The 14th Annual Meeting of the OIE/FAO FMD Reference Laboratory Network

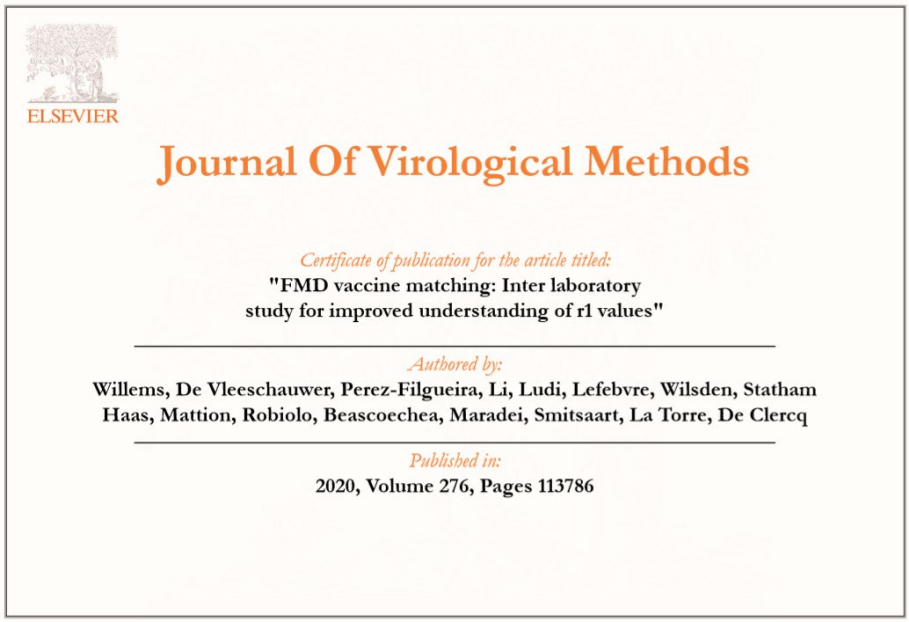
Hosted by: Animal and Plant Quarantine Agency (APQA), Republic of Korea

NETWORK MANAGEMENT SESSION

3rd December 2019

Recent achievements of the OIE/FAO Foot-and-Mouth Disease Reference Laboratory Network

- **Publication of the 2018 Annual Network Report summarising the global situation regarding the distribution of FMD in different regions of the world**
- **Real-time data exchange between partners to monitor the spread of emerging FMD virus lineages in North Africa, South Africa, West Eurasia, Southeast and East Asia**
- **News story: Recent acceptance of peer-reviewed publication describing a "FMD vaccine matching: Inter laboratory study for improved understanding of r1 values" in *Journal of Virological Methods* organised by the Network**


ELSEVIER

Journal Of Virological Methods

Certificate of publication for the article titled:

"FMD vaccine matching: Inter laboratory study for improved understanding of r1 values"

Authored by:

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Attendance:

Delegates from ten OIE and FAO laboratories attended the Network management meeting: IZSLER (Santina Grazioli, Giulia Pezzoni), Sciensano (David Lefebvre, Kris De Clercq), ANSES (Labib Bakkali Kassimi), RRL-SEA (Wilai Linchongsubongkoch, Rompruke Udon, Sahawatchara Ungvanijban), LVRI (Jijun He, Jianhong Guo), APQA (Jong-hyeon Park, Bok Kyun Ku), FBGI-ARRIAH (Svetlana Fomina), PANAFTOSA (Edviges Maristela Pituco), NCFAD (Charles Nfon) and WRLFMD (Anna Ludi, Don King). Representatives from OIE (Min Kyung Park), FAO (Samia Metwally) and AU-PANVAC (Nick Nwankpa) were also present. Apologies were provided from: OVI (Francois Maree), BVI (George Matlho [attended Day 2-3]), SENASA (Andrea Pedemonte), USDA-APHIS (Consuelo Carrillo), PD-FMD India (Professor RK Singh).

The meeting was opened with a welcome address from Commissioner Dr Bong Kyun Park. The delegates expressed thanks to the meeting hosts, APQA, and to the OIE, FAO and EuFMD for supporting the meeting. A vote of thanks was also given to Sarah Belgrave and Julie Maryan at WRLFMD for assistance with the meeting logistics. Sponsorship for the meeting was obtained from Careside Co. Ltd., Pharos Vaccine Inc., Dong Bang Co., and Boehringer Ingelheim.

Opening and review of the Network (Don King)

This presentation briefly reviewed the history and work of the Network emphasising the benefits of data-sharing to understand the epidemiology of FMD (such as the continued spread of the O/ME-SA/Ind-2001 and O/EA-3 lineages). Recent data from the Network also highlights epidemiological gaps which motivates the development of improved methods for FMD virus and sequence recovery from poor-quality samples submissions. The OIE/FAO FMD annual reference laboratory report for 2018 is now published on the website (www.foot-and-mouth.org) and all network laboratories (except for India), have received a final printed version of the Network MoU (thanks to Min Park at OIE for organising the printing of this document).

Discussion – Has there been an increase in submission of samples since 2013?

