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INTRODUCTION

A Session of the Research Group of the Standing Technical Committee ("Research Group") of the European Commission for the Control of Foot-and-Mouth Disease (EUFMD) was held in Paphos, Cyprus, between 16 and 20 October 2006, and hosted by the Government of Cyprus.

The Session was chaired by the Chairman of the Research Group, Dr Kris de Clercq. The first three days were held in Open Session, with some 130 Observers in addition to the 10 Members of the Research Group. The final day was held in Closed Session. The list of Members of the Research Group and Observers in attendance is given in Appendix 67.

Introduction to the Open Session

The Session was opened by the Mr Photis Photiou, Minister of Agriculture, Natural Resources and Environment, Government of Cyprus. Cyprus had remained free of FMD for the past 40 years, despite the constant presence of the infection in the region of the Middle-East. The success gave no reason for complacency, and continued effort was required to maintain the status of freedom from infection. The international organizations played their part in encouraging countries to put in place control policies that would reduce risk, and Cyprus was pleased to support the efforts of the EUFMD Commission as a member country. Dr Sumption in reply thanked the Minister for the excellent and timely offer to host the meeting, which enabled the transfer of the meeting because of the difficult security situation in mid-2006 in Israel. In particular he thanked Dr Giorgios Neophytou, Chief Veterinary Officer of Cyprus and the staff of the Veterinary Services Department for assistance to organize the Session at short notice. He also welcomed the Observers from the partner organizations of the EUFMD, the European Commission (Dr Fussel), and the OIE (Dr Yehia, Regional Representative of the OIE for the Middle-East). Since the meeting was being held 5 years after the type epidemic in north-west Europe, which had had an enormous economic and social impact, the world expected that the research programmes initiated as a consequence would now bring forth some major new findings and tools for improving prevention and control of FMD. The number and quality of papers submitted was a testament to this new impetus, and it was clear that some new breakthroughs would be reported, and more would be imminent if research funding is sustained. The challenge for all would be in translating the breakthroughs into practice, and this usually did not happen without effort to link developers with the practitioners in the field. FAO was pleased to assist in this process and urged research funders to continue to support the area, which was threatened by the attention given to avian influenza.

In organizing the Session, papers had been accepted in the major fields of importance for the prevention and control of FMD in the free regions of the world. The meeting did not primarily concern itself with FMD control in the endemic regions; the importance of surveillance and control was a central principle of FAO work but not the main focus of this meeting.

Introduction to the Closed Session

Kris de Clercq, Chairman of the Research group, welcomed the members and observers to the Closed Meeting. In addition to the Chairman, the members present were Aldo Dekker (AD), Emiliana Brocchi (EB), Mark Bronsvoort (MB), Bernd Haas (BH), François Moutou (FM), Soren Alexandersson (SA), Georgi Georgiev (GG) and Dónal Sammin (DS). David Paton (DP) attended as ex-officio member for the World Reference Laboratory. Professor Willeberg represented the OIE and the EUFMD Executive, and Alf Fuessel the EC (DG-SANCO). Additional Observers present for Item 1 and 2 were Dr Linda Logan, USDA, and Dr Mahravani and Dr Otorod from the EUFMD/IVO FMD project in Iran. From FAO (EUFMD) were the Secretary, Keith Sumption (KS), Tom Murray (TM), Nick Honhold (NH), Carsten Potszch (CP) and Francis Geiger (FG).
Item 1 - Lessons learnt from the recent events in FMD control in the region

Three presentations were given on recent events and lessons learnt. The first paper concerned the recent FMD epidemic events in Turkey, Iran and Egypt (Keith Sumption, Secretary of the EUFMD Commission, FAO, Appendix 2); the second highlighted the impact and importance of biosecurity measures in the control of FMD in the UK in 2001 (Nick Honhold, Appendix 3), and the third analyzed the factors that led to FMD outbreak distribution in Uruguay in 2001 (Ariel Rivas, Appendix 4). Three papers were also presented on FMD risk assessment, by Rebecca Garabed from UC-Davis (Appendix 5), Hubert Deluyker, highlighting findings made during the risk assessment for entry of FMD into Europe co-ordinated by EFSA (Appendix 6), Georgi Georgiev, concerning Bulgaria (Appendix 7), and concerning illegal importation of livestock products into Europe by Francois Moutou (Appendix 8).

The papers and discussion can be summarized as follows:

Considering that:
1. lack of early warning of the emergence of new antigenic types of FMD type A has contributed to the scale of the subsequent regional epidemic in the I. R. of Iran and Turkey;
2. incursion of an African type A virus into the Mediterranean region has occurred for the first time in Egypt in 2006, leading to a widespread and severe epidemic in the naive animal population;
3. regional or national vaccine banks do not currently exist in the countries of the Middle-East and that there is often a prolonged lead time before delivery of vaccine from commercial suppliers;
4. delay in diagnosis of the new virus incursions has resulted from the use of diagnostic methods and reagents that did not sensitively detect emergent viruses of a different type or antigenicity;
5. there is a need to identify the extent of biosecurity measures to prevent new farm infections given the cost and impact of culling and vaccination programmes, given the widespread dissemination of the type A epidemics in Turkey and Egypt, and the type O epidemic in the northern Europe in 2001 which occurred during periods of cool and humid winter conditions which favoured virus transmission;
6. significant quantities of animal products are brought by air traffic into European countries every day by passengers from FMD endemic countries in Africa and elsewhere;
7. there is an increasing trade-driven movement of livestock commodities from FMD-endemic areas in Asia.

Concludes that:
1. the level of virus surveillance and typing has not been sufficient to detect the emergent type A Iran 05 virus before spread or the circulation of the A Egypt 06 strain in East Africa in the previous 8 years before the recent incursion;
2. the antigenic variation in type A and SAT type viruses and dynamic nature of the disease situation requires continuous monitoring and risk assessment;
3. studies on the importance of each of the transmission routes for farm to farm infection in the 2001 epidemic in the United Kingdom indicate that efficiency gains in biosecurity could be an effective means to significantly reduce transmission and could strongly contribute to the control of an epidemic.

Recommends that:
1. full genome sequencing and research on the antigenic variation in type A viruses from west Asia be conducted to define the expected extent of vaccine strains required for this virus ecosystem;
2. guidelines be developed on the rate of sample collection and virus typing required to achieve early detection of new variants in west Asia and other endemic regions where antigenic variation is expected;
3. increased effort is placed on virus type surveillance effort in east Africa and sample submission to the OIE/FAO RL network;
4. the RG/WRL at each Session provides a list of priority virus strains to which diagnostic tests in the Europe and neighbouring regions be adapted, and where required revises diagnostic reagents to ensure sensitive detection of emergent viruses;
5. a review of the impact of biosecurity measures in FMD control programs in emergency FMD campaigns non-vaccinated, and the benefits: cost of raising biosecurity performance in affected and at risk zones during epidemic;
6. that guidelines for reducing risk of transmission between dairy farms in infected areas be developed or reviewed following experience obtained in the 2001 epidemic and on the basis of changing practises;
7. studies be conducted to identify the relative importance of intentional and unintentional animal products to the introduction and release of FMD into livestock in Europe, and on the likely impact of deterrent measures.

Item 2-Contingency planning and simulation exercises

Five papers were presented in this section. The first of these, presented by Tom Murray (EUFMD Commission) reviewed lessons from recent FMD simulation exercises undertaken by European countries (Appendix 9). The other three papers, from teams in Canada and New Zealand (Appendices 10 and 11) summarized advances made in the development, validation and application of models for preparing or improving contingency plans, including assessment of requirements for vaccine bank reserves, and the prediction of areas at risk of airborne spread risk (Appendix 12).

Considering that:
1. the EU requires member countries to have contingency plans against FMD and to carry out simulation exercises of outbreaks of FMD;
2. mathematical models are very useful tools for simulating outbreaks and contributing to the process of policy formulation and decision making.

