REPORT

OF THE

SESSION OF THE RESEARCH GROUP OF THE
STANDING TECHNICAL COMMITTEE

OF THE

EUROPEAN COMMISSION FOR THE
CONTROL OF FOOT-AND-MOUTH DISEASE
(EUFMD)

HELD AT

ERICE (ITALY)

14-16 OCTOBER 2008 (OPEN SESSION)
17 OCTOBER 2008 (CLOSED SESSION)

FOOD AND AGRICULTURE ORGANIZATION OF
THE UNITED NATIONS
ROME, 2008
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REPORT ON DISCUSSIONS HELD IN THE OPEN SESSION - 14-17 October 2008

An Open Session of the EuFMD Research Group of the Standing Technical Committee was held in Erice, Italy, between 14th and 17th October 2008, with 11 members of the Committee and over 170 observers from across the world. Eight Technical Items were considered, relating to technical constraints to improved regional and global control of FMD. The Session considered seven keynote papers and sixty-six presentations, relating to the eight items. Two debates were held, and forty two posters presented. A panel discussion, with representatives of OIE, European Commission (EC), of the President of the EuFMD Commission, and the Global FMD Research Alliance (GFRA), followed the final presentation on development of a global strategy for progressive control of FMD. The Agenda of the Session is found at Appendix 1; the list of participants is found in Appendix 2.

OPENING CEREMONY –OPEN SESSION

The Session was opened by Dr. Gaetana Ferri, Deputy Chief Veterinary Officer, Ministero della Salute, Government of Italy. Her full address is given in Appendix 3. She emphasised that foot-and-mouth disease is still one of the diseases that calls for the greatest efforts in prevention and control of the national and international health agencies, because of its extreme contagiousness and the direct damage it causes to animal production and the severe trading restrictions connected to outbreaks. She drew attention to the international institutions that have made collaboration at all levels a pillar of their action, with indisputable results, and gave a special thanks to the EuFMD Commission, for organizing this important multidisciplinary congress, as well as for its continual activity in supporting and enhancing prevention in its 35 European member states, in close collaboration with the European Commission (DG SANCO). She drew attention to the importance of the OIE in promoting a more transparent exchange of information on the occurrence of this disease in countries all around the world and, in the framework of the SPS agreements, for attaining the full harmonization of the health measures and diagnostic standards.

In regard to international actions, she drew attention to the importance of European support for projects in developing countries, including those funded by Italy in central Asia and elsewhere, and the significance of the solid commitment of the European Union in funding research. Of central importance to FMD control is the collection of epidemiological data and the funding of surveillance plans should be the priority, especially in those countries where there is still scarce knowledge concerning the presence of the disease and the kind of serotypes circulating. Epidemiological surveillance is a valid instrument to assess the risks entailed by the disease, and therefore provide for an optimization of resources and enhance the effectiveness of vaccination plans.

Finally, she stressed the need to reinforce veterinary services, for they play a vital role in all the aspects related to the implementation of the control measures for FMD. She expressed the hope that the Session would offer a relevant contribution to solving various problems that are faced in different parts of the world, and would enable improve international strategies for effective control.

Dr Christianne Bruschke, on behalf of the President of the EuFMD Commission, Dr Peter de Leeuw, thanked Dr Ferri for opening the Session and emphasised the importance of scientific research and technical developments to make possible changes in policy and control measures against FMD. The global nature of the FMD threat makes the subject of control of infection in endemic regions of importance to free countries in Europe.

On behalf of the OIE, Professor Willeberg, Secretary General of the OIE Scientific Commission for Animal Diseases, indicated that the OIE viewed the Session as a valuable preparatory meeting ahead of the international conference on FMD to be held in Paraguay on 24-26th June, 2009. The outcome and recommendations should assist in developing documents and positions for that meeting, and he thanked the organisers for their efforts to ensure the major technical issues were addressed.

Dr. Alf Fuessel, for DG-SANCO of the European Commission, supported the previous comments and emphasised the importance of scientific decisions reached in the Research Group Sessions to the European Community. The EC strongly supported the work of the EuFMD Commission to reduce the risk of FMD to the European member states, and wished the Session a great success.
**RECOMMENDATIONS OF THE OPEN SESSION**

**Session 1: Global FMD control through regional co-ordinated actions: opportunities and constraints**

The keynote paper presented by Keith Sumption [Appendix 4] and seven papers [Appendix 5, 6, 7, 8, 9, 10 and 11] were discussed, relating to regional FMD control, eradication of type C, and co-ordination of research.

**Considering that:**
1. FMD is a "one world" problem, requiring preventive actions both in countries that are endemic and at-risk;
2. There is an enormous variation in risk and capacity to control disease within and between geographical regions;
3. FMD serotypes and antigenic strains show a regional specificity and distribution;
4. Many countries have no coherent long term strategy for FMD control, and that national efforts are at risk if the neighbouring countries or regions do not take effective action in parallel;
5. Expertise on FMD is scattered across the continents and there is a need for sharing of ideas, technical information and expertise between FMD experts and to build effective regional networks to improve technical information available to disease control agencies;
6. FMD Type C incidence has markedly declined over the past 20 years to a point that circulation in the wild may have ceased.

**Recommends that:**
1. The approach of developing regional roadmaps in each of the seven major virus pools for the control of FMD is adopted as a central part of the global strategy for progressive FMD risk reduction by FAO and OIE, and should involve a greater effort to foster effective laboratory and epidemiology networks within each region;
2. Regional roadmaps should utilise, to the greatest extent, public-private partnerships to overcome financial, social and technical barriers to delivery of FMD control programs in endemic and at risk regions;
3. Effort is continued by the EuFMD Commission and FAO (EMPRES) after the current Session to ensure that FMD expertise in each region is able to benefit from the global and regional discussions at the Session, and they should support or develop a global network of FMD expertise that fosters greater participation in future in the regional and global efforts against FMD;
4. A pathway towards verified international freedom from circulating Type C infection is developed by FAO and OIE, that should include the cessation of vaccination against Type C, surveillance efforts in the last known reservoirs, and emergency planning for possible escape or re-appearance of infection.

**Session 2A: Optimizing programs in a situation of limited resources**

The keynote paper presented by Aldo Dekker [Appendix 12] and three papers [Appendix 13, 14 and 15] were discussed relating to timing of vaccination and dose requirements.

**Considering that:**
1. Vaccine coverage is the major constraint in control of FMD by vaccination mainly due to insufficient vaccination, and partly due to decreased quality of the vaccine at time of vaccination or poorly timed vaccination programmes. A vaccination coverage lower than 100% will hardly be sufficient, because current vaccines are not 100% effective (3 PD50 vaccines only protect 75-85% of the cattle);
2. Global FMD vaccine production is constrained by a lack of demand in parts of the most affected regions in Africa and Asia, and significant public and private investment in vaccine production would be needed to increase supply using current production methods, over many years;
3. Financial resources to fund vaccination are limited in most countries, and optimization of programs e.g. the protection of young animals before they enter the animal movement chain, could have positive financial and epidemiological impacts;
4. Intra-dermal application of FMD vaccine is very promising and could be a simple way to expand the number of doses available given current antigen production methods;
5. Good quality vaccines can give a long-lasting protection from clinical disease for at least 6 months, but good vaccines need to be applied correctly in the field. Special attention...
should be given to the cold chain as that can affect the antigen stability, and good quality vaccines can induce an antibody response in presence of maternally derived antibodies, but it is important to revaccinate in time to increase the vaccination coverage in young animals.

**Recommends that:**

1. The FAO/OIE Global Strategy should place emphasis on vaccination policy guidance and technical support to Veterinary Services (VS) to assist them to rationalize and optimize programs to achieve the greatest reduction in transmission and/or reduction in disease impact, through targeting vaccine to critical populations and ages (being mainly young animals). The support should be channelled through the existing regional specialised agencies and animal health centres of FAO/OIE, and make effective use of the technical expertise in the EuFMD Research Group and associated technical network;
2. Countries buying vaccine should check the vaccine, for both the antibody inducing capacity at the time of delivery and also half-way through the shelf-life;
3. Countries using prophylactic vaccination should on a regular basis test for the optimal moment to immunise young animals, because this could be influenced by the quality of the vaccine used in both dams and offspring, and carry out field studies to determine the duration of immunity following a single application of an FMD vaccine, when using the selected vaccine in their own population;
4. New vaccines should be developed that induce a higher protection level in the population and that are less sensitive to problems in the cold-chain;
5. Further studies should be carried out to validate the finding that intradermal inoculation could enable reduction in the dose and cost of vaccination programs.
Session 2b: Vaccination: overcoming antigenic diversity in order to simplify preventive programs

The keynote paper presented by Bernd Haas [Appendix.16], and two papers [Appendix. 17 and 18], were discussed relating to vaccine matching methods and prediction of antigenic sites from cross-reactivity data.

The papers and discussion can be summarized as follows:

Considering that:
1. Harmonization of vaccination programs, in terms of vaccine performance and antigenic spectrum, has provided positive benefits to regional FMD control in South America and in Europe;
2. There is a lack of guidance to decision makers on vaccine suitability in much of sub-Saharan Africa and parts of Eurasia;
3. High payload vaccines against type A FMDV have been found to confer a significant protective effect even against FMDV where the r-value suggests a poor level of protection.

Recommends that:
1. In order to promote and develop regional control efforts, the OIE/FAO FMD Reference laboratory network are encouraged to produce an annual guidance paper on vaccine strain selection for each region/virus pool, and on the availability and properties of vaccine strains worldwide;
2. To assist the above, efforts to identify the prevalence and continually monitor the characteristics of FMD strains in the seven regional “virus pools” should be internationally supported, and the international agencies, working with the Ref Centres, co-ordinate efforts to determine whether established vaccine strains offer protection against new field strains;
3. Members of the OIE/FAO FMD Reference laboratory network as well national reference laboratories (NRLs) and laboratories of vaccine producers should exchange protocols, data and sera in order to standardize methods for r-value determination;
4. Further research should be funded on the correlation of heterologous protection with parameters that can be determined in-vitro, in particular serum titres, and on epitopes relevant for protection (e.g. cross-reactivity, structural and sequence data).
Session 2C: Novel vaccine delivery approaches: progress updates

Three papers [Appendix. 20, 21 and 22], were presented and discussed in this section, on trails of a Baculovirus expressed empty capsid FMD vaccine, on use of modified vaccinia virus, and on marker vaccine using an FMDV with a VP1 G-H loop deletion.

Considering that:
1. Enhancing the duration of immunity after vaccination will have a profound effect on the practical implementation of control programmes;
2. Improvements in vaccine efficacy will significantly increase stockholder's confidence in vaccination programmes;
3. Research into vaccine stabilization, targeting of antigen to antigen presenting cells and providing the appropriate "danger signal" in vaccines is likely to improve vaccine efficacy;

Recommends that:
1. Research and Development on new vaccines is supported long term as a central pillar of the global strategy against FMD;
2. Research into In vitro expression of empty capsids to substitute for conventional vaccine antigen production should be pursued. However, studies to address whether a 'single sequence' capsid provides equivalent protection to a quasi species of capsid (conventional vaccines) should be explored;
3. Research into the use of GH Loop negative viruses as vaccine antigen shows promise. The applicability for other serotypes should be explored.
Session 2D: FMD vaccine standards required for global control

The Keynote paper of Nesya Goris [Appendix 24] and four presented papers [Appendix. 25, 26, 27 and 28], were discussed and can be summarized:

Considering that:
1. There is a need for buyers and users of FMD vaccines to have confidence in the claims of the producer and to have sufficient information on duration of protection, stability, and cross-protection to enable rational design of programs;
2. There is a need for buyers to be able to check independently the performance of vaccine without requiring a full vaccine challenge under high containment conditions.

Recommends that:
1. FMD laboratories that have performed quality assessments should share the data on vaccine quality assessment to improve analyses through the use of larger datasets;
2. Laboratories performing challenge tests should standardize their methodologies for assessment of immune responses, as well as the analytical techniques, on a statistical sound basis;
3. Based on statistical evaluations the OIE and European Pharmacopoeia should choose a measure of vaccine quality which matches previous potency tests and the epidemiological needs;
4. OIE and FAO should support the monitoring and communication of vaccine quality based on serological responses in target population using standardized laboratory tests or international accredited laboratories.
Session 3: Biosecurity and buy-in

The keynote paper presented by Nick Honhold [Appendix 29], the two presented papers [Appendix 30 and 31], were discussed and can be summarized:

Concludes that:
1. Risk based disease surveillance using analysis of livestock production and marketing chains and livestock production systems must be a guiding element in decision-making and control interventions;
2. Governments have a responsibility to:
   a. Craft FMD control strategies and plans based on objective assessment of the risks in different epidemiological, economic and social settings and within different production and marketing chains;
   b. Facilitate and sustainably finance processes that will require key stakeholders to listen to each other and take each other’s concerns into account in planning FMD control, and to look for areas of joint interest and potential gain;
   c. Ensure that up to date information is available on all prevention and control measures through a range of media;
   d. Work in partnership with animal keepers, veterinary staff, intermediaries and owners of gathering points to develop biosecurity measures that are feasible and agreed for peacetime, raised risk periods and outbreaks;
3. Researchers and those who finance research have a responsibility to provide more documented evidence on the impacts of applying biosecurity;
4. Farmers, intermediaries and operators of gathering sites have a responsibility to consider the impact of their actions on the livestock sector and to apply good management including preventive biosecurity;
5. Veterinarians have a responsibility to ensure that their knowledge of FMD prevention and control is up to date, to encourage farmers to adopt a range of control measures including preventive biosecurity. Others who communicate with farmers e.g. vaccine providers can also be a valuable source of information.

Recommends that:
1. The global strategy being developed by FAO/OIE should address the issue of how public and private investment in FMD prevention and control can be encouraged, and in particular the promotion and safeguarding of stakeholder investment in prevention and control efforts in endemic regions;
2. In developing the global strategy, the potential impact upon investment and FMD risk of changes to the standards affecting compartmentalisation, commodity based trade, and criteria for gaining or retaining FMD freedom should be examined;
3. FAO/OIE should encourage countries to develop National FMD risk reduction plans, based on realistic assessment, and stakeholder consultation and engagement, of the risk of introduction and circulation of FMD virus and an assessment of the policies, capacity, incentives and opportunities for risk reduction;
4. FAO/OIE should assist in implementing and update risk assessment in FMD endemic settings using critical risk control point (CCP) identification and livestock market chain analysis to assist countries to identify how FMD is maintained, spread and the possible control interventions for reducing or breaking FMD transmission;
5. The research and development communities should work together over the next few years to develop projects and guidance that will enable CCP to be identified in major regions/countries within each FMD virus pool, to support the progressive control of FMD in endemic settings.