Yes, in general the numbers of sample submissions are increasing. The WRL has seen an increase of about 10% in the last two years (approximately 500 samples per year). Biggest hurdle is the logistical cost and paperwork to ship and get samples from the field to OIE/FAO reference laboratories. LFDs are being distributed (via EuFMD-funded projects) for the collection of samples. The FAO has funding in 2020 for two years to support collection of samples in 11 countries; work which will be led through Nigeria and Senegal.

Discussion – do the endemic pools require updating?

The pool concept is an established system that describes seven epidemiological ecosystems that maintain specific FMD virus lineages. However, recent work from the Network has documented a number of long-distance trans-pool movements (particularly in North Africa, South East and East Asia). These events and the fact that the "stylistic ovals" do not always accurately reflect that situation in countries and priorities for regional roadmap meetings, indicate a possible need to represent the pools differently. These points were discussed by the group. Document in Appendix 1 has been drafted in an attempt to highlight connectivity between countries.

ACTION C1-19 (ALL): Please review Appendix 1 and return any comments or suggestions for improvement to Don King. Ahead of next year's meeting, WRLFMD will prepare a table (for discussion) which lists the countries present in each of the endemic pools.

Progress on actions from previous meetings (Open ACTIONS in white boxes) – Anna Ludi

Action number	Owner(s)	Description and review
C4-17	David Lefebvre, Labib Bakkali Kassimi, Andrea Pedemonte, Consuelo Carrillo and Charles Nfon	To establish a working group to coordinate the review of the FMD chapter of the OIE Terrestrial Manual. Update: Open but no imminent update in the OIE Manual is planned for 2020
C5-17	Kasia Bankowska	Investigate the potential of adding the Nomenclature Working Group web address to the GFRA and EuFMD websites.
C6-17	WRLFMD	WRLFMD to provide email updates on the progress of FMDV Tools and implementation of new functionality (CLOSED)
C7-17	ALL	Feedback on PRAGMATIST tool (CLOSED)
O1-17	WRLFMD/ALL	Compile a list of dangerous good couriers that could be used for shipments of FMDV samples – (CLOSED, information now available on the website)

O2-17	ANSES, NCFAD and WRLFMD	Review data from samples that generated inconsistent NSP results and report back to the Network with these findings. – ONGOING A short publication on the NSP harmonisation exercise is in draft and awaiting feedback from all collaborators. NCFAD should also be included in these conversations.
C1-18	WRLFMD	The following details need to be updated on the OIE/FAO network website: ANSES, France is now an FAO and an OIE laboratory, QIA, Republic of Korea has been renamed to APQA, CODA-CERVA, Belgium has been renamed to Sciensano – CLOSED, updates have been made
C2-18	Min Kyung Park and Don King	Investigate whether a short article for the OIE bulletin can be published– CLOSED, OIE bulletin for the 13th Annual OIE/FAO Network Meeting was published.
C3-18	WRLFMD	All members will receive the final copy of the MoU (with all signatures) – CLOSED, all laboratory have received this except for the Indian laboratory (this is because of management changes in their laboratory).
C4-18	Min Kyung Park	Send out the report on the transport of biological samples to all partners – CLOSED
C5-18	WRLFMD/ALL	WRLFMD (and other partners) to consider whether a review article should be written to collate historical information on serotype C and to recommend the process to formally remove this serotype from FMD viruses circulating in endemic countries – ONGOING: A manuscript has been drafted by David Paton and will be submitted for publication in 2020.
C6-18 (see C4-17)	ALL	Working Group to prepare recommendations for appropriate modifications to the sections in the OIE Manual that describe vaccine-matching methods – including any relevant comments from the GFRA meeting held in 2017 – ONGOING - There are no OIE manual updates planned for the next six months. This action will remain ongoing as work is still being carried out by Network members to determine the best course of action
C7-18	Min Kyung Park	Send out Q&A document once it is available (link to the "living" document sent in email). – CLOSED, this has been distributed
C8-18	WRLFMD	Links from Nomenclature Working Group page need to be made available on other websites. CLOSED, the link is now available on other websites
C9-18	Nomenclature Working Group	Working Group to finalise (and publish) new SAT topotype nomenclature Kasia Bankowska has left the Institute and therefor this group needs a new secretariat to move key points forward (see action C2-19)
C10-18:	Labib Bakkali Kassimi	Working Group to prepare a questionnaire will be send out to help standardise sample nomenclature (lab coding maybe included) - ONGOING
C11-18	WRLFMD	Recommended country codes (currently adopted by WRLFMD) will be placed on the Network and WRLFMD websites – CLOSED, the country codes are now available

O1-18	ARS-FADDL	FADDL to investigate whether a summary of ARS data can be included in reports CLOSED; ARS data was included for the 2018 report and it is hoped that data from ARS will be included in future reports
O2-18 (see C1-19)	Don King	Don King to send around a draft figure of how viral pools are linked. ONGOING – figure attached to these minutes (see Appendix 1) with feedback requested for early 2020
O3-18	Anna Ludi	To draft a document containing the BVS currently available at The Pirbright Institute. Other institute including industry could then add to this list (large quantities would only be included). This could include a reference panel. - ONGOING
O4-18		Invite vaccine manufacturer from China to next year's meeting – CLOSED
O5-18	ALL	Delegates to provide feedback on a figure developed from ideas raised last year's Network meeting regarding who takes responsibility for Vaccine QA/QC. – CLOSED
C2-19	Min Kyung Park and Don King	Investigate whether a short article for the OIE bulletin can be published for 2020
C3-19	ALL	The Nomenclature Steering Group requires anew coordinator (since Kasia Bankowska left WRLFMD)– Please send any nominations to WRLFMD

Update from OIE (Min Kyung Park)

The OIE website now has a link to the Network. During 2019, there were seven country applications for OIE disease status recognition for FMD; six of these were for free status/endorsement.