Concludes that:
1. simulation exercises vary a lot between countries in terms of their scope and purpose;
2. the results of simulation exercises are not always easily available;
3. the outcome of mathematical models was very sensitive to between farm contact rates. Models in general therefore require accurate data and assumption on mechanisms of spread in order to produce reliable outputs;
4. mathematical modelling must be carried out as a multi-disciplinary process involving modellers, field epidemiologists, virologists etc;
5. mathematical models should not be used to produce policy directly but as a part of the process of policy formulation and decision support;
6. mathematical modelling is most appropriately developed and validated in between outbreaks rather than in an emergency situation.

Recommends that:
1. an expert group on FMD simulation exercises should be established which should produce a standard for the core components that national simulation exercises should contain and a standard format for reporting the results and outputs of such exercises;
2. the reports of simulation exercises should be made available on an EU website;
3. where possible, simulation exercises should include national emergency planners and representatives from neighbouring administrations;
4. data on between farm contact rates, differentiating between direct, indirect and airborne routes are required;
5. the availability of weather data and a model to estimate viral spread should be included in contingency plans. It may be helped by establishing an international database of such resources;
6. mathematical models should include realistic resource constraints;
7. models can be used to help policy makers estimate the required size of vaccine banks and their distribution and allocation in the face of different outbreak scenarios;
8. systems for establishing collaboration between mathematical modellers, field operations and virologists should be established;
9. discrepancies between models should be addressed by establishing a consensus on simulation models and their parameterization in order to improve simulation banks of possible disease spread within and between European countries for different outbreak scenarios. The QUADS process forms a good starting point for how this might be done.

Item 3-Epidemiology and Surveillance and Freedom from Disease Sessions

This section was global in coverage, concerning a global overview on FMD epidemiology (Appendix 13), the recent spread of Asia-1 (Appendix 14) in Asia, the recent epidemiology of type A strains in the middle-east (Appendix 15), recent findings on FMD epidemiology in Pakistan (Appendix 16), and three papers on FMD epidemiology in East Africa including an assessment of the role of wildlife
(Appendices 17, 18 and 19). Three papers were given on methodological developments applicable to forensic FMD epidemiology, on spatial analyses (Appendix 20), full length sequencing for genetic tracing of FMD spread in the UK (Appendix 21) and in Turkey (Appendix 22).

**Considering that:**
1. there continues to be the threat of introduction of FMD into the EU with increases in Asia1 outbreaks in Asia, new A and O strains in the Middle East and incursion of a new African A virus to Egypt;
2. Africa continues to have outbreaks of SAT 1, 2, 3, O and A with low reporting across most of the continent;
3. there are potentially few vaccine strains available to protect EU livestock populations from FMD;
4. molecular techniques are advancing rapidly allowing full genome sequencing;
5. there are new international FMD projects in affected countries, e.g. on buffalo in Pakistan;
6. persistent infections in African buffalo is still of concern;
7. NSP testing being widely used in South America and interpreted using serological profiling and cluster analysis;
8. a number of newer techniques are being developed for analysing spatial and temporal clustering of outbreaks;
9. there is still poor understanding of local spread of FMD.

**Concludes that:**
There needs to be continued efforts to collect samples and report findings from outbreaks in endemic countries particularly in Africa and the Middle East with a good and harmonized record of all relevant data;
1. there is great potential for full genome sequencing in FMD epidemiology, e.g. to identify the main routes of transmission between farms;
2. there needs to be a much better understanding of the interpretation of NSP data and the use of serological profiling and cluster analysis for differentiating true and false positive outbreak clusters;
3. there need to more study of vaccination in the face of outbreaks, both under laboratory condition and field situation.

**Recommends that:**
1. the standardization of all the reporting to the WRL should be encouraged, from the farms to the laboratory. This is also linked to the standardization of diagnostic tools, methods and reagents. Comparison of data should then be facilitated and encouraged;
2. full genome studies of selected UK outbreaks be supported to compare reported transmission routes and contacts from outbreak investigations with the most likely contacts from sequence analysis allowing prioritization of local control activities;
3. there should be more discussions/workshop with the South American epidemiologists to exchange experiences on use of NSP tests and their interpretation;
4. collaborations with sub-Saharan Africa should be intensified and expanded to better understand the epidemiology and identify the full range of viruses circulating in the region;
5. all the countries organize and standardize epidemiological surveillance systems and be supported in sample submission where necessary;
6. research and data collection is intensified regarding wildlife species of potential epidemiological importance in FMD epidemiology. However, most of the risk is linked to domestic species and to their trade.

**Item 4-Virus transmission, the art of understanding FMD spread**
Five papers were presented in this area. Two concerned research to determine the transmission risk from wild ungulates in North America (Appendix 23) and dromedary camels (Appendix 24). Two provided quantitative data on FMD transmission between cattle (Appendix 25), and n possible differences between calves and cattle (Appendix 26). One paper concerned development in modelling airborne spread (Appendix 27).

**Considering that:**
1. contingency plans should consider the role of all relevant susceptible species in FMD outbreaks, there is a lack of data regarding inter- and intra species transmission of FMDV in wildlife and camels;
2. there is a need for improved knowledge of transmission and spread livestock populations, especially those at high risk of infection (cattle).
Concludes that:
1. regarding susceptibility of selected North American wildlife to FMD:
   Bison (*Bison bison*), developed severe clinical FMD and could become infected from cattle,
   they did not transmit to calves within the studied time frame and there was no conclusive
   evidence of long term (>28 d) infection or shedding.
   Elk (*Cervus elaphus nelsoni*) are susceptible to FMD, but clinical disease is mild. There is
   little clinical or laboratory evidence of transmission between elk or elk and cattle.
   Pronghorn (*Antilocapra Americana*) are susceptible to and capable of transmitting FMD;
   lesions can be severe and would likely result in death.
   Mule deer (*Odocoileus hemionus*) are highly susceptible to FMDV and develop both oral and
   foot lesions. FMD would cause at least moderate mortality in wild mule deer. Intra and
   interspecies transmission occurred;
2. regarding susceptibility of dromedary camels to FMD:
   Dromedaries appear to be of very low susceptibility to infection with FMDV serotype O.
   Although they may become infected at low level after direct inoculation, they appear not to
   transmit infection even by close direct contact; therefore dromedary camels are unlikely to
   play any significant role in the natural epidemiology of FMD. Dromedary camels appear to
   only develop a limited initial antibody response to FMDV and no antibodies to NSP were
   detected;
3. regarding FMDV transmission between cattle:
   Transmission occurred between inoculated to donor animals (incubation period varied
   between 1 and 5 days) and FMDV infected cattle have been infectious for 4 days. No
   occurrence of transmission by the indirect contact route was observed, indicating the
difficulty of airborne transmission;
4. regarding FMDV excretion and transmission between dairy cows and calves:
   Dairy cows showed more severe clinical signs than calves and excreted virus longer in
   cows, this also depended on mode of infection. No significant difference in virus
   transmission in groups of calves and dairy cows was observed;
5. modelling airborne spread of FMDV is very complex and valid estimates require combining
   laboratory findings, good field work, modelling and experience of past outbreaks.

Recommends that:
1. more research needs to be done on the inverse age effect of FMD in cattle, including
   looking at susceptibility and differences in infectivity, and a possible association with strain-
   dependency. The relevance of the findings for contingency planning should be evaluated;
2. continued systematic and well-planned experiments in dromedary and also in Bactrian
   camels with other serotypes and isolates should be encouraged and funded by relevant
   authorities and should in due time lead to a re-evaluation of the significance, if any, of FMD
   in camels;
3. in relation to airborne spread, that more work on current serotypes including Asia1, Sat2,
   and A be carried out; to immediately initiate experiments on any new outbreak strain from
   Europe;
4. skills on clinical diagnosis and ageing of FMD lesions should be regularly up-dated;
5. the possibility of using model ensembles should be explored;
6. further studies on the role of wildlife in FMD outbreaks relevant to a range of geographical
   regions are needed.

Item 5-Vaccine development, production and selection
Four papers were presented; one on new insights into protective immune responses that provide a
rationale for vaccine development (Appendix 28); two relating to improved identification of strain
variation through monoclonal antibody profiling (Appendix 29), and on cross-protection between O
Manisa and O Campos in cattle (Appendix 30), and a paper on the characteristics and duration of
immunity in the three major species to vaccination with the oil adjuvanted Cedivac-FMD vaccine
(Appendix 31).

Considering that:
1. whereas existing vaccines can suppress clinical signs and limit the spread of disease, they
   cannot prevent the carrier state. They also cover only a limited number of strains and after
   several months to a year revaccination is required to maintain protection. In order to be
   able to develop improved and new vaccines, we need a better understanding of the
   immune mechanisms protecting an animal from FMDV infection. In particular, the roles of
   cellular immunology and cytokines need to be investigated;
2. in a field situation, the "challenge strains" circulating in a population will mostly deviate to
   some extent from the vaccine strain used. FMD-free countries maintaining a vaccine bank,
which can only contain a limited number of strains, will have to use an existing vaccine when FMD is introduced. It takes several months to adapt a field isolate to a production system and perform the necessary tests on the new seed strain and the vaccine derived from it. From many field isolates satisfactory master seed strains for vaccines can not be produced at all. Since the decision on which vaccine strain should be used – or whether vaccination is not an option due to the lack of a vaccine suitable for the strain that was introduced - has to be made within days, it has to be based on in-vitro methods. However, the results of existing in-vitro methods for the choice of vaccines (e.g. ELISA- and SNT – based r-values) currently can only be interpreted according to “rules of thumb” lacking a sound scientific basis;

3. since the number of available vaccine doses is limited and also due to the costs and logistic problems of a vaccination campaign, the question whether or not (and when) a revaccination has to be performed requires careful consideration, for which - especially in a “heterologous” situation - a satisfactory data base may be missing.

Concludes that:
1. the immune response to an infection and the mechanisms providing protection must be studied in more detail;
2. there is an urgent need to test the ability of vaccine strains to protect against heterologous strains and correlate it to the results of in-vitro methods like r-values, sequences and mab-binding profiles;
3. there is insufficient knowledge on the duration of immunity, in particular in respect to heterologous strains.

Recommends that:
Research projects should be funded to improve the scientific basis for the development of new vaccines as well as the improvement, selection and usage of existing vaccines.

Item 6-Vaccine control: Validation, Quality Control and Quality Assurance

Four papers were presented; one concerned interpretation of potency test results in light of new findings on between test variability (Appendix 32), and on variables that affect the relationship between potency of a vaccine and protection (Appendix 33); the other two concerned potential use of cell mediated immune responses as an additional read out after immunization (Appendix 34) and the use of proteomics methods in production quality control to characterize the amount and integrity of FMD vaccine antigens (Appendix 35).

Considering that:
1. vaccine control remains essential especially in the framework of emergency vaccination;
2. a study on the variability of the European Pharmacopoeia FMD vaccine potency test clearly indicated wide confidence intervals around the obtained PD50 result. Therefore, it is not possible to discriminate between a vaccine with a PD50 of 3, 6 or 10 based on the outcome of a single potency trial;
3. the relationship between vaccine potency and the proportion of protected cattle is influenced by serotype, type of adjuvant, valency and method of potency test;
4. a positive correlation was found between IFN-gamma response in cattle and protection against clinical disease;
5. novel proteomics techniques can be used for in process control of vaccine antigens leading to faster process development and cost efficient manufacturing.

Concludes that:
1. the design of the Ph.Eur. FMD PD50 potency test leads to low in vivo repeatability and reproducibility;
2. the potency of a vaccine might be better represented by estimating the proportion of protected animals rather than the amount of PD50;
3. preliminary findings on cell-mediated immunity related to protection against FMD are promising.

Recommends that:
1. statistical validation of alternative potency methods is needed to make any further revision of the FMD Ph.Eur. Monograph possible;
2. further studies are required to verify whether changing to proportion protected animals will makes it easier to replace vaccine potency tests by serological tests;
3. confirmation of the preliminary positive correlation between IFN-gamma response in cattle and protection against clinical disease is needed, also regarding other serotypes.
**Item 7-Vaccine application**
The increased attention to vaccine application issues has given rise to seven papers in this field, and the experimental results involved the major three species. Two papers concerned antibody responses (Appendix 36), including the use of Cedivac-FMD as a marker vaccine (Appendix 37). Two concerned the effect of high potency vaccines on protection against contact challenge (Appendix 38) and impact of vaccination on transmission of virus between sheep (Appendix 39); a further concerned response to vaccination and infection in pigs (Appendix 40). Two further concerned immunoprophylaxis with antibody fragments (Appendix 41) and protection of pigs against challenge with a peptide vaccine (Appendix 42).

**Considering that:**
following regulatory revision in the EU, FMD emergency vaccination without subsequent slaughter of vaccinates is an option in emergency disease management.

**Concludes that:**
1. presently available FMD vaccines promote levels of antibodies in susceptible species, which are likely to provide protection from challenge providing adequate time is allowed for the response to develop. The time required to develop an adequate response depends on the intensity of the challenge;
2. vaccination reduces virus replication (and therefore virus excretion) in cattle pigs and sheep, which would potentially reduce transmission during an outbreak;
3. FMD vaccines licensed for use in Europe do not induce antibodies against non-structural proteins, allowing the use of FMD emergency vaccination during an outbreak and the consecutive testing for spread of virus using ELISAs that can detect antibodies against non-structural proteins;
4. recombinant antibody fragments are still unable to protect pigs completely although virus excretion was reduced;
5. dendrimer peptides including B and T cell epitopes show potential for providing protection in pigs;
6. development of IgA responses following vaccination may provide for a more effective protection.

**Recommends that:**
1. in order to rapidly apply vaccination in crisis situations, governments should identify areas where FMD emergency vaccination will be necessary if an FMD outbreak occurs;
2. further studies on the correlation between IgA response after vaccination and protection are needed.

**Item 8-Diagnostics: Detection and Typing of Infection**
Five papers were presented. One concerned development of MAbs for characterization and diagnostic test development for SAT1 and SAT2 viruses (Appendix 43); one on diagnosis in water buffaloes (Appendix 44); and three on development of rapid FMD diagnostic methods, including validation of RT-PCR for FMDV performed on mobile equipment (Appendix 45), the use of thermal imaging to screen animals for febrile conditions that may assist selection of animals for FMD testing (Appendix 46), and a novel and simple diagnostic method involving LAMP amplification that may provide a simplified alternative to PCR (Appendix 47).

**Considering that:**
1. early detection and typing of FMD viruses may reduce the number and severity of FMD epidemics;
2. antigen detection and antigen typing assays may benefit from the use of monoclonal antibodies;
3. in addition to laboratory-based molecular diagnostic assays with high throughput and sensitivity, more user friendliness devices based on genome detection (portable PCR technology, isothermal techniques) or antigen detection (ELISAs, Lateral flow chromatography) are being developed.

**Concludes that:**
1. in a further step done in the characterization of the antigenic structure of FMD viruses by using monoclonal antibodies: the G-H loop of VP1 was confirmed to contain a major antigenic determinant also in SAT 1 and SAT 2 serotypes, and in addition new conformational sites were detected in these serotypes;
2. simplified ELISAs using pan-FMDV or type-specific monoclonal antibodies showed potential for the detection and typing of all the seven FMDV serotypes;
3. a range of sensitive molecular diagnostic techniques with different levels of automation, speed and throughput are available for use in central and regional laboratories or in the field. A new isothermal method (RT-LAMP) may be particularly suitable as sensitive, simple and cheap test at the pen-side level;
4. the thermal imaging instrument for detection of the acute temperature and heat production at the feet of pigs and ruminants during the acute phase of FMD is not specific but can be used as support device for detection of FMD suspected animals in large sick herds.

Recommends that:
1. the activities of the laboratories producing and characterizing monoclonal antibodies should continue and be sustained as one of the strategic sources for diagnostic reagents, suited for typing of emergent FMD viruses;
2. validation, including investigations of field samples, of novel diagnostic platforms either based on genome or antigen detection should be conducted with high priority. Resources and further studies should be dedicated particularly to the development and exploitation of cheap, simplified and rapid test-devices usable in the field;
3. guidelines for use of field-based tests, as part of contingency plans and in developing countries, should be established;
4. further data, including measurements in field cases, should be collected with the thermal imaging instrument.

Item 9-Diagnostics: DIVA tests
Eight papers were presented, relating to remaining issues with DIVA tests, including serum panels for NSP test evaluation (Appendix 48), and novel approaches to the analysis of DIVA test results, using a Bayesian framework (Appendix 49) and likelihoods ratios (Appendix 50). Two studies related to validation of DIVA test for use in vaccinated pigs (Appendices 51 and 52). Three studies reported on #ABC (Appendix 53) or 3D ELISAs (Appendix 54) as potential confirmatory test (Appendix 55).

Considering that:
DIVA tests are important tools in substantiating freedom from infection following an FMD outbreak. Some of them have been extensively validated and guidelines on the application of DIVA tests in post outbreak serosurveillance programmes are available. Apart from the six validated DIVA tests, new assays are being developed based either on the same NSP antigen or on alternative approaches (e.g. detection of serum antibody to FMDV-3D and FMDV-specific IgA in saliva).

Concludes that:
1. in addition to the more classical comparison of different tests, other methods, such as Bayesian analysis and the use of likelihood ratios, are being applied to compare the performance of diagnostic tests. These methods can be of assistance in the interpretation of test results;
2. the bovine serum panel that has been developed could be a valuable tool in evaluating recently developed and future NSP-based assays;
3. detection of FMDV-specific IgA in saliva has been shown to be a supplementary source of information in differentiating between vaccinated and infected cattle; the same should be true for both pigs and small ruminants;
4. in a field study of vaccinated and vaccinated and infected pigs, infection was readily detected by each of three NSP tests although discrepancies and differences in diagnostic sensitivities and specificities were observed between tests.

Recommends that:
1. ovine and porcine serum panels should be assembled in order to evaluate the performance of different NSP-based DIVA tests in small ruminants and pigs; an inventory should be prepared of all of the available sera which have been collected from experimental animals (small ruminants and pigs) by the different laboratories participating in these test evaluation studies;
2. conditions attaching to the use of serum panels should be established and should be circulated in the form of "guidelines" to all potential users; participating laboratories should agree to abide by these conditions/guidelines, in advance of receiving serum panels;
3. in order to reliably estimate sensitivity and specificity parameters for different DIVA tests in pigs, more data is needed on the occurrence of subclinical infection in vaccinated pigs and on the performance of the various tests in subclinically-infected herds;
4. FMDV-specific IgA responses in saliva should be evaluated in both small ruminants and pigs, for both vaccinated and vaccinated and infected animals.
Item 10-Diagnostics: Confidence in results: Quality Control/Quality Assurance

This section mainly concerned the results and lessons learnt from the most recent FAO supported laboratory proficiency exercises (Phase XIX), which included for the first time both a proficiency panel for FMDV detection (Appendix 56) and serology (Appendix 57). The issue and measurement and reporting of uncertainty in ELISA tests was the subject of one paper (Appendix 58).

Considering that:
1. it is essential that laboratories understand the performance characteristics of their tests and that there are common standards in testing between laboratories;
2. it is a relatively simple matter to establish the degree of confidence in a particular laboratory test result by performing repeatability studies on samples covering the entire range of test result values;
3. inter-laboratory testing exercises provide a valuable opportunity to compare which tests are used, how they are done and how their results compare after testing a common set of coded samples. This can provide a platform for improvement and harmonization of methods.

Concludes that:
1. a simple method can be established within each laboratory for correlating confidence in a given qualitative test result to the quantitative read-out of the test itself;
2. the recently conducted Phase XIX inter-laboratory comparative trial has provided information on usage and performance of many tests in a large number of laboratories within Europe and the wider world;
3. many conclusions can be made about differences between laboratories, but one striking discrepancy was in the sensitivity of methods for virus isolation in cell culture.

Recommends that:
1. the results of Phase XIX should be further analysed and discussed in detail at the forthcoming meeting of the National EU FMD Reference Laboratories in Brussels next month and should be discussed with EUFMD;
2. it is important that participants are given individual feedback concerning their performance and consideration needs to be given to other follow-up in relation to discrepancies identified. In this respect there is a need for a clear procedure to be followed taking into account the relationship with the CVO;
3. consideration should also be given to establishing small-scale, but more regular system of external quality assurance using panels of virus-free sera, possibly distributed by a company specialising in this process;
4. future studies should aim to harmonise serology used for monitoring the efficacy of vaccination;
5. phase XX should include inactivated antigens to enable PCR tests in laboratories without BSL3 facilities.

Item 11-Virus - host interaction

The papers in this section related to cytokine induction at tissue level during persistent infection of cattle (Appendix 59), pre-natal infection of lambs (Appendix 60), the question of persistent infection in piglets (Appendix 61), and detection of amino-acid changes in FMDV VP2 associated with persistent infection (Appendix 62).

The use of anti-viral agents in vitro (Appendix 63) and in vivo, where inhibition of virus excretion in pigs was reported (Appendix 64), provided evidence of potentially new strategies and tools for outbreak FMD control.

Considering that:
1. local cytokine responses in cattle (during the acute stages of FMDV infection in cattle) differ between sites of viral persistence and lesion predilection sites;
2. persistence of FMDV in the oropharynx of cattle is associated with a single amino acid change in the VP2 protein of the infecting virus;
3. using RT-PCR, virus has been detected in tonsillar tissue of pigs at more than 28 days after experimental infection;
4. anti-viral agents have been shown to inhibit the replication of FMDV both in vitro and in vivo.
**Concludes that:**  
1. both virus- and host-related factors appear to play a role in the development of the "carrier" state in cattle;  
2. FMDV infection may persist in the oropharynx of infected pigs, for longer than previously thought (albeit at a much lower level than in cattle);  
3. anti-viral agents have been shown to inhibit FMDV replication both in vitro and in vivo and may have potential for use in controlling the spread of infection during an outbreak.

**Recommends that:**  
1. further studies on FMD pathogenesis and virus-host interactions should be considered as a high priority area for research funding;  
2. viral and host factors which may lead to persistence of FMDV infection should further investigated; the scope of such studies should be broadened to consider different serotypes of the virus and virus isolated from naturally-occurring "carrier" animals;  
3. the safety and efficacy of anti-viral agents should be studied in a field (disease outbreak) situation in an FMD-endemic area; further studies should also focus on the likelihood of FMDV developing resistance to these anti-viral compounds.

**Item 12-Poster Session**

Seventeen posters were presented, containing novel and important findings, and falling under 6 themes.

**Considering that:**  
1. a platform of simple ELISA based on the selected monoclonal antibodies has been used for the specific typing of all FMDV serotypes and for the type independent detection pf any FMDV strain;  
2. automated extraction methods have been developed to simplify and increase RNA isolation efficacy for effective FMDV PCR implementation;  
3. a novel artificial recombinant CPMV viruses, containing sequences that can act as internal controls for the diagnostic rRT-PCR for FMDV and SVDV have been developed;  
4. development of rapid “field – portable” diagnostic equipment for RT-PCR has been described. Real time RT-PCR assay foe FMDV is developed on the basis of Bio-Seq TM;  
5. a strain specific rRt-PCR assay for analysis of FMDV replication in vivo has been developed;  
6. a sensitive real time RT-PCR method have been developed (TaqMan) for specific detection of all seven serotypes of FMD virus;  
7. an Adenovirus system has been used for gene delivery system. Four different adenoviruses in cocktail inhibiting FMDV replication and clinical symptoms in vivo;  
8. molecular characterizations of FMDV virus isolates from 2002 in Korea have been done. The biology and nucleotide sequences in pig and cattle isolates were present;  
9. the first generation of microarray is capable of determining different serotypes of FMDV. The second generation is now on the way;  
10. FMDV was reproduced in Drsophila Snaider 2 cell system for driving a non-infectious material – virus-like particles for research purposes;  
11. two types of derivates of FMDV (differing by plaque formation, their biological characteristics and growth in cell cultures) were studied in pathogenesis in mice;  
12. the mechanism of cell mediated immune response in FMDV vaccine protection was studied and the role of cytotoxic T- lymphocyte response was investigated;  
13. two dominant B–cell epitopes of FMDV were modified and the experiments for the better understanding of the mechanisms of FMDV antibody protection were carried out;  
14. the efficacy of T-1105 –Na antiviral agent was evaluated by subcutaneous injection of FMDV infected pigs and measurement of the virus excretion;  
15. a sensitive validated alternative batch potency test based on serology (e.g. SNT, ELISA) has been established to develop a laboratory independent statistically valid correlation between serology and protection;  
16. 3D protein was cloned, expressed and used in NSP ELISA for surveillance purposes;  
17. the studies on comparative virulence of SVDV from Italy 1992-1997 showed a reduced virulence but they can elicit clinical signs and lesions. This phenomenon has no explanation till now;  
18. a network of FAO and OIE for FMD RL has been established for the informatics network trough world web site.