Session 4: Measure progress in global and regional fmd control, and early warning of fmdv emergence

Two keynote papers were presented by David Paton [Appendix 32] and Andres Perez [Appendix 33], and seven papers [Appendix. 34, 35, 36, 37, 38, 39 and 40], relating to improving surveillance for emergent virus threats through use of inactivated samples in shipment to reference laboratories, use of thermal imaging, full genome sequencing for epidemic virus characterisation, and monitoring of vaccination programs through measurement of NSP positive rates and through surveys for population coverage.
Considering that:
1. Very little attention has been placed in international reporting systems on the use of measurements of incidence, force of infection and risk of new FMD infections, which constrains the rational design of preventive measures in at-risk and affected countries;
2. Monitoring of progress against FMD requires a set of comparative indicators, to measure change in risk, incidence and capacity to detect and control FMD epidemics;
3. The submission of live virus samples to reference laboratories is constrained by high transport costs, and carries some risk that may be reduced by use of alternative sample handling arrangements and use of services within the affected region.

Recommends that:
1. The FAO/OIE and their reference laboratories should develop a multilateral, multiagency, international strategy and infrastructure to survey FMD globally for FMD capture, sample collection, reporting, modelling, and development of indicators of FMD prevalence and risk at global and regional scales, and in selected countries and regions specifically targeted;
2. International and regional activities should be developed that promote team-working between disease control agencies and reference laboratories, and the application of state-of-the-art epidemiological methods, and field, theoretical/informatics-based and molecular epidemiology techniques;
3. Greatly increased support is required for strategic centres and epidemiological projects to better understand and sample ecosystems in each of the virus pools, where local capacity/incentives are insufficient. This should address the requirement for better and more complete field epidemiological information submitted together with samples for analysis by national and international reference laboratories. The existing Network of Reference Laboratories should be sustained and twinning projects should be established to support the development of laboratories and associated surveillance projects in the Middle East, West Africa and East Africa. New opportunities for simplified sample submission should be explored;
4. FAO/OIE are encouraged to produce, at least twice a year, a report on the Global FMD risk situation incorporating the OIE/FAO laboratory network report and an analysis of key epidemiological indicators that provide insight into factors contributing to increasing and to decreasing risk. Key epidemiological indicators should include, for example, quantitative estimates of risk, vaccine-induced immunity, attack and transmission rates, reproductive ratio, spatial distribution of population at risk, and patterns and frequency of animal movements and trade;
5. The global strategy being developed by FAO/OIE is encouraged to promote greater monitoring of the evolution and efficacy of control programs, using indicators such as vaccine coverage, incidence of FMDV exposure, and estimates of the reproductive ratio in countries or regions that are not free of infection.
Session 5: Diagnostics: making quality service available where needed

Two keynote papers were presented, by Dr Donald King [Appendix 41], on development and potential application of new diagnostic test systems relevant to endemic and at risk areas, and Kris de Clercq [Appendix 44], on raising the performance standards of national and regional reference laboratories through their involvement in a global system of proficiency testing. A further seven papers [Appendix. 42, 43, 45, 46, 47, 48 and 49], were presented and discussed, and a debate was held on the priorities for new diagnostic kits for use in endemic regions.

Considering that:
1. Progress has been made to develop and validate rapid and simple penside test systems for FMD;
2. Virus type information is usually vital to planning of immediate follow-up control actions in endemic as well as normally free countries;
3. On behalf of FAO, and supported by EuFMD, the WRL at Pirbright distributes panels of samples as part of a proficiency testing service (PTS), but participation of non-European laboratories is limited;
4. Currently most national reference laboratories in endemic regions currently do not participate in proficiency testing schemes, and therefore confidence is lacking in their services at national and regional level.

Concludes that:
1. Assay validation should exploit statistical methods in order to define uncertainties of measurement. A clear strategy for dealing with samples that generate weak values is required.

Recommends that:
1. As part of a co-ordinated global effort, the international agencies promote the continued development and application of the new rapid and simple FMDV test systems to assist every endemic and at risk country to establish a sufficient level of diagnostic capacity for the early confirmation of FMD;
2. International Reference standards (IRS) for assay validation and calibration should be developed and made available to NRLs. These materials are required for all FMDV serotypes – including SATs;
3. Support for the organization of proficiency testing schemes (PTSs) for FMDV should be continued: resources required to undertake this work should be prioritized;
4. Guidelines and optimized protocols for effectively transporting inactivated FMDV between the field and NRLs (and WRL) should be developed and the potential of replacing live virus transport in international surveillance programs further developed by the international agencies.
Session 6: Components and capacity for effective control

Three papers [Appendix. 61, 62 and 63], were presented, followed by a wide discussion on level of capacity required to implement effective control programs in endemic regions.

Considering that:

1. There is a lack of reliable surveillance data from many countries;
2. Participatory epidemiology has shown an ability to provide detailed indications of the perceived importance, occurrence and epidemiology of the disease at farmer level;
3. The provision of improved laboratory facilities is important but highlights weaknesses in control programs because of weak capacity of field services and political will;
4. It is important to ensure that improvements in capacity are sustainable.

Concludes that:

1. There is a need to ensure that required capacity is available at all levels of the key actors in control such as farmers, private veterinary services, government veterinary services, diagnostic laboratories and research institutes;
2. The reasons for low levels of disease surveillance and reporting varies between different countries;
3. Financing of vaccination schemes should be considered to examine if farmers can pay for all or some of the vaccination to release resources for surveillance;
4. The EuFMD meeting organizers are to be congratulated on fostering the broader scope of the meeting to address capacity and biosecurity issues.

Recommends that:

1. The global FMD control strategy being developed by FAO and OIE should address the issue of capacity for surveillance in every FMD affected country and promote actions at all levels of the key actors in control such as farmers, private veterinary services, government veterinary services, diagnostic laboratories and research institutes. There must be a focus on ensuring the sustainability of these capacities and on capacities for disease surveillance and reporting as well as post-vaccination sero-surveillance;
2. The global strategy should also address the financing of vaccination schemes and examine if farmers can pay for all or some of the vaccination to release resources for surveillance. Public-private sector co-operation should be encouraged to contribute towards these;
3. At regional and national level, studies of the costs and benefits of different control strategies (including the impact of FMD at farmer level) should be undertaken to indicate if refined control strategies may be as or more effective than broad control strategies such as blanket vaccination;
4. The EuFMD Commission should expand subject areas such as biosecurity, capacity building and disease surveillance and reporting systems in the EuFMD research group Sessions and efforts should be made to increase attendance by representatives of veterinary field services.
Session 7: Prospects for integrating anti-viral approaches

The two papers [Appendix. 69 and 70], and discussion can be summarised as follows:

Considering that:
1. Promising studies have provided information on the structure of the 3C protease of FMDV, which is required for the generation of infectious virus output, and new tools to easily screen potential inhibitors;
2. Studies indicate that anti-viral compounds reduced the level of clinical disease and virus excretion in pigs challenged with the porcinephilic O TAW/97 but administered the previously reported potential anti-viral compound T-1105 only 1 hour before challenge followed by administration of the same compound twice a day for 7 days.

Concludes that:
1. Very promising specific approaches and tools are available for anti-viral studies targeting the important 3C protease of FMDV;
2. Certain compounds already show significant promise for potential use in a control strategy including administration of anti-virals.

Recommends that:
1. Further studies should be funded at a level enabling focussed screening of potential anti-viral compounds directed against the 3C protease of FMDV;
2. Additional studies are needed to look at already established potential anti-viral compounds showing promise in reducing disease and in particular excretion and transmission and such studies should be aimed producing evidence supporting the efficacy and safety, including the potential for generation of escape mutants, during simulated field conditions.
Session 8: Strategy for regional and global control

The keynote paper of FAO, presented by Dr Joseph Domenech [Appendix n. 71], was discussed by a panel comprising Dr. Alf Fuessel, DG-SANCO (EC), Professor Preben Willeberg (OIE Scientific Committee on Animal Diseases), Dr. Christianne Bruschke (Deputy CVO, the Netherlands) and Dr Cyril Gay (Global FMD Research Alliance).

The paper and discussion can be summarized as follows:

Considering that:
1. FAO and OIE are in the preparation phase of a global initiative for the progressive control of FMD, to be developed and presented at an International Conference in Paraguay in June 2009;
2. There is a need for buy-in at national Government level to FMD control and to progressive and co-ordinated control at regional level, and for advocacy and convincing arguments of the benefits of FMD control at all levels;
3. There is a need to fund international surveillance for FMD in endemic regions, and Research and Development of new tools, if change is to occur in the capacity at national level to control FMD.

Concludes that:
1. The current Open Session addressed some of the most major issues affecting long term FMD control in endemic regions, and the recommendations of the Session should therefore be taken up by FAO and OIE in preparing the Global FMD Control Strategy.

Recommends that:
1. The regional approach based on the concept of actions within the 7 major virus type ecosystems/"pools" is promoted in the FAO-OIE International Initiative for the progressive control of FMD, with co-ordination and progress monitoring involving a global platform and a Secretariat;
2. The FAO and OIE continue to develop the regional and global strategy papers, based on a progressive risk reduction approach, making full use of expertise available to the EuFMD Commission, the OIE/FAO Reference Lab network, and in the global FMD research and development community;
3. A series of regional workshops is organized by FAO and OIE to develop the long term vision and regional FMD control strategies (road maps). The EuFMD Commission should support these to the extent possible, contributing to the efforts of FAO EMPRES and in close collaboration with Regional Organizations;
4. The FAO and OIE should address, in the global strategy, how increased investment and effort in FMD control by stakeholders in the most affected and at-risk regions can be encouraged and sustained, and this element should be a major component of a future Conference on controlling FMD in the worst affected regions;
5. Socio-economic issues affecting investment and uptake of FMD control measures by stakeholders in endemic and at-risk countries be addressed in the strategy;
6. FAO with OIE produce an annual global FMD report to indicate the progress made in the seven major virus pools, that will bring together virological, epidemiological and programmatic progress in each region;
7. The next Open Session of the EuFMD in 2010 is utilised as a major technical forum that will assist technical progress to the global FAO OIE initiative.
A Closed Session of the Research Group was held on Friday 17th October, 2008, at Erice, Italy. The Session was chaired by Dr Aldo Dekker, with Keith Sumption as Secretary. Nine members of the group (Aldo Dekker (AD), Naci Bulut (NB), Georgi Georgiev (GG), Bernd Haas (BH), Hagai Yadin (HY), Kris de Clercq (KdC), Emiliana Brocchi (EB), David Paton (DP), Soren Alexandersen (SA) were present. Apologies were received from Mark Bronsvoort, Stefan Zientara and Donal Sammin; the work of the latter for the group was represented by Eoin Ryan (ER). One member (Hakan Vigre) had resigned from the group as his professional position had changed. Additional participants for technical items were Dr Jef Hammond (JH), Head of the WRL Pirbright, Dr Graham Belsham (GB) Lindholm, Dr Gavin Thomson (GT), SADC FMD project. Observers included Christianne Bruschke (representing the Chairman, EuFMD), and Dr Alf Fuessel (AF; DG-SANCO, EC) and Susanne Munstermann (SM), FAO Gaborone, Botswana.

The list of participants is found in [Appendix 81]

Item 1. Agenda of the Session [Appendix 82]

Two additional items were added to the Agenda:

1) EB requested the issue of technical guidance on testing of animal products coming from an affected European country for the presence of FMDV be discussed. The issue was clarified by AF, who agreed that some guidance to Chief Veterinary Officers (CVOs) was needed. The unanimous opinion of the group was that it is not feasible to rule out the presence of FMDV in consignments of meat through sampling and lab testing. Such an answer would require a very high level of sampling and sensitivity of diagnostic procedures. DP drew attention to a previous opinion (of the SCAHW, 2003, on FMD diagnostic tests) which supported the above.

Conclusion:
1. The testing of consignments of meat for presence of FMDV cannot be used to rule out the presence of levels of FMDV that could pose a risk of infection if fed to pigs.

2) Concept Notes presented to the 76th Executive Committee of the EuFMD, June 2008

Three concept notes had been presented to the Executive, and each were recommended as important studies; the EC had indicated their financial support in principle. One proposal (on the role of sheep in transmission of FMDV, and relating to the question of benefit of vaccinating sheep to prevent transmission to cattle) arose from the Closed Session of 2007. The other two arose from the Final Workshop in March 2008, of the EC funded FMD surveillance support program in Turkey operated by EuFMD (2007-3/2008). These were: a study on the use of full length sequencing, to address issues of type A epidemiology (focus on the new antigenic variant) but also to better identify if Full length sequencing can be used to predict the number of unreported outbreaks; and a study on the stability of FMDV 146s in oil adjuvanted FMD vaccines. Implementation of each study had not commenced, but letters of agreement had been developed with IAH Pirbright and Lelystad, respectively. AD answered questions on the stability study; the intention was in addition to the in vitro results to compare with results with longitudinal serological studies in Turkey. Dr Bulut explained the initial response of the SAP Institute to the proposed study, and was confident that within a month their support would be given to providing the vaccine batches required. AF made clear that the support of the official veterinary service (OVS) for such a study would be helpful and that FAO should also liaise with them if difficulty to gain the required study materials, and use of the results, remained an issue.

Item 2. FMD Laboratory Minimum Containment Standards

2.1 Minimum Containment Standards (MCS) for FMD Laboratories [Appendix 83]

The Secretary indicated that the RG was formally asked to give their technical clearance on the final version of the revised Minimum Containment Standards (MCS) for FMD Laboratories. This document had been prepared by a working group which had invested over 300 hours of time in
revision and review; the document had been circulated to all FMD laboratories in the member states that were listed as working with live FMDV, and comments reviewed by the Chairman of the working group, Bernd Haas. The final stage was therefore the clearance of the document after the above consultation.

BH indicated that he had taken each comment from consultation, and considered only two areas of concern, the first being to clarify the risk categories in the risk table, and the issue of inclusion of infectious RNA as a risk on page 3. It was agreed that the latter should be mentioned in the hazard identification section.

Conclusion:
1. The document, with final editorial changes agreed from the Session, was technically cleared by the Group;
2. The final Standard (Appendix would be provided within a week of the Closed Session, for the Report and for utilization by interested parties including DG-SANCO, with the expectation that the document would be formally approved by the General Session of the EuFMD in April 2009).

2.2 Minimum standards of biorisk management for laboratories undertaking diagnostic investigations of low-risk samples during an outbreak of FMD [Appendix 84]

BH presented a second document, relating to emergency FMDV labs for serology and for testing inactivated samples. This document was proposed to the group to supersede the previous two biocontainment guidelines relating to FMDV sero-diagnostic facilities and confirmation of FMDV through RNA or antigenic detection procedures not involving non-live virus manipulation.

Conclusion:
1. The Group supported the consolidation of the previous Guidelines into a single document, with updating to bring into line with the new Minimum Containment Standards for FMDV laboratories;
2. The Group agreed that the document should be referenced in the Minimum Containment Standards for FMDV laboratories, but could also be added to the FMD diagnostic manual being prepared by the CRL for use by European NRLs;
3. The biorisk assessment and management sections of the guideline should be harmonised with the MCS document, and should include a statement on avoiding RNA in contact with cell culture.

Action: Secretariat to arrange consultation on the revised Guidelines, with the NRLs following the RG Session.