- The Department of Pando in Bolivia is now FMD-free without vaccination.
- Botswana has one approved zone without vaccination.
- Kazakhstan has separation of the officially recognised free zones without vaccination (five FMD free zones from one).
- Suspension of FMD free status for Colombia (10/8/2018) and South Africa (2/1/2019), while Russia has recovered its FMDV free status on 20/5/2019.
- There was a mission in Thailand (March 2019) to assess the progress on Thailand's OIE endorsed official control programme for FMD.
- The OIE code chapter for FMD has not changed; however internal discussions regarding these chapters is ongoing.

Update from FAO (Samia Metwally)

- The FAO has PCP support officers (PSO) and if countries are interested in obtaining assistance they should email the FMD WG through an official letter from their CVO. The network for PSOs available is expanding to include areas such as: epidemiology, diagnostics, socioeconomic, economics, vaccine and vaccination. If anyone is interested in becoming a PSO please contact: FAO-FMD@fao.org and OIE-FMD@oie.int. The FAO is in need of people who speak French, Arabic and Russian.
- An FAO book "veterinary vaccines for livestock – principles and applications" has now been published.
- It is suggested that a link between the Epi Network and OIE/FAO Network is developed. One possibility is that the leaders from the Epi Network are invited to the Network meeting.

OIE Update – Kris DeClerq

Two points relating to proposed changes in the OIE Code were discussed. A containment zone can be established while outbreaks may continue to occur to minimise the impact on the entire country or zone. This has been accepted but is not included in the FMD chapter – instead these points are now found in a horizontal Chapter (4.4: Zoning and Compartmentalisation). Although not yet in this chapter, it is also anticipated that there will be new rules to cover the establishment of a temporary protection zone within a country (or zone free from FMD) if there is a potential risk of incursion.

Proficiency Testing Scheme

Within European and the European neighbourhood, there will be two schemes for 2020 – (i) for FMD free countries (run by the EU-RL) and (ii) for FMD endemic countries/global reference laboratories tailored to expected capacity/capability required for countries at different stages of the PCP (run by WRLFMD). The invitation letters from the WRLFMD will go out early 2020.

Level	VIROLOGY (Panel 1)		SEROLOGY (Panel 2)	
	Minimum test requirements	**Expected lab capability**	**Minimum test requirements**	**Expected lab capability**
PCP 0	-	n/a	NSP ELISA	Define infection history (FMDV+/-)
PCP 1	either AgELISA or RT-PCR	• FMD virus present • FMDV serotype	NSP ELISA	Define infection history (FMDV+/-)
PCP 2	either AgELISA or RT-PCR	• FMD virus present • FMDV serotype	NSP ELISA SP ELISA	• Define infectious status • vaccination status • serotype • +/- PVM
PCP 3 PCP 4+	AgELISA rRT-PCR +/- sequencing +/- VI*	• FMD virus present • FMDV serotype • topotype, lineage	NSP ELISA SP ELISA +/- VNT*	• Define infectious status • vaccination status • serotype • +/- PVM
OIE/FAO Reference Laboratories	Enhanced genome sequencing*	• FMD virus present • FMDV serotype • topotype, lineage, and relationship between FMDV positive samples in panel	NSP ELISA SP ELISA +/- VNT*	• Define infectious status • vaccination status • serotype • PVM • identify cross-reactivity

* If able to receive the infectious panel

ACTION C4-19 – Is there any feedback on the proposed capabilities required for each PCP pathway (see table above)?

FMDVToolbox – hosted by WRLFMD

Toolbox is live but there appears to be some problems in accessing it. Please contact WRLFMD if you have any difficulties.

The 14th OIE/FAO FMD Reference Laboratories Network Annual Meeting

OPEN SESSION

3rd – 5th of December 2019

Hosted by Animal and Plant Quarantine Agency (APQA), Republic of Korea

Additional attendees: Abraham Sangula (Embakasi, Kenya), Daniel Gizaw (NAHDIC, Ethiopia), Hussaini Ularumu (NVRI, Nigeria), Pelin Tuncer Gottuna (SAP, Turkey), Wilna Vosloo (AAHL, CSIRO, Australia),

Representation from meeting sponsors: Sunyoung Sunwoo, Young Kook You (Careside), Ickjae Kang, Yongjun Ahn (Dongbang), Jaehoon Edward Kim, Jeonggil Lee, Pascal Hudelet (Boehringer Ingelheim), Jungwook Jae, Sangbeom Moon (Pharos Vaccine)

Apologies received from – LNERV Senegal

DAY 1

Global Headlines 2019 – WRLFMD

During the first 3 months of 2019, more samples were sent to WRLFMD than are usually received in a year. Key headline events:

- As in past years, serotype O is the predominant serotype followed by serotype A.
- Further expansion of the O/ME-SA/Ind-2001e lineage during 2019 into Pakistan. These new outbreaks raise concern as it is the first time that this lineage has been detected in a West Eurasian country that has the potential for onward spread into countries such as Iran and Turkey.
- Continued outbreaks of O/EA-3 (2018/19) in North Africa (Libya and Morocco) following on from cases due to A/AFRICA/G-IV during 2017. There are now two distinct viral lineages

responsible for the cases detected in North West Africa (Maghreb) and North East Africa (Egypt). The shipment of these samples has been difficult and alternative methods have been used to characterise FMD viruses such as lineage specific rRT-PCR, and transfection methods for "live" virus recovery from RNA.

