Report of the 3rd Roundtable meeting on FMD control in the Middle-East and North Africa

(Organised by GF-TADs Regional Steering Committee for the Middle East)

Damascus, Syria, November 6-7th 2006

Draft report –version 1

Introduction

A 3rd FMD Roundtable meeting on FMD Control in Middle-East and North Africa was held in Damascus, Syria, November 6-7th November 2006. The meeting was opened by H.E. Dr Adel Safar, Minister of Agriculture and Agrarian Reform, and hosted by Dr Khoury, President of the GF-TADS Regional Steering Committee for the Middle-East.

Several countries and international organizations have participated in the meeting including Bahrain, Egypt, Iran, Jordan, Kuwait, Lebanon, Oman, Pakistan, Saudi Arabia, Sudan, Syria, Turkey, United Arab Emirates, Yemen, FAO (Rome), OIE (Central Bureau and Regional), WRL (Pirbright, UK), USDA APHIS IS Cairo Area Office, the Russian FGI-ARRIAH and French Ministry of Agriculture. The vaccine production private sector was represented.

The Agenda of the meeting is given in Appendix 1, and the list of participants in Appendix 2 (to add).

The Session considered the current risk situation and recent events in FMD epidemiology in the region, the selection of FMD vaccines to counter the risk, and the improvement of performance and standardisation of FMD laboratory diagnosis.

Summary

From the results of the questionnaire survey, and from the reports to the meeting, it is clear that FMD remains a significant drain on the budgets of the national veterinary services of MENA countries and on the livelihoods of livestock owners across the MENA area. Almost all countries operate vaccination programs in large ruminants, some in all ruminant species. These vaccination programs utilise vaccines from a wide variety of sources, including producers based within the region and international suppliers from Europe and India; the lack of standardisation may be a factor affecting control. In 2005-6, the ME has been very hard hit by rapid invasion and impact of two distinct serotype A viruses, one which emerged in Iran (Iran 05) in 2005-6, and an incursion of an African type A virus into Egypt causing widespread outbreaks in January-July 2006. In Turkey and Iran, the type A vaccines in routine use did not prevent the new strain from spreading. The A Iran 05 strain continues to circulate in Turkey and I.R of Iran, and which has been detected in Pakistan and Saudi Arabia in 2006. Type O remains endemic, but the risk of Asia-1 appears diminished with the last reported occurrence in Iran in August 2005. SAT viruses have not been reported in the region since 2003 (SAT-1 in Libya), but serological evidence of SAT infection in Sudan was presented.

The dynamic situation requires continuous monitoring, not least because first detection of new strains in the centre of countries rather than at the borders, and because of rapid animal trade movements, and also because other antigenic variants of serotype A were observed in 2005 and may continue to persist in the region and give rise to later re-emergence. Further, the proximity and importance of trade with countries in the Horn of Africa, and in west and central Asia, has the potential to introduce exotic FMD viruses from these regions.

The meeting also reviewed the risk situation, including possible introduction of exotic FMDV, and how selection of vaccines against FMDV could be improved across the region. It also considered if antigen banks could play a role to avoid shortage of vaccine in emergency situations, and on improvement and standardisation of diagnostic laboratory performance.

Report – by Item of the Agenda/Proceedings of the meeting:

Item 1. Evaluation of FMD status in the Middle east and North Africa Region (MENA):

Dr Yehia, OIE Regional Representative for the Middle East, summarised the responses to the questionnaire sent to member countries before the meeting, together with information provided annually to the OIE. The aim of the survey was to provide additional information on vaccination, diagnostic laboratory usage, and on state of contingency plans. The report is given in Appendix 3.

Country Presentations

Short presentations were made by on recent FMD experience and current control measures, by representatives of the veterinary services or the national vaccine producers, from Egypt (given by Dr el-Bendary, Appendix 4), Sudan (given by Dr Aziz , Appendix 5), Yemen (given by Dr al-Eriani, Appendix 6), Syria (given by Dr Georgos Maksoud, Appendix 7), Jordan (Appendix 8), Turkey (given by Fuat Özyörük, Appendix 9), Pakistan (given by Dr Usmani, Appendix 10), and Iran (report of the Razi Institute, given by Dr Mahravani; Appendix 11). The representative of the Kingdom of Saudi Arabia (KSA) gave a verbal report.

The presentations provided much valuable information and indicated that FMD has occurred the last years as new serotypes of FMDV emerged unpredictably in some regional countries and caused serious damages. Their uncontrolled spread represents a high risk of transmission to neighbouring countries

FMD Type A was diagnosed in 2006 in 8-9 governorates in Egypt this year. Genetically, this new serotype A differs considerably from the Middle Eastern viruses and was closely related to FMD viruses from East Africa.

During 2005 a new FMDV A lineage spread throughout Iran and moved westwards into Saudi Arabia and Turkey (including Thrace). In 2006 it was also detected in Pakistan.

Turkey has reported an outbreak of FMD virus serotype (A) in 2006. The outbreak in Thrace was first detected on 21 January 2006 and confirmed at the beginning of February 2006. The source of infection is reported to be the introduction of new animals or animal products from Anatolian to European part of the country.

Item 2 Risk situation: Risk of FMD evolving from endemic to epidemic

Global situation and risk of exotic viruses entering the MENA region

On behalf of the FAO World Reference Laboratory (WRL) for FMD, Dr Ferris presented a global overview (Appendix 12) of the major events in FMD epidemiology, as detected from the samples submitted to the WRL and to the other laboratories in the OIE/FAO FMD Laboratory Network. Of importance to note is that epidemiology in South America has been relatively stable compared to that in the middle east and in east Asia (China and South-East Asia). In Africa, the epidemiological information is scarce and insufficient samples are received each year to determine major trends, although types A, O and SAT 1, 2 and 3 have been detected from outbreaks in the current year. In Asia, the circulation of several genetic types of FMDV serotype Asia-1 is a concern, highlighting the fact that at any time multiple virus strains are simultaneously circulating, and which may be a risk to the middle east where vaccine against Asia-1 is not used in all countries.

Risk situation: early warning system in Iran for detection of risk from west and central Asia

The activities of the project supported by FAO, EC and the Iranian Veterinary Organisation (IVO) to improve the early warning of FMD viruses in west and central Asia, which should benