of additional diseases, depending on the situation. Representatives of Turkey agreed. Almansa de Lara Valentin, representative of Spain, although acknowledging that there are advantages and drawbacks for both options (criteria *versus* a list of diseases), would advise to start with a list of diseases.

Lena Hellqvist Björnerot, representative of Sweden, also acknowledged the comments given by Alf Füessel. A list of agreed diseases based on specified criteria could be a good idea as a framework. However, also flexibility and regular prioritization at each general session between the listed diseases - based on the disease situation at the time and a risk analysis - is needed. Such a procedure would give transparency and set the frames, but also provide flexibility and outline the priorities for the respective two-year periods. At all times, FMD must remain the top priority.

Fabrizio Rosso brought to the attention of Member Nations that the amendment of the Constitution is a long process. If the decision is made to include a list of disease in the Constitution and such list need to be revised, amendments of the Constitution might bring significant delays.

Hendrik-Jan Roest (NL) agreed that in the context of a Constitution, guidelines (i.e. elements of similarity and criteria for prioritization) might be more appropriate than a list of diseases. Fabrizio Rosso proposed to investigate again with FAO legal services to have an Article that would refer to a list of diseases to be included in the Rules of procedures (the latter being easier to amend).

Richard Irvine (UK) acknowledged the merit in there being provision for flexibility to new disease threat that may emerge; however, he suggests having a fixed list of diseases that may not be necessarily subject to change *versus* a flexible list of diseases. Martin Blake ensured that the Executive Committee would give significant consideration to this matter following the meeting.

The discussion also allowed to highlight that one element of similarity to FMD included in the proposed amendments, the 'transmission pathway and risk factors', is non-applicable to vector-borne diseases such as RVF

The rest of the amendments were not commented at the session.

Conclusion

The Secretariat will collect the written comments to the proposed amended text of the Constitution and Rules of procedure. The comments provided will be verified with the Legal service of FAO.

A special session of the Commission will be convened in presence to cover this specific item following procedures indicated in Art XIV of the Constitution.

Updated minimum standards for laboratory containment of FMDV[3]

Key Messages

1. The Minimum Standards for Laboratory containment are of outmost importance for FMD freedom in Europe.
2. The last revision process (2020-2021) was delayed by the CoViD-19 pandemic and the updated version have mostly minor editorial changes.
3. There is a list of outstanding issues of which some require in-depth risk analysis; these will be discussed at in-person meetings of the Special Committee on Biorisk Management during the next biennium.
4. Development of the Tier A and Tier B parts of the standard, for FMD laboratories in endemic countries, is a significant task that needs to be prioritized.

Summary

KirstenTjørnehøj presented a summary of the work done on revision and development of the EuFMD Minimum Biorisk Management Standards (MBRMS) (**Appendix 17**). The revision process was carried out by the working group coordinated by Michael Eschbaumer.

Europe is a wide FMD-free area and countries have agreed and accepted to have a number of high-containment facilities where live FMD virus is kept and propagated for research purposes. These facilities ensure physical and procedural control by adhering to the EuFMD MBRMS, a core document of for FMD freedom in Europe.

The revision goals in the last biennium were to finalize the comments from 2018 and 2019. However, the working group of the SCBRM was not able to meet in-person due to the pandemic and decided to pursue the more readily-accessible changes and postpone the evaluation of principal matters for 2021. Tiers A and B of the MBRSM have not been developed during the last biennium and the working group noted this would require participation of biorisk professionals from FMD endemic countries. The revision process was implemented through a series of online meetings. The revised document was circulated in March 2021 to Member Nations, EC and OIE. Minor changes suggested by the EC were implemented and the final version presented at this 44th General Session. The changes that were done during the revision process were not significant and covered editorial amendments, added reference to the new EU Animal Health Law and rephrased reference to the 2007 FMD release in UK. Dr Tjørnehøj also pointed out to some of the more significant changes, which relate to requirements regarding effluent (specific requirement59), the example of a risk rating system (Annex I, Chapter I) and the threat assessment (Annex I, Chapter III).

The list of issues that SCBRM plan to address during the next MBRMS revision was presented. Notable issues include drafting the Tiers A and B, development of acceptance criteria for alternative procedures, drafting number of minor recommendations and chapter on operational hazards from forces of nature. In addition, the remaining issues from 2019 will be addressed and these relate to: restrictions on inactivated non-FMDV samples which originate from FMD containment, the risk associated with the full-length FMDV RNA, provision of clear definition for “routine exclusion testing”, risks from the homogenization of non-inactivated samples prior to carrying out antigen ELISAs and LFD tests in Tier C laboratories, and the risk from the accidental propagation of

[3] Presented for adoption

FMDV in Tier C laboratories. The next revision will also address some of the major issues identified during the 2021 revision. Notable issues here are consideration of the level of technical details desirable for specific technical proposals from the MBRMS, edition of Tier C to clearly differentiate between what applies to Tier C laboratories from Category I, Category II or both categories, and possibility of dividing the Tier D laboratories into two categories.

Ms. Tjørnehøj ended her presentation by stressing once again that the MBRMS are crucial for handling the risks in the high-containment facilities.

Conclusions

SCBRM will need support from biorisk professionals coming from the FMD endemic countries to draft Tier A and Tier B parts of the minimum standards, which are applicable to FMD laboratories in the endemic countries.