- Retrospective data confirms the presence of the SAT 1 lineage X in Cameroon in 2016.
- There has also been a new incursion of SAT 2/VII lineage into Egypt – most closely related to sequences from Ethiopia.
- New outbreaks of O/EA-2 in central Zambia and Comoros have been caused by two different lineages (15% nt difference). The Comoros lineage is most closely related to samples collected in Tanzania. The Zambia outbreaks appear to represent a southern movement of the virus.
- An outbreak of SAT 2 in South Africa has resulted in a suspension of FMD-free status

A new document has been prepared to define transboundary connectivity and show how FMD viruses move between pools (see Appendix 1). Please send any feedback or comments on this figure to WRLFMD.

The WRLFMD E-learning course is now available and it is anticipated that this will be run again in 2020 (with EuFMD). A project at WRLFMD is developing a databases for FMD sequences; once this is ready, input will be sought to understand how other Network laboratories will interact with it. Wilna Vosloo highlighted that CSIRO are also working on a system that will have capacity to recognize and interact with different databases - reinforcing the importance of ensuring that these systems are able to communicate with each other.

ACTION O1-19: Other reference laboratories that are not OIE/FAO may also need to sign a type of MoU so that can be shared more easily within the Network, specifically sequencing information. WRLFMD will investigate this further

Pool 1: South East Asia – RRLSEA (Pakchong) Thailand

During 2019, sample submissions (n=118) have been received from Thailand for FMDV detection, using multiplex rRT-PCR and FMDV GD. Serological analyses have detected positive results for serotypes Asia 1, O and A (reflecting annual vaccination with trivalent FMDV vaccines – O. A, Asia 1), while ELISA-typing and sequencing has detected only serotypes A and O with the most common viral lineages being O/ME-SA/PanAsia, O/ME-SA/Ind-2001e and A/ASIA/Sea-97. No serotype Asia 1 has been detected since 1998 in Thailand, although there was an outbreak of Asia 1 in 2017 in Myanmar. The next PTS supplied by RRL-SEA Pakchong will for the first time include an antigen panel for RT-PCR.

Pool 1: East Asia and China (LVRI, China)

Pro-active surveillance using RT-PCR and serological testing is still ongoing in China. During 2019, the serotypes and lineages identified by sequencing (both outbreak and surveillance) were: O/CATHAY, O/ME-SA/Ind-2001e (closely related to viruses in 2018), O/SEA/Mya-98, O/ME-SA/PanAsia (potential re-introduction), and A/ASIA/Sea-97 (possibly due to a new incursion). In 2019 the number of FMD outbreaks has decreased, potentially due to the incursion of ASF which has led to an increase in biosecurity and a decrease in the number of backyard animals.

A PGP study in pigs for both monovalent (serotype O) and bivalent (serotype A and O) vaccines against the O/CATHAY virus O/18074 shows promising results with protection of 100% and 81% respectively. PD_{50} studies have also been carried out using vaccine from nine manufacturers and a strain from the O/ME-SA/Ind-2001 lineage. All vaccines had a PD_{50} above 6. There is currently no international vaccine available in China, only locally produced are available.

Discussion – Surveillance samples (OP fluids) were collected from healthy animals in the field as well as slaughter houses. Questions were raised whether these events should be considered as "outbreaks" according to the OIE Code. The lack of clinical signs could be due to vaccination supressing the clinical presentation of FMD.

Discussion – Vaccines used in China: vaccine does not include O/CATHAY as it is not clear whether this virus is actively circulating in China or whether cases are due to regular virus incursions.

Pool 1: Korea and East Asia (APQA, Republic of Korea)

During January 2019, three FMD cases due to O/ME-SA/Ind-2001e in cattle were reported from the central part of South Korea. These outbreaks led to the culling of 2,272 heads of cattle on 29 farms. This virus is genetically similar to the strains detected in China (99.5%) and Malaysia (98.4 to 98.7%). There have now been twelve outbreaks since 2000 and since 2010 vaccination has been used from international companies for pigs (serotype O) and since 2015 cattle (serotype A and O). Currently, both serotype O and A vaccines are used in cattle and pigs. Plans are in place to carry out a national proficiency test and scientific/technical training courses for the region. Diagnostic kits are being supplied to Myanmar.

Discussion – The use of South America vaccine viruses has been robustly verified in both *in-vitro* and *in-vivo* tests.

Discussion – After an outbreak, if NSP positive animals are found, these animals are re-bled at 3 to 4 weeks later and NSP levels are monitored monthly. Probang testing is not carried out as environmental testing and re-testing of the animals takes place.