**Concludes that:**  
1. application of new variants of RT-PCR method for screening of a large number of samples for FMDV diagnosis gives the guarantee for efficacy and accuracy diagnosis;
2. the novel generation of microarray assay for determining different serotypes of FMDV is a new approach of FMD diagnosis;
3. studies on biological properties and pathogenesis of FMDV should attempt to develop new specific virus inhibitors;
4. studies on humoral and T-cell mediated immunity of FMDV helps for the better understanding of the mechanisms of FMDV antibody protection.

Recommends that:
Work on optimization of and validation of a portable RT-PCR machine for the detection of FMDV should be done.

List of titles presented in Poster Session

I. FMDV diagnosis using the molecular biological methods and monoclonal antibodies as follows:

1. Santina Grazioli et al.
Monoclonal antibody-based multiplex ELISA for the detection and typing seven serotypes of FMDV
A platform of simple ELISA based on the selected monoclonal antibodies has been used for the specific typing of all FMDV serotypes and for the type independent detection of any FMDV strain.

2. Katja Ebert et al.
Comparison of RNA extraction methods for RT-PCR diagnosis of FMDV
Automated extraction methods have been developed to simplify and increase RNA isolation efficacy for effective FMDV PCR implementation.

3. Donald King et al
Development of a novel encapsulated internal control for rRT-PCR
A novel artificial recombinant CPMV virus, containing sequences that can act as internal controls for the diagnostic rRT-PCR for FMDV and SVDV has been developed.

4. Donald King et al.
Detection of FMDV using a field – portable PCR equipment
Development of rapid “field – portable” diagnostic equipment for RT-PCR has been described. Real time RT-PCR assay for FMDV is developed on the basis of Bio-Seq TM. Work on optimization and validations of the reaction are on the way.

5. J. Horsington et al.
Development of a strand specific real-time RT-PCR assay for analysis of foot and mouth disease virus replication in vivo

6. Lily Polihronova and Georgi Georgiev
Application of TaqMan real time RT PCR for diagnosis of FMDV and correlation with SYBR Green PCR data
Sensitive real time RT-PCR methods have been developed (TaqMan and SYBR Green). TaqMan real time RT-PCR is sensitive method for specific detection of all seven serotypes of FMD virus. Application of this assay will increase the capacity of the laboratory to process larger number of samples and to get the results in one working day. This is very convenient for screening of large number of samples and will guarantee our diagnostic ability for FMDV laboratory confirmation in case of FMD outbreak in Bulgaria.

II. Studies on biological properties and pathogenesis of FMDV

1. Kwangnyeong-Lee
Antiviral strategy for FMD control in pig using adenovectors
Adenovirus system has been used for gene delivery system. Four different adenoviruses inhibiting FMDV replication in vitro and in vivo.

2. Kwang – Lee
Molecular characterization of FMDV isolates from Korea 2002
Molecular characterization of FMDV virus isolates from 2002 in Korea has been done. The biology and nucleotide sequences in pig and cattle isolates were present.
3. Julliet P. Dukes et al.  
**Development of microarray for viral characterization**
The first generation of microarray is capable of determining different serotypes of FMDV. The second generation is now on the way.

4. Michelle Remond et al.  
**Towards the production of FMD virus-like particles in Drsophila Snaider 2 cells**
FMDV was reproduced in Drsophila Snaider 2 cell system for driving a non-infectious material – virus like particles for research purposes.

5. Kozuki Morioka et al.  
**Comparison of the pathogenicity to suckling mice using O/JPN/2000 derivate of FMDV**
Two types of derivates of FMDV (differing by plaque formation, their biological characteristics and growth in cell cultures) were studied in pathogenesis in mice.

**III. Studies on humoral and T-cell mediated immunity of FMDV:**

1. Annette Barfoed et al.  
**Identification of immuno-dominant but non-protective FMDV CTL epitope in Balb/C mice**
The mechanism of cell mediated immune response in FMDV vaccine protection was studied and the role of cytotoxic T lymphocyte response was investigated.

2. Tina Friman et al.  
**Humoral immunity against FMDV - significance of dominant and sub-dominant protective B-cells epitopes**
Two dominant B-cell epitopes of FMDV were modified and the experiments for the better understanding of the mechanisms of FMDV antibody protection were carried out.

3. Seiichi Ohashi  
**Examination of control of FMDV excretion in the infected pigs by subcutaneous injection of antiviral agent _T-1105 –Na**
The efficacy of _T-1105 –Na_ antiviral agent was evaluated by subcutaneous injection of FMDV infected pigs and measurement of the virus excretion.

**IV. Molecular-biological studies on structural and non-structural proteins of FMDV:**

1. Kaiser Claude et al.  
**Cloning, expression and use of non-structural protein 3D expressed in insect cells for the surveillance of FMDV**
3D protein was cloned, expressed and used in NSP ELISA for surveillance purposes.

**V. Studies on biology and virulence of SVDV:**

1. Kristen Tjornehoj and Soren Alexandersen  
**Virulence of SVDV: Preliminary studies of comparative virulence of Italian SVDV isolates from 1992-1997**
The studies on comparative virulence of SVDV from Italy 1992-1997 showed a reduced virulence but they can elicit clinical signs and lesions. This phenomenon has no explanation until now.

**VI. Web Information system of OIE and FAO for FMD and other exotic diseases**

1. Julie Stirling et al.  
**Plus for the exchanging FMD RL information via the World Wide Web**
A network of FAO and OIE for FMD RL has been established for the informatics network through web site.
REPORT ON DISCUSSIONS HELD IN THE CLOSED SESSION

20 October 2006

Item 1 - Update from FAO

1. Crisis Management Centre (CMC)
KS updated the Session on the opening of the CMC in FAO in early October 2006 with funding from a number of donors, with the objective to increase the efficiency of response to new animal health and food chain emergencies and in particular to ensure a rapid response to new AI situations. The CMC Manager will be Dr Karin Schwabenbauer, former CVO Germany and Chair of the EUFMD Commission. He indicated that one advantage for the group might be ease of setting up tele/video conferencing to assist the task forces in their actions and as required set up other forms of virtual group meetings. In addition the CMC was developing its rosters of experts to be called upon in crises and since the RG members were de facto part of the EUFMD crisis management team, he invited members of the group to indicate willingness to serve also as experts for the CMC.

Action:
KS to arrange for RG members to be contacted to provide information for the CMC roster of experts.

2. FAO Reference Laboratory (RL) and Collaborating Centre positions
KS indicated that FAO had frozen the process of registration of new RL for more than 2 years, but that that re-opening was expected in some few weeks time. The terms and responsibilities to be expected of RL designation were in process of finalization and he was not in a position to circulate these to the group, but would do so as soon as he was able.

He suggested that the process would be similar to that of the OIE and that since FAO were developing a number of lab networks with the OIE that there would be opportunity to expand the membership of the OIE/FAO FMD RL network with additional FAO laboratories which could significantly address issues of coverage of the RRL.

In discussion it was agreed that the interests of NRLs should be recognized by FAO, and that the possibility of non-regional RL be recognized in order to address issues of participation and global coverage; that clear tasks should be set and that the identification and monitoring of these tasks could be the work of laboratory networks.

Action:
KS to provide the draft or finalized criteria and terms for RL to the members as soon as possible.

3. Recent and upcoming Regional FMD (network) meetings under GF-TADS
KS highlighted the new possibilities for FMD surveillance and technical networking under the arrangements with OIE, for example through the Regional GF-TADS for the priority setting at CVO level and through the use of the personnel newly placed in FAO/OIE Regional animal health centres (RAHC) to support project implementation for sample collection and typing. The 3 RAHC in Africa should be of major interest (Bamako, Nairobi and Gaborone) which will be operated together with the AU-IBAR. He indicated that there had been a successful meeting in Nairobi in August for the East African/Great Lakes region countries which had agree the need to establish an east African network on FMD surveillance and control and was developing proposals for supporting surveillance, looking to BVI Botswana, WRL Pirbright and the Danish funded project in Uganda to support virus typing.

He indicated the upcoming FAO/OIE regional meeting in Damascus for the middle-east countries to which he and Nigel Ferris (WRL) would be the EUFMD and WRL representatives.

The group discussed if EUFMD Commission or RG should be present at FMD regional network meetings and agreed that the FAO/OIE organisers should invite representation.

Action:
FAO to bring the importance of invitation of EUFMD/WRL to the attention of the secretaries and organisers of the regional network meetings on FMD surveillance.

Recommendation:
Since disease movements are often inter-regional, GF-TADS Committees should routinely invite representatives from the neighbouring regions to their meetings.
4. **Location of next EUFMD RG meetings**

2007 – Egypt, with a suggested extra day included for a seminar or information exchange with Egyptian FMD experts including visits to relevant laboratories. The fall back location would be The Netherlands.

2008 – Open Session; Southern Italy (Sardinia/Sicily), but the possibility of holding the Open Session to mark the 50th Anniversary of the founding of the WRL should also be considered, and options to be presented for decision at the next EUFMD Executive.

**Action:**

KS to identify dates and reconfirm the interest of the SVSRI Egypt to host the 2007 Session. EB and Secretariat relating to the Italy 2008 and DP/KS relating to possible event to mark the 50th anniversary of the WRL.

**Item 2 - FMD situation report and technical issues arising from EUFMD/EC programmes and missions**

1. **Turkey (NH: Nick Honhold, FAO)**

a. Recent FMD outbreak distribution and vaccination program in Thrace and Anatolia

NH provided an update; over 700 outbreaks of FMD had occurred in 2006, peaking in June and followed by 65 in period July-September; of concern was the wide distribution of recent outbreaks, affecting 33 of the 81 Provinces. The autumn campaign had been affected by lack of vaccine, although the 2.7 million doses from the EU-VB had been an enormous help. To date of report, the latter campaign had achieved only 14% coverage in Anatolia, 58% in Thrace and 16% in Marmara regions. The GDPC had placed great emphasis on the protection of Thrace as a matter of national pride and regional responsibility, and so had agreed to the proposed early revaccination of Thrace as recommended by the EUFMD Commission.

b. Vaccination vs type A Iran 05 (discussion on A22 suitability; DP/WRL)

DP reviewed the data from vaccine matching of A22 vaccines for use against the A Iran 05 strain; he considered that the data indicated acceptable r1 values with A22 Iraq and A22 Mahmatli, but far lower with A22 550/Azb64. Since both WRL and the SAP Institute (via EUFMD) had supplied A Iran 05 isolates to FGI-ARRIAH, they should be in a position to undertake their own cross-matching studies and identify if better alternatives to A22 550/Azb 64 exist. He indicated that the most recent virus isolates had not yet been vaccine matched and that he had not been aware of GDPC concerns that A22 Mahmatli did not provide cross-protection.

He recommended that if possible FAO/EUFMD should support GDPC to strengthen FMD outbreak investigation this autumn/winter, for example through recruiting national consultants to train regional staff to investigate FMD in their areas.

Data from vaccinated and exposed herds in the field would assist to understand the perceived problem with A22 Mahmatli protection in the field.

**Action:**

Field data should be assembled relating to A22 protection in the face of field outbreaks in Turkey and other locations.

Similarly, evidence should be provided from Iran to back claims that A Iran 87 (Merial) protects against field exposure to A Iran 05 type.

c. Progress on the Thrace sero-surveillance – including Balabancik study conducted under FAO Letter of Agreement (LoA) with SAP Institute (NH).

Field and laboratory activities in the Balabancik village study have been completed. The study was designed by Koen Mintiens (VAR Belgium), on mission for EUFMD, working with the GDPC, and implemented by the SAP Institute; preliminary data available indicated a prevalence of 5.14% in 3385 cattle sampled, of which only 33% of positive animals were on diseased farms. In contrast sheep exposure was low, less than 1% of the 600 sheep sampled. Further analysis of the data is required.
Action:
Koen Mintiens/Naci Bulut to work together on analysis.

d. Autumn sero-surveillance in Thrace: support to surveillance – autumn/winter 2006 (NH)
   Sample collection is thought to have occurred; information from Naci Bulut/SAP Institute is needed on this.

Action:
Secretariat to request progress report and serological findings; GDPC report expected before 17th November Tripartite meeting. Mark Bronsvoort to assist Naci Bulut on the analysis of NSP data.

2. Iran (Francis Geiger, Vinod Otorod)
   a. Project progress report
      FG provided an overview of the project progress, focussing on the FMD surveillance in pilot study areas and the new line management within the project to improve quality and speed of information flow. Since Feb 2006 the project has made good progress on several fronts, including several training missions to Iran and to Pirbright, and workshop on virus circulation in the region.
      VO then presented results from the 7 pilot study areas (Appendix 65). Through mapping of disease outbreaks in relation to use of vaccination, he indicated that:
      • there are significant gaps in application in villages surrounding outbreaks which may allow local spread and persistence;
      • vaccination tends to focus on fattening and dairy farms, and areas without these tend to have little or no vaccination;
      • Provinces with extensive village based livestock such as west Azerbaijan tend to have low vaccination cover.
      In future it is hoped that the local vaccination management will be assisted by more rapid identification of non-vaccinated populations.
      Further, the project had decided to focus attention on FMD in hotspots, such as major animal markets where the chance to recover a recently introduced FMDV virus seemed greatest; this should provide evidence of virus circulation within Iran and possibly from distant locations including Afghanistan.
      He confidently predicted that with development of the project to help design control programs, in 5 years FMD should be controlled in Western Iran.

Action:
The 6 month of a scientist to WRL to undertake training and collaborative research on molecular epidemiology should produce significant results/report before next meeting. Technical assistance to implement SP tests at CVL Karaj may require further RG assistance (FG/WRL/KdC).

   b. Technical issues; serology (LBPE or other SP tests)
      FG indicated that there had been major problems to import LBPE kits (cold chain breakdowns on shipment) and asked for RG opinion on alternative kits or on the use of stabilized/freeze dried reagents in LPBE.
      The group discussed the alternatives for SP ELISA for the purpose of vaccination monitoring.

Conclusion:
At present, the LPBE should continue to be used but that studies on the correlation between LPBE and SPCE should be conducted on sera from potency test experiments to identify threshold values in SPCE for protection (new task of the RG; AD to lead).

1 Presentations prepared:
V. Otarod: "Iran GISVET: FMD Surveillance in the 7 pilot areas from 03-2006 to 09-2006
Francis Geiger: " FMD Surveillance in Iran: potential solution for better knowledge of FMD situation at regional level"
H. Mahravani will present a ppt in open Session: "Evolution of FMDV in Iran in 2005 and 2006. Abstract in booklet
3. **Caucasus (Georgia, Armenia and Azerbaijan)**
   
a. **Update - Vaccination and surveillance plans – EUFMD/EC supported program (Carsten Potsch; CP)**
   
   CP (EUFMD-FAO, Tbilisi) provided a progress report on the progress of the buffer zone project in the Caucasus (Georgia, GEO, Armenia, ARM, Azerbaijan, AZB) in 2006 (Appendix 66). Since establishing an office in Tbilisi for the project, several opportunities had arisen for technical studies in the field which would not have occurred otherwise. The vaccination for the autumn campaign in the BZ is with quadrivalent (QV) vaccine (two A types, A22 550/Abz 64, A Armenia 98, O and Asia-1); ARRIAH have been provided with recent A Iran 05 viruses and will be undertaking cross-protection assays and should have results by mid November 06. If these are not satisfactory (ARRIAH are required to report to FAO) then ARRIAH should replace their A22 with a better matched vaccine, possibly homologous to A Iran 05. He indicated that since his recruitment in June 2006 he had had several opportunities to address technical questions arising from decisions taken at national level to purchase non-OIE standard vaccines. The use of a range of vaccines in the countries presented a challenge for post vaccination surveillance which should lead to some interesting technical studies over the next year.

   AF asked for map of the current vaccination progress in the BZ, and indicating national funded vaccinations particularly in GEO and AZB where national vaccination effort has been reduced compared to previous years.

   **Action:**
   
   CP will provide updated vaccination maps on monthly basis to EUFMD/EC.

b. **Technical issues arising:**
   
   i. **Surveillance design**

      It was agreed that the sero-surveillance design for 2007 should be discussed and agreed by a wider task force from the RG, following the results of the 2006 autumn sero-survey in the BZ. A specific meeting may be called on this. Nagornyi-Karabakh; this area should not be omitted in sero-surveillance.

   ii. **Frequency of vaccination and duration of immunity of current vaccines**

      CP asked for technical guidance on replacement of aqueous Al-OH with oil adjuvanted vaccines; AD indicated that there are indications that Oil vaccines are less stable, and for the purpose of vaccination of ruminants aqueous vaccines are probably as effective. The only advantage of Oil vaccines in ruminants might be the possible induction of an immune response in young animals with maternally derived antibodies.

   **Recommendations:**
   
   - Pre-vaccination surveillance is used to identify if there is a problem of immunity in the current 6 month interval program in the BZ.
   - An analysis of options is made, considering the performance of oil based vaccines and benefit/cost of vaccination at intervals of more than 6 months.
   - The project considers feasibility of stability testing in the field (vaccines held at different temperatures for extended periods and tested for serological response in a controlled trial in one of the countries).

   **Action:**
   
   CP to draft protocols to undertake the above recommendations, requesting RG support as required.

   i. **NSP induction by lapinized /other vaccines**

      The project had initiated a study on NSP and SP induction by lapinized vaccines (Kyrgyzstan and Armenian produced), using OIE and EC position paper protocols. The serum from these experiments would be provided to IZS Brescia, together with samples from the sero-monitoring pre- and post- the autumn vaccination program; the results should be important to determining if NSP serology is possible in areas that have used these vaccines.

   **Recommendations:**
   
   - To obtain permission to send the vaccine batches to the WRL for analysis of virus type and content.
   - Collect serum, just before 2nd vaccination, for supply to WRL where reactivity against A Iran 05 type field isolates can be measured.
ii. Laboratory issues - serological testing – 2006 (CP/EB)

The IZS Brescia had agreed to provide training for lab staff in SP and NSP methods, supplementing that provided by GG in 2004 and preparing the way for introduction of standardized tests, protocols and performance monitoring in 2007. IZS Brescia would also test sera for post-vaccination antibody titres (SP tests) and NSP (in house test). EB would distribute some post-vaccination sera to AD and DP for comparative testing using Cedi SP ELISA and LPBE respectively. Following the testing and training a decision will be taken regarding the SP tests to be introduced into national labs in ARM and AZB in 2007. In GEO the US funded project has established LPBE and Cedi-test as the SP and NSP test methods. GG was concerned that the NRLs will have received different reagents/kits (ARRIAH, Cedi, Brescia) and that an agreement on standardization was essential.

iii. Policy on selection of SP and NSP tests and establishment of laboratory performance for application (discussion)

NSP test; it was agreed that the Cedi-NSP test will continue to be standard NSP test kit for NRLs in the EUFMD projects, in line with recommendations for Turkey.

SP tests: decision should be taken in spring 2007, after the planned testing of samples from the 2006 serology and training on SP test performance and standardization.

4. Egypt: vaccination vs Type A Egypt 2006:

a. Development of epidemic in Egypt

KS updated the RG on what was known of the development of the epidemic in Egypt. He indicated a strong need for developing collaboration between the RG and the Egyptian veterinary service to assist the state laboratories in diagnostic test capability and performance, and significant value in collaboration on field studies, to follow up the recent epidemic and to assess the level of vaccine application and the lack of virus circulation. He suggested a laboratory twinning might assist, and called for volunteers with experience also in vaccine production/control (Lelystad?).

Action:
KS will follow up with GOVS at the FAO/OIE Roundtable on FMD control, in Damascus (Nov 6-7th).

b. Progress report of heterologous challenge (A22 Iraq vaccination) (LoA with FLI - Bernd Haas; BH)

This study had been funded by EC via the EC Trust Fund in FAO (MTF/INT/003/EEC). The standard EP protocol had been used to challenge A22 vaccinated cattle with A Egypt 06. The potency was estimated at 10 PD50, and by serology the initial estimate of the PD50 expected from a homologous challenge was 32. The results justify the experiment and suggest A22 Iraq could be used in vaccination; very careful consideration should be given before the use of other A22 Iraq vaccines could be considered unless the homologous PD50 was at least as high.

5. Common technical issues – opportunities for collaborative projects (discussion)

Example: Diagnostic issues: improving field collection procedures.

The problem of FMDV inactivation during submission to the lab was discussed. Possible use of virus stabilizers other than glycerol or of RNA stabilizers (such as TriZol) before RT-PCR are options that could be evaluated in Iran and/or Turkey.

Action:
FG agreed that could be developed into a field trial under the project in Iran, with the involvement of Nazem Shirazi (seconded under the IVO/EUFMD project to WRL)
**Item 3 - Technical issues referred from EUFMD Executive (panel discussion)**

1. Antigenic variation in type A
   a. Naming of antigenic variants
      DP indicated the current convention for FMDV; serotype>topotype>strain>. He agreed that problems in strain nomenclature remained, which can lead to confusion.

**Conclusion:**
Since NRLs in endemic regions are increasingly virus characterization including sequencing it will be important that they adopt the WRL standard for naming and are able to make comparison to reference sequences from each topotype. DP updated the plans for this to be made possible via the WRL website.

**Action:**
WRL (DP/Nick Knowles) to provide a short working definition of the currently used nomenclature categories and to make available sequences representing all topotypes via their website to assist countries to standardize description of FMDV in their reporting (e.g. to OIE/FAO).

b. Variation; guidance on expected extent and frequency of type A variation
   KS indicated the interest of the Executive in the issue of the extent of variation in antigenic types that could be expected from within the west Asian pool of type A viruses, given that A22, A Iran 96, A Iran 99, A Iran 05 have emerged from possibly the same pool. The practical value of this should be to predict the range of type A vaccine antigens required for region required by the vaccine banks. It was agreed that this was an important and researchable question; both historic analysis, full genome sequencing (to better define the relationships of type A viruses from the region) and virus epitope/structural predictions might be required.

**Action:**
DP (with Nick Knowles, WRL) and SA should provide a summary of what is currently known and what studies are required to better define the expected antigenic range.

2. Reducing the period required to demonstrate FMD freedom
   Prof. Willeberg reported that the OIE Scientific Commission had been asked to review the length of the current period required before countries could be accepted as FMD free, and comment on possible Code changes. A position paper from the RG could make a valuable contribution to the any debate on such issues as how short could the period be, and on the question of different treatment for localized compared to widespread outbreaks. Prof. Willeberg indicated that the 30-60 day period will be the main discussion point.
   An issue raised in discussion was whether OIE should ask for any external validation of the information (e.g. external serology or analysis) provided by countries in the dossiers. It was generally agreed that time elapsed does not provide any guarantee of freedom.

**Action:**
Keith Sumption would draft the outline of such a paper, by mid November, and have it reviewed by AF, AD, and KdC.

**Item 4 - Workplan 2005-7: progress on specific tasks**

Other tasks; if not already reported upon covered during open session
Dr de Clercq went through the WP requesting position statement from each RG member on the tasks agreed at the Riems Session.
Progress has been made on most; some problems related to the need for more continuous monitoring of progress by the Chairman/Secretariat. A summary of Progress is given below.

1. Simulation exercise on post-emergency vaccination sero-surveillance (Kris de Clercq)
The exercise is in the planning stage; following the first planning meeting (KdC, Jorgen Westergaard, AF) the idea to hold several exercises to address the major scenarios was proposed; for example vaccination scenarios for livestock systems involving dairy cattle, extensive sheep/beef, in densely populated pigs, etc.
Significant interest had been expressed from CVOs which supported the value of the exercise to assist policy making on use of vaccination in epidemic control.
Action:
KdC to keep the group informed and involved in plans; lessons learnt from the first exercise should be provided to the EUFMD General Session 2007.

2. Phase XIX and follow up (DP)
Since Phase XIX had been reported at the Open Session, in two parts (virological and serological), and since further discussion will take place at the November meeting of EU National Reference Laboratories for FMD in Brussels, results were not discussed further. Some general points raised at the Open Session were discussed.

a. KJS proposed that despite the opportunity provided by the forthcoming Brussels meeting, the needs of the non-EU labs will need to be considered separately. There was discussion as to how to assist labs to optimize tests for post-vaccination protective antibody levels, but it was agreed that this should not be an aim of next year’s Phase Study interlaboratory comparative testing exercise. It was agreed further work was required to define the pass-levels for expected protection, thereafter how to standardize NRL test performance (single dilution/ titrations, need to test > 1 serotype after multivalent vaccination).

Aldo Dekker agreed to review data and prepare recommendations/lead the work over the next year.

b. On the issue of testing for antibody to each type after vaccination.

Recommendation:
To continue testing for antibody to each serotype after multivalent vaccination, and to review the accumulated data from Turkey, Caucasus, Iran etc, to identify if a change to single type testing could be supported.

3. Type C : global strategy towards certified eradication (Keith Sumption)
On this Item, FAO had decided to hold an expert consultation, probably in 2007, to bring together experts to define the procedures and safeguards necessary under different models of progression towards certified global freedom from type C infection. The model of the global RP eradication pathway (GREP), with its stress on non-vaccination would be evaluated for relevance to type C, given the availability of DIVA strategy for routine or emergency vaccination. Issues to be addressed include: possible reservoir locations for remaining type C; surveillance strategy for these regions; certification measures where type C had not been observed for long periods of time (historical freedom); type C vaccine reserves to support non-vaccination; biosecurity relating to type C virus seed viruses and isolates.

Item 5 - Workplan 2006-8: priorities
Dr de Clercq proposed that the priorities for the next workplan, to be presented at the EUFMD Executive and General Sessions in 2007, should be based on:
- the remaining questions and significant tasks from the 2005-7 workplan;
- technical questions raised at the Open Session, which should be reviewed/prioritized in the Executive Committee (at the next Session);
- issues raised by the Executive, at their most recent Session.

In addition there may be substantive issues need to be clarified where the RG could play a valuable role; the Secretariat should consult on these, which may include vaccination issues; do we need papers reviewing vaccination issues by each species and farming system; such as question of vaccinating sheep in endemic and epidemic control.

Action:
KdC / Secretariat to revise the Workplan indicating progress and remaining tasks. Secretariat to consult with Member nations / Executive, and with the Co-ordination Action (David Paton) to avoid overlap, on issues to be addressed in next workplan.
Item 6 - Finalization of Open Session report
It was agreed that RG members would each peer-review one section of the Open Session report and provide their feedback to the Secretariat by 25th

Closure
Dr de Clercq thanked all the members and observers for their efforts over the past year and over the week in Paphos. The Session was closed at 7.05 pm.
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<thead>
<tr>
<th>Theme</th>
<th>Task (blue italic = associated task)</th>
<th>Who</th>
<th>Draft/frequency</th>
<th>Completion</th>
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<tbody>
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<td>1. Global Surveillance</td>
<td>1.1 Global surveillance maps/models</td>
<td>Liaison person DP to actions between CA, FAO and OIE</td>
<td>Yearly progress report</td>
<td>Ongoing</td>
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<tr>
<td></td>
<td>1.2 Establish regular risk reporting – virus types circulating in Iran, Pakistan, Afghanistan</td>
<td>FG, KS, DP (link)</td>
<td>3 monthly</td>
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<td>1.3 Improving delivery of viruses from risk areas</td>
<td>Secretariat, WRL</td>
<td>Yearly report on gaps/progress</td>
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<td>1.4 Priority antigens for the European Ag banks</td>
<td>WRL</td>
<td>6 months Every 2 years</td>
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<td>1.5 Minimum size of vaccine stocks in EU vaccine banks – position paper</td>
<td>AD, (Paul Barnett), KS, AEF</td>
<td>Outline Progress report 2006</td>
<td>2007 (pre-General Session)</td>
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<td>1.7 Procedure for naming of FMD strains/subtypes</td>
<td>DP (Nick Knowles)</td>
<td>Closed Session - 2007</td>
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<td>4. EQA FMD Diagnostics</td>
<td>4.1 Establish EQA support for 2007– virus detection and serology (Phase XX)</td>
<td>DP, KDC, BH, EB, KS, AEF</td>
<td>Meet to coordinate with CRL.</td>
<td>Closed Session - 2007</td>
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<td></td>
<td>4.2 Harmonization of the serology used for monitoring the efficacy of vaccination</td>
<td>DP, EB, AD, KDC</td>
<td>Progress report Gen Ses 2007</td>
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<td>5. PVS</td>
<td>5.1 Test/optimize guidelines on the use of NSP tests through simulation at workshop (using selected scenarios)</td>
<td>KDC, DP, AD, EB, DS, AEF</td>
<td>Progress report Gen Ses 2007</td>
<td>Closed Session - 2007</td>
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<td></td>
<td>5.2 Complete analysis on sheep and pigs, buffalo</td>
<td>KDC, DS, GG</td>
<td>Progress report Gen Ses 2007</td>
<td>Closed Session - 2007</td>
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<td>10. LCP</td>
<td>Laboratory Contingency Plans: to be placed on the website Scaling up diagnostic capacity: Workshop on upscaling serology – only interesting for eastern European countries, particularly that are not candidate countries</td>
<td>Secretariat (link to CA) Secretariat, GG, CA</td>
<td>CA will send around as Manual</td>
<td>Gen Ses 2007 Check timetable- end 2007</td>
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<tr>
<td>11. Potency test</td>
<td>Potency test evaluation (Turkey) - FMD_ImproCon - Position paper on potency tests in pigs - do we require vaccines to be tested in pigs, and are there new alternatives? *link to China</td>
<td>Link person KDC AD, AEF, DP-Zidong*, BH SoA(epidemiology)</td>
<td>Progress report Gen Ses 2007</td>
<td>Closed Session - 2007</td>
</tr>
<tr>
<td>12. Sample transport</td>
<td>Sample transport guidelines – to be sent around</td>
<td>BH (Nigel Ferris)</td>
<td>Gen Ses 2007</td>
<td></td>
</tr>
<tr>
<td>13. Meeting</td>
<td>Closed meeting (October 2007) (Egypt / the Netherlands) Open meeting Italy (Sardinia, Sicily)</td>
<td>Secretariat KDC EB</td>
<td>Progress report Gen Ses 2007</td>
<td></td>
</tr>
</tbody>
</table>

**Abbreviations:**


CA = Co-ordination Action – FMD and CSF laboratories (DG-Res)
CRL: European Community Reference Laboratory
WRL: World Reference Laboratory