A list of issues, of which some require in-depth risk analysis, political consideration and/or scientific assessment, has been identified by the SCBRM; these issues are planned to be addressed with the next revision.

All EuFMD MNs should ensure that their national FMD laboratories operate in full compliance with the minimum biorisk management standards.

The updated standards for laboratory containment of FMD are adopted by the General Session.

Financial report, budget and membership contributions biennium 2022-2023

Presenter: Cecile Carraz, EuFMD

Key Messages:

1. Following endorsement at 43rd General Session to index the biennial budget contributions of Member Nations, for each category level of contributions to a standard measure of inflation, applying the mid-point between the CPI consumer price index (CPI) for the Eurozone countries and that of the European countries, as recorded by the Organisation for Economic Cooperation and Development (OECD). Using the OECD data for the CPI change in the two-year period of the previous two full calendar years before each Session, thus 2019-2020 for the 44th General Session in April 2021.

2. Contributions MNs for the biennium 2022-2023 on the basis of the mid-point CPI (Eurozone and EU28_2019 &EU27_2020) of 2% for the two full calendar years (2019-2020). (**Appendix 18** table 1).

3. Review of the ranking and categories in which countries are placed for contribution, was to occur during the 44th General Session, considering the uncertainty to hold the General Session in physical settings, it is proposed to postpone the review at the next Session in presence.

4. The proposed budget for Biennium 2022-2023 of the Administrative Fund based on the proposed total annual contributions of US$ 656,600 (**Appendix 18** table 2).

5. The proposed budget for Biennium 2022-2023 of the EuFMD Emergency & Training Fund as indicated in **Appendix 18** table 3**.**

Summary

Administrative Fund MTF/INT/011/MUL

The Secretariat manages five Trust Funds, for the Administration (MTF/INT/011/MUL, contributions from the EuFMD Member Nations), the EU Funded Activities Program (GCP/GLO/026/EC-2019-2023 Phase V), two Emergency and Training Funds into which additional voluntary contributions have been received for provision of Virtual & real time trainings. (MTF/INT/004/MUL/CHILD) which includes Ireland, France Contributions, (MTF/INT/004/MUL/Baby01AUS/NZ), and two Contribution Agreements for learning activities, (MTF/GLO/016/TEX-F Texas A&M University) and for Competency-based training of veterinary paraprofessionals (VPPs) (MTF /INT/610/BMG).

In fulfilment of the commitment made by Member Nations (MN) on entry into membership, the MN must support the Secretariat through an annual contribution, the amount of which is agreed at the General Sessions of the Commission.

Each General Session must include in its Agenda to consider the financial position, review the Budget for expenditure for the coming biennium and agree upon the scale of contributions needed to support the administration of the programme.

The 43rd General Session agreed the overall budget of Fund based on the proposed total annual contributions including the mid-point inflation rate CPI (Eurozone and EU28) of 4.5% for the four full calendar years from 2015-2018 of US$ 643,725 for Biennium 2020 and 2021. For subsequent sessions, the proposals are based upon the change in the CPI, for the previous full two-year period (thus 2019 and 2020, at the 44th General Session).

Review of the current scale of contributions adopted at the 41st General Session in 2015, with five categories, based on a formula for classification agreed by the Commission in 1997, which used two equal criteria, a) the FAO contribution and b) livestock population (formula – 1 for cattle, 0.5 for pigs, 0.2 for sheep and goats) was planned to be implemented during the 44th General Session in 2021.

Applying the policy endorsed at the 43rdGeneral Session in April 2019 for biennium increase in contributions, based upon the change in the Consumer Price Index (CPI), for the previous full two-year preceding the session.

The increase in contributions for 2022-2023 based on a mid-way point between Eurozone EU28_2019 & EU27_2020) with an index of 105.5, represents a 2% rise over the past two years (2019-2020). Contributions proposal for 2022-2023 for each EuFMD Member Nations for a total annual contributions of US$ 656,600**.**

Appendix 18, Item 11 – Tables 1 and 2

Review of the ranking and categories in which countries are placed for contribution, was to occur during the 44th General Session, considering the uncertainty to hold the General Session in physical settings, it is proposed to postpone the review at the next Session in presence.

In addition to the Administrative Fund, the Commission manages additional Trust Funds through which funds have been received from MN and others, and disbursed for activities which are agreed with the Commission at its General Sessions and/or Executive Committee meetings. The MTF/INT/004/MUL Fund started in the first years of the Commission and in particular was important in the management of contributions for the fight against FMD in Thrace, before a specific fund was established with the EC to relieve the burden on the EC/EU members.

From 2012, contributions to cover the costs of additional training activities and operational support for Virtual Learning delivery requested by FAO Reg. Offices, Member Nations and others, have been received and disbursed through MTF/INT/004/MUL. Use of funds is reported in table 3 **appendix 18**, together with a projection of the committed and predicted contributions up to 2023 and the outgoing expenditure expected.

Conclusions

The President thanked for the presentation and considering there were no comments from the floor, he considered that the proposals for the postponement of the review of countries' ranking at the next Session in presence, for EuFMD Trust Funds Contributions and Budget for Biennium 2022-2023, as shown within item 11 (**Appendix 18**) in the circulated documentation to be approved by the Session.

With the support of European Commission

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