Pools 1 and 3 (FGBI-ARRIAH Russia)

Outbreaks due to serotype O have been reported in the regions of Primorsky, Khabarovsk, and Zabaikalsky Krais. VP1 sequencing of 41 samples has identified serotype O/SEA/Mya-98 in Primorsky and Zabaikalsky and O/ME-SA/Ind-2001e in Zabaikalsky. For confirmation of freedom over 20,000 samples were tested by LPBE and it is thought that the positive results are connected to residual antibodies after vaccination in these regions. Samples have also been collected from wild animals to prove freedom of disease; these were all negative. Each year there is movement of Saiga antelope from Mongolia to Russia; in 2018 the laboratory was able to sample these. Although no virus was detected the serum samples were positive for serotype O and NSP.

Vaccines suitable for the buffer zones include those from international vaccine companies; however, regional and state veterinarians and experts tailor which vaccines to use within the buffer zone. No proficiency testing scheme was carried out this year, but training programmes have been undertaken.

Pool 2: India (ICAR-DFMD, India)

No presentation was received.

Pool 3: Turkey (SAP Institute, Turkey)

This year there has been a reduction in the number of samples received. There has also been a decrease in the number of serological positive samples. For 2019, all isolates were from the sublineage O/ME-SA/PanAsia-2^{QOM-15}. Twenty samples were received from Iran (O, A and Asia 1). Vaccine matching indicates that the current circulating strains are covered by the local vaccine which is the only vaccine used in Turkey. No local proficiency testing scheme was undertaken, and no reagents

were distributed this year; however, training has occurred. A collaboration with the US to improve biorisk management has also been undertaken.

Pool 4: Kenya-East Africa (Embakasi, Kenya)

Antigen ELISA testing from Kenyan samples has shown serotype O, A, SAT1 and SAT 2 with the most predominant serotype being SAT 1. Twenty samples will be submitted to the WRLFMD shortly. Recent serological testing has provided evidence of high rates of seropostivity within the country (741/1140 sera positive by NSP ELISA). Vaccine matching is ongoing with SAT 1 being prioritised, results should be available for the final report. Locally produced vaccines are currently being used.

A collaboration project with ARS, Univ. of Minnesota and Kenya wildlife service is studying the transmission dynamics between cattle and buffalo.

Discussion – It is thought that the high number of NSP positive samples is most likely due to the animals previously being infected and not vaccination.

Pool 4: Ethiopia and East Africa (NAHDIC, Ethiopia)

Seventy-six samples from 20 outbreaks were received and typed as serotypes O, A and SAT 2. A subset of viruses were sequenced as serotype O and A. Compared to last year there appears to be a decrease in the proportion of outbreaks caused by SAT 2. SAT 2 and SAT 1 were only detected in a few outbreak samples that were tested by antigen ELISA. These were not sequenced this year as samples were sent to WRLFMD. SAT 1 on antigen ELISA could be due to cross-reactivity as SAT 1 has not been detected for the last 12yrs.

Discussion – A brief update on the East African Network was provided by Abraham Sangula and Daniel Gizaw. There is the potential to organise a skype meeting of the Network through EuFMD support. It is encouraged by the Network that these type of meetings occur as not to lose the momentum within this network.

Pool 5: Nigeria (NVRI, Nigeria)

Serotypes O, A and SAT 2 have been detected but it appears that the IZSLER ELISA could not detect a particular lineage of SAT 1 (as discussed in previous years). Due to limited resources, efforts have been concentrated on outbreak samples, not surveillance. No recent sequencing has been carried out, but the suggestion is that there is continuous circulation of the same lineage in the country. No vaccine matching has been undertaken since 2013. Samples are to be sent to Canada as part of a new collaborative project.

Update from NCFAD Winnipeg, Canada

NCFAD has continued to receive positive samples for Seneca Valley virus (SVV) collected within Canada. As discussed above, NCFAD has new collaborative projects with Nigeria (and Colombia via PANAFTOSA). For the work in Nigeria samples sequenced were serotype O and SAT 2 (2017 and 2018) identifying an equal distribution of serotype O/EA-3 and SAT 2/VII.

Most reagents this year have gone for the supply of commercial kits, including hybridomas and recombinant NSP antigens. Further collaborations include APQA (vaccine studies in cattle), North American FMD Vaccine Bank (use of monoclonal antibodies for vaccine matching and antigenic cartography) and BI (vaccine matching in pigs).

Action – O2-19 – The O/EA-3 sequence data should be shared to study how this lineage is moving across Africa. This could include strains from WRL, ANSES and NCFAD.

Pool 5: West Africa (LNERV, Senegal)

Not able to attend the meeting but they have e-mailed with a short summary. The samples tested this year have all been negative for FMDV.

Pools 4-6: Sub Saharan Africa (BVI, Botswana)

During 2019, samples have been received from Zambia (O/EA-2), Malawi (SAT 2/I) and Namibia (SAT 3/II). There has been a decrease in the number of submission due to financial constraint caused by the drought. For the samples submitted from Botswana no positive cases have been obtained. Vaccine strains include SAT 2035, SAT 251, SAT 306, SAT 309 and O Manisa; this will be updated next year with new strains received from BI/Merial.

Discussion – Is SAT 3 more widespread? It is difficult to answer this. Perhaps, due to the drought animals are moving to new areas, but many countries do not regularly submit samples.

Pools 4-6: Sub Saharan Africa (OVI, South Africa)

SAT 2 topotype I has been detected by VI and rRT-PCR. The presentation included a SAT 2 phylogenetic tree of the South African strains which appeared to show that there are distinct events taking place in the country. Surveillance activities have been carried out in South Africa, Namibia, Zimbabwe and Uganda. No vaccine matching has been done for these strains. Locally produced vaccines, not yet available on a full scale.

Discussion – The most likely SAT topotype to cause outbreaks outside of Africa is the SAT 2/VII as it is readily transmitted from cattle to cattle (as shown previous in Egypt).

Update from Sciensano – David Lefebvre

Sciensano is now the joint EU-RL with ANSES, France. Sciensano has tested samples from Luxembourg and Ethiopia. The Ethiopian samples were: O/EA-3, O/EA-4 and A/AFRICA/G-IV. Surveillance has also been carried out by serology: NSP ELISA (pigs 2.1%, cattle 24.4%). Sciensano is part of collaborative programs with Nigeria, Burundi and Botswana.

Update from ANSES – Labib Bakkali Kassimi

ANSES is the joint EU-RL with Sciensano, Belgium and more information can be found on the website http://eurl-fmd.anses.fr.

This year, ANSES has received samples from Morocco, Tunisia, Algeria, Mali, Ivory Coast and Comoros. Topotype O/EA-3 was isolated in Morocco, Tunisia, Algeria, Ivory Coast and Mali. For the Comoros topotype O/EA-2 was identified and the isolates appear to be closely related to Tanzania. Comoros represents a new example of the introduction of FMDV into an island that was previously FMDV-free (Mauritius was the previous example).

Thirty-seven countries participated in the Proficiency Testing Scheme in 2019. Reagents have been supplied to regional laboratories.

Discussion – The recent spread of viruses into North Africa could be due to the roads that have recently been built although it is likely that illegal movement of animals still occurs.

Update from IZSLER

IZSLER has received samples from Algeria (ovine and bovine) and carried out tests by ELISA, rRT-PCR, virus isolation and sequencing. Algerian viruses belong to O/EA-3 and these are closely related to those

from Libya. Sixteen FTA cards smeared with epithelium tissue, swab or blood from cattle and sheep have also been submitted to IZSLER from Libya. From the FTA cards containing epithelium tissue, rRT-PCR was carried out and the topotype O/EA-3 was identified.

IZSLER has also been involved in a small field vaccine trials which included the Maghreb countries as well as Transcaucasus (Armenia, Azerbaijan and Georgia). Samples were tested by NSP, SP-ELISA and VNT. The conclusions include (1) booster vaccination is necessary and (2) SP-ELISA provides results consistent with VNT for the booster vaccination. Training has been provided as well as a tailored proficiency testing scheme (PTS) for Cyprus and Turkey. A regional PTS was also carried out. A total of 2,106 kits have been supplied to 54 countries, mostly for SP serotype O. Collaborations continue with University of Glasgow and Tanzania, this is a longitudinal study from 2012 to 2018 and includes both clinical samples as well as sera.

Discussion –. Currently IZSLER is developing a multiplex LFD using later flow with four lines (O, A, Asia 1 and PanFMD). This will use the same monoclonals as are currently in the antigen ELISA kit. S. Korean lateral flow multiplex to look at the different serotype is being used in North Africa. For subsequent molecular testing, it is not clear how long LFDs and FTA cards can be stored for before being processed. However, it is recommended that an original sample is kept alongside the LFDs and FTA cards.

Pool 7: South America (PANAFTOSA, Brazil)

Except for Venezuela where the FMD status is unknown, there have been no suspected cases of FMD in South America in 2019. A retrospective genetic study looking at the FMDV isolates from Colombia (Serotype O/Euro-SA lineage 6) highlights a relationship between the viruses of the Andean region (90% similarity). Venezuela does not have OIE-recognized FMDV status and there is concern that the vaccination coverage is dropping. There is also concern of illegal trade because of the increase in meat prices elsewhere.

Brazil will suspend vaccination in 2023. It is expected that vaccination will cease in some regions in 2020 and that surveillance for FMDV will increase. PANAFTOSA has carried out vaccine matching and EPP for the Colombian outbreak strains; the O1 Campos strain has good vaccine matching and EPP results against O/Colombia 2018 both after single and booster vaccination. The recommendation to Colombia is to strengthen vaccination strategy to avoid immunity deficiencies (recommended vaccine coverage >80%).

Argentina is the only country in South America to use tetravalent vaccine that contains A/Arg/2001 as well as C3 Indaial; all others use O1 Campos and A24 Cruzeiro.

A proficiency test has been organised for 12 countries in the region and a training course has been delivered, along with a simulation exercise. Reagents have also been supplied to the region.

Discussion – Vaccine matching is carried out on trivalent vaccines using both single and booster BVS.

Update from CSIRO/AAHL, Australia

Recent work has shown that inactivation of epithelial samples works with RNAShield but takes 24hrs, which is too long and additional work is being carried out to facilitate faster inactivation. An additional study has shown that a more cost-effective protocol for rRT-PCR can be established by decreasing the volumes and amount of master mix used in the test – without negatively influencing assay performance.

A new model for producer-led surveillance which improves partnership among stakeholders has been developed, and the strengthening of the model to study the potential spread and control of outbreaks,

including the cost benefit of vaccination, is in place. In some situations, vaccination decreases the cost (for small outbreaks) but in others (larger outbreaks of longer duration) it didn't make a difference.