Item 3. Minimum Diagnostic Capacity in EuFMD Member States for the laboratory confirmation of FMD [Appendix 85]

KS introduced this Item; the issue was raised because of the low participation in the annual proficiency panel exercises organized for EuFMD and EC by the WRL/CRL of the NRLs of EuFMD member states that are outside of the EU, for example in the western Balkan countries. Following the 75th Executive Committee, the Secretariat produced a paper on Minimum Diagnostic Capacity that has the aim of harmonizing non-EU countries towards the expected diagnostic capacity stipulated for the EU member states (Council Directive 2003/85/EC). The RG were asked to review the paper, which would affect mainly non-EU countries if adopted by the EuFMD General Session in April 2009.

Conclusion:
1. The Minimum Diagnostic capacity paper should assist to clarify expectations for countries outside of the EU in respect of FMD diagnostic services and was technically cleared by the group.

Action:
1. Feedback on the paper is expected from Dr Yadin and Dr Bulut, representing countries that are EuFMD members but not in the EU;
2. The Secretariat should organise a consultation with NRLs in the non-EU European countries before the 77th Executive Committee.
Item 4: Sampling instructions for field veterinarians to collect samples with the primary biocontainment at the point of sampling for use in RT-PCR.

Item 5: Position paper on the options of decentralized testing.

The RG were requested to give clearance to this position paper [Appendix 86] whose development had been led by Donal Sammin. The paper was briefly presented by Eoin Ryan.

The Chairman thanked the authors for their excellent work, and opened the item for discussion.

It was agreed that:
- The paper should continue to retain the focus on free countries but could mention issues or options for decentralized testing relevant to non-free countries;
- Company or trade names must be avoided;
- Use of swabs must be added;
- If possible, a summary table to give decision makers the options and issues relevant to different situations in which DCT is applicable should be made;
- The need for a system to deliver sufficient and correct materials for DCT to the field operatives should be mentioned;
- The example decision tree is relevant and should be retained as an example, and emphasis given to each MS adapting a decision tree for its own circumstances.

Action: finalization of the paper within one month (Dr Eoin Ryan and Dr Donal Sammin).

Item 5.1 Transport of FMDV RNA rather than live virus; Optimization of viral recovery by transfection of infectious RNA

KS presented the background to this item; the 76th Executive Committee had recommended that studies be conducted to reduce or replace live virus shipments while maintaining the possibility of recovery of live virus from RNA.

Graham Belsham (Lindholm) outlined a proposed study for the optimization of methods to recover live virus from RNA [Appendix 87]. The variables to be studied included electroporation conditions, cell type (BHK, BTV), and time of harvesting. The proposed study would be conducted within the next 6 months and at a cost of circa 20,000 US$ (laboratory costs only, the personnel would be provided through a visiting scientist funded through an FAO project).

In discussion, it was agreed that the safety issue also needed to be studied, since viral RNA retained infectivity, although of a quite different level of risk to live virus.

Conclusion:
1. The group fully supported the proposed study, and requested a report to the next Session;
2. Bio-risk studies should be conducted, at least in mice, to better identify the level of infectivity of FMDV RNA

Action:
1. Secretariat to follow up with EC following the approval in principle given at the Session to fund the study, and the Letter of Agreement with Lindholm.

Item 6. Sero-surveillance in Turkey: the question of harmonizing the performance/interpretation of SP antibody data with/between RG member laboratories [Appendix 88]

Presenters: Naci Bulut, Carsten Potzsch (PC)

NB summarised the situation: to end of September 2008, Turkey had reported 30 type O, and 130 type A outbreaks; a relatively big upsurge in type A compared to 2007. As a result of vaccine matching, the vaccine to be applied in 2009 should contain or cover the A TUR 06 antigenic type.

Sero-surveillance in Thrace and Anatolia; this is being implemented from September 08, after assistance in design from EuFMD RG members; the NSP and SP serological testing is not expected to be finalised until after March 2009.

For sero-prevalence of FMD exposure, some 33,900 samples will be collected, using a 2 stage sampling, 565 villages selected, prevalence of 2% infected villages and 10% intra-unit prevalence. Sixty cattle per village will be sampled aged between 4-24 months.
Villages (20,000) with less than 100 cattle were excluded from the survey (in total 166,000 cattle in total, average 8 per village).

For vaccine efficacy, 3 provinces (and 3 villages in each) within each of 7 regions were selected, out of those selected for sampling for NSP sero-prevalence, in total the sera of 60 cattle in each of 63 villages will be tested, in total 9780 sera.

In Thrace region, 9780 samples between 4 and 24 months of age, from 152 villages will be sampled.

The issues for discussion

1) SP surveys: validity of thresholds for protection in ELISA tests conducted by the SAP Institute

NB explained the basis for the threshold currently applied by the SAP Institute to interpret test results.

Action:

AD include data of the Turkish laboratory in the international comparative study and to review the current threshold applied.

2) Design of surveys in 2009:

CP proposed that future surveys are examined and commented upon by the RG, before implementation in Turkey. Dr A. Fuessel drew attention to the fact that as EuFMD are invited to the National FMD task force meetings, then this can be used to introduce the proposed surveillance design, but the end result has to be agreed by the National FMD project SC, involving the CVO, and must meet the requirement in the project document for minimum number of samples.

Action:

1. EuFMD Secretariat, in liaison with the CVO of Turkey and NB, should propose a meeting of RG experts next May or June for analysis of the results of the 2008 survey, and to design the 2009 survey, to occur ahead of the national TF and SC meetings.

3) Inter-laboratory proficiency testing scheme:

For NR Ls in countries where the EuFMD is implementing capacity building programs under the support of the EC TF (GEO/ARM/AZB/TUR/IRAN).

CP proposed that a more frequent ILPT is implemented for this set of countries to expedite raising of the performance, given the importance placed on sero-monitoring in the programs in each country and the very limited experience in the Caucasus and Iran in FMD sero-diagnosis. It was agreed that each laboratory should participate in future in the WRL/CRL annual scheme, but the current requirements for these labs are different from the majority of FMD free countries and specific panels could assist with harmonisation of SP serology.

Action:

1. WRL to select from available sera for a pool relevant to west Eurasia, and would further identify sera that could be of similar use in the other virus pools (e.g. African pools, south and east Asia).

Item 7. Vaccine selection and potency of antigens in the EuVB for use against the current SAT2 FMDV circulating in Botswana/Namibia

The issues raised by the ongoing SAT2 epidemic in Botswana/Namibia were reviewed by Kris de Clercq; David Paton reviewed the vaccine matching results for African recent African SAT2 viruses.

Major issues include:

- Potency of the SAT2 vaccine formulated from antigens in the EU vaccine bank against the SAT2 epidemic type or other relevant SAT2 viruses;
- The lack of a comprehensive set of cross-matching and heterologous potency studies on SAT2 vaccines against the range of genotypes of SATs that exist in Africa.

Discussion points:

- The EU vaccine bank contains both SAT2 Zimbabwe and SAT2 Eritrea antigens;
- SAT2 Eritrea has been used in vaccine matching by WRL following potency tests, not the SAT2 Zimbabwe;
- On which body or how to influence producers to develop new /adapted SAT vaccines;
On a heterologous potency test to determine if the EuVB antigen would give at least least 3 PD50 in challenge.

Conclusions:
1. A heterologous challenge test was recommended by the Chairman, with a representative challenge virus from the ongoing epidemic of SAT2;
2. A subgroup of the RG should follow keep in close contact to follow up the discussions and identify studies or actions required (members: JH (WRL), DP, KdC, AD, HY, KS)

Item 8. Remaining business, workplans and tasks


Action:
1. Guidelines need finalization with comments of BH and SA.
2. Membership of the Group; SA would remain a member of the group, until the next EuFMD General Session (April 2009).
3. A replacement for Hakan Vigre should be identified that could bring epidemiology experience; possible replacements to be approached for interest include Jean-Francois Valarcher (Sweden) and Nick Honhold (UK);
4. Workplan: AD would revise the workplan and send for comments within 4 weeks, after liaison with the Vice Chairman and Secretariat on priorities;
5. Next meeting: the date and location of the 2009 Session were not fixed but would be expected to occur in September/October.

ITEM 9: LIST OF ACTIONS

1. Agreement with CVO Turkey and SAP Institute to supply vaccine batches for stability analysis at Lelystad;
2. Minimum Standards for emergency labs;
3. Minimum Diagnostic Capacity;
4. Position paper on decentralized testing;
5. Study: optimization of live virus recovery from RNA;
6. SP survey - thresholds values for protection;
7. Workshop to design 2009 survey;
8. Identify panel of standard sera for use in SP serology for EuFMD beneficiary countries in West EurAsia;
9. Guidelines on clinical examination – cattle and sheep;
10. Workplan.
CHAIRMAN’S AGENDA LIST - FROM 2007 SESSION:

Priority list for Research Group

HIGHEST PRIORITY

1. Position paper on the options of decentralized testing (DS 1 December 2007);
2. Sampling instructions for field veterinarians to collect samples with the primary biocontainment at the point of sampling for use in RT-PCR;
3. Minimum Diagnostic capacity in EuFMD Member States for the laboratory confirmation of FMD:
   a. Requirement for ISO17025;
   b. Every year a proficiency test.

MEDIUM PRIORITY

1. Definition and reporting of epidemiologically significant events: guidance paper, based on criteria developed under the EuFMD/EC/IVO program in Iran [Action point: delivery 12/07];
2. Paper on the risk of spread from wild boar in the Israeli circumstances;
3. Report on the use of thermal imaging camera for use in extensively kept cattle for the purpose of detection of febrile animals (HY, to be reviewed by DP);
4. Complete the review of duration of immunity after type O vaccination, to include the antibody decline by VNT, and the data should be analyzed with linear mixed effect model. (by 12/07);
5. Draft contract or form of agreement whereby a network of FMD labs in Europe could agree to provide services to NRLs that are temporarily incapacitated;
6. Revised position paper, as an addition or addendum to the document on live virus facilities, to include the requirements for applying non-live FMD techniques in serology and for RT-PCR (BH 31 December 2008);
7. Finalize paper on standardization of information collection and information output (Carsten Potzsch);
8. Discuss the protocol for RNA stabilisation study in Pakistan before referring it to the Exec committee;
9. In vitro stability study for FMD vaccines;
10. Role of sheep in maintaining or spreading FMD in a temperate European climate with mixed sheep and cattle farms (UK, 2001);
11. Application of tools for high-resolution FMDV molecular epidemiology in Western EurAsia.