Recent collaborative studies have shown that the A/GVII (from BI) vaccine does not protect against A/ASIA/IRN-05 field isolates (approx. 2 PD_{50}).

Discussion – Is FMDV RNA is infectious? The network felt that there was a low risk of this and that there needs to be a statement that from a biosafety point of view, RNA is not infectious.

Update from FADLL USA – presented by Don King

NBAF is to replace ARS and APHIS and Dr. Alfonso Clavijo will join NBAF as director. In order to prepare for the move viruses have been sequenced from the repository. There will now be a separate US vaccine bank; however, the US will still be part of the North American vaccine bank. A local PTS as well as training has been carried out.

ACTION O8-19: The annual report will be started in the New Year. Please reply to Mark Henstock e-mail regarding laboratory reports for 2019 activities

Environmental sampling: a new approach to enhance FMD surveillance? A short presentation was provided to review the benefits of environmental sampling where swab/cloth samples can be collected in areas where animals are present (such as farms truck, markets etc..). This sampling approach can be carried out using dust cloths and results have shown that viral RNA can be collected 60 days after the last clinical cases. **Introduction/request for collaboration:** Claire Colenutt and Simon Gubbins from The Pirbright Institute are looking for partners to validate environmental sampling for FMD. Please contact simon.gubbings@pirbright.ac.uk for further details.

DAY 2

Global FMD strategy with emphasis on vaccines -Samia Metwally

West and Central Africa is where many countries are still in PCP stage 0. The total investment has been $56M and gaps including vaccine and vaccination have been identified. These include low vaccine coverage, unaffordable vaccine and the ineffectiveness of the vaccination program. Actions are to be taken by international organisation and partners (GF-TADs FMD WG) to establish a prequalification system (including OIE, FAO and EuFMD). In addition, this will include designated vaccine quality control reference centres in Africa, Asia and Middle East. Training of PVM will include serological tests for PVM supported by vaccine producers, GFRA and reference centres. A list of regional lab network objectives has been defined and support from the Network for training will be requested.

Discussion - Regional Expert Group in South East Asia met twice this year to write guidance documents for testing algorithms for serology and molecular techniques. These documents have gone out for consultation.

Challenges of establishing a QA/QC pipeline for FMDV vaccines – the importance of heterologous response – Don King

This presentation introduced a new OIE Twinning Project between AU-PANVAC and WRLFMD which has the goal to establish a pipeline for vaccine QA/QC for endemic countries in Africa. It is anticipated that this project will connect with OIE/FAO Network and Dr Nick Nwankpa has been invited to the meeting this year to build this connection. The project will focus on heterologous testing of the final formulated product supplied to the customer and adopting standardised protocols for post-

vaccination sampling using the PVM guidelines. A gap still exists to define the "correlates of protection" using the available serological tests.

This presentation also introduced the AgResults FMD vaccine challenge project which will launch in January 2020, managed by GalvMed. This project will supplement the cost of the vaccine; the country gains because a high quality vaccine will be delivered at a lower cost. This project is a long-term investment over at least seven years.

Establishment of an independent FMD Vaccine quality control system at AU-PANVAC: An Introduction – Nick Nwankpa

AU-PANVAC international is concerned with independent quality control of all veterinary vaccines produced or imported into Africa. AU-PANVAC falls under the African Union Technical Centre and was originally established for Rinderpest. AU-PANVAC is an OIE collaborating centre, FAO reference centre, FAO/OIE Rinderpest holding facility, ISO 9001-2015 certified and ISO 17025 accredited. PANVAC carries out five different test: identities, sterility (free of extraneous agents), innocuity, efficacy and stability. There are a total of 12 tests for each batch of vaccine. Currently, AU-PANVAC does not have capacity for QC for FMD vaccines. Currently a MoU is in place with BVI for the control of foot-and-mouth disease and funding from US-DTRA and SANDIA lab is investing in a new laboratory.

Harmonisation of serological approaches and selection of FMDV reference antigens and sera for endemic settings in (East) Africa – Anna Ludi

A technical presentation was provided on the AU-PANVAC twinning project (and links to the AgResults initiative). This led to active discussion between delegates to consider the approaches that should be used for vaccine QA-QC as well as what the criteria for acceptance should be. The heterologous testing approach proposed by WRLFMD/AU-PANVAC was broadly endorsed and the Network agreed to contribute to work to select FMD viruses for a common Reference Panel (initially covering virus lineages in East Africa). There was agreement on the following points:

1. The method to select the Reference virus panel will initially be based on phylogenetic analysis. The viruses selected will then be tested against a panel of serum before the final panel will be selected. The Reference virus panel will be kept as small as possible due to the possibility of developing diagnostic reagents with these strains, but aim include representatives of each currently circulating clade. NB: It is not essential that all sequenced viruses are included since some viral clades may be extinct
2. Testing should encompass the final formulated vaccine
3. The panel will need to be reviewed (annually – at this meeting) to insure it stays up to date

The criteria of acceptance of a vaccine needs to be clearly defined. Current feedback from Ag-Results indicates that a 70% pass rate (at serotype level) will be defined for the initiative that will be launched in January 2020. The following concerns were raised:

- There was concern that these criteria (i.e, 70% - where only 3 out of 4 viruses in each serotype need to pass) might lead to a gap in vaccine coverage
- The criteria should evaluate a vaccine using sera collected from multiple animals (to accommodate animal-to-animal variability in responses)
- The serological criteria used to define a "pass" needs clarification. One possibility is to use the values described in the Barnett paper, or perhaps a more pragmatic a 1/100 (ELISA) or 1/45 (VNT) could be adopted. Validation of these values (espec. before Jan 2020) will not be

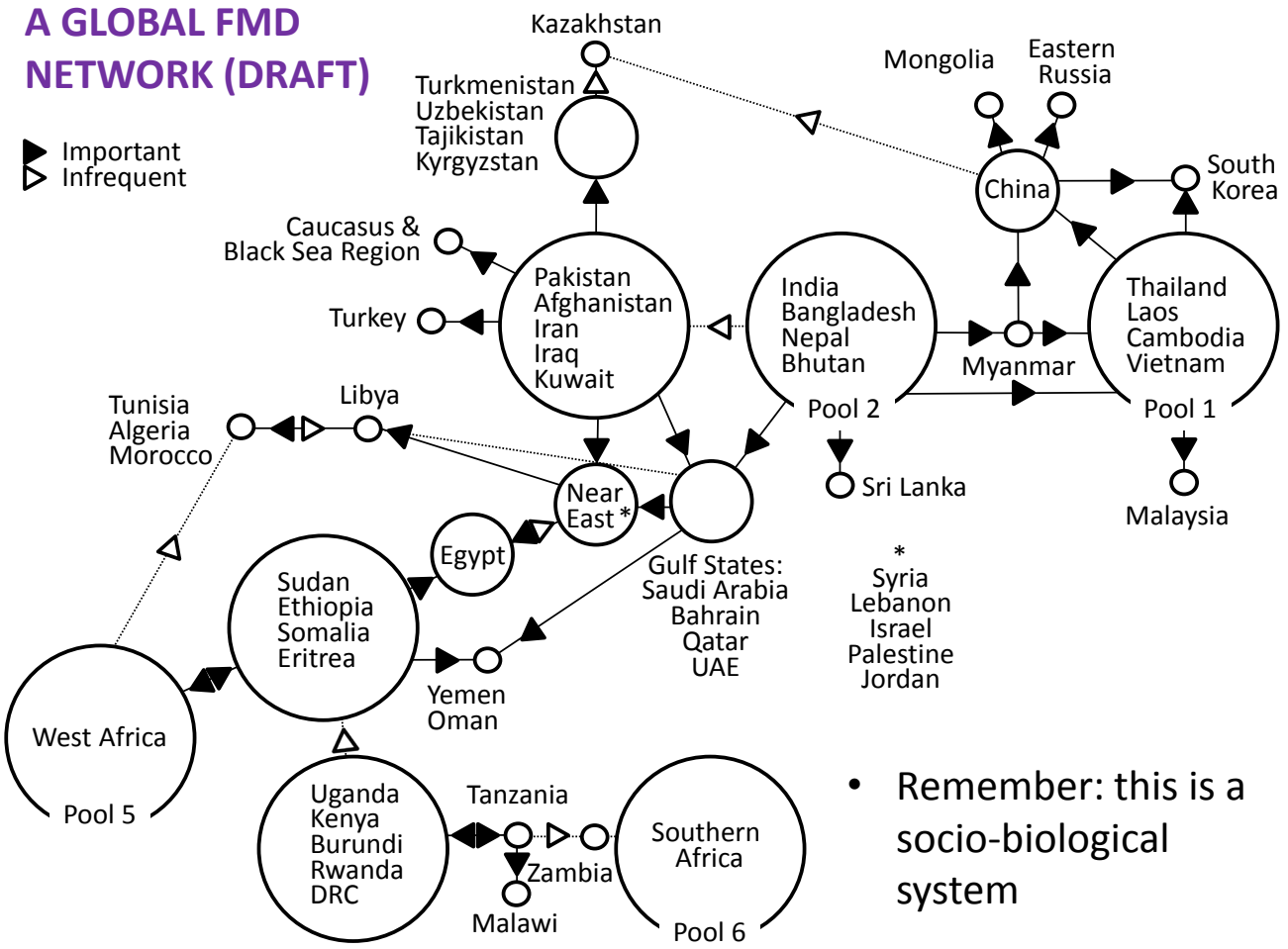
possible since there is not enough data for heterologous protection for African viruses (similar to the EPP table used in S. America).

Nagoya Protocol – Pascal Hudelet

The Nagoya Protocol states that countries have sovereign rights over their natural genetic resources (genetic material with actual or potential value for future generations of humanity). To use genetic material, you must obtain formal approval from the country of origin and negotiate or obtain evidence of mutually agreed terms with the provided country. This presentation highlighted the impacts of the Nagoya Protocol on the generation of new FMD vaccine seed strains where countries have (i) not responded to requests from vaccine producers, (ii) asked for an unrealistic proportion of vaccine profits, or (iii) refused to transfer rights without local investment into vaccine capacity and research. This is causing long delays for the development of new FMDV master seed strains and these issues may also impact upon the development of diagnostic kits.

ACTION O5-19: There is a tri group reviewing Nagoya (representing OIE/FAO/WHO). Samia Metwally will get the most updated information from this committee.

Appendix 1: Transboundary connectivity of FMD (draft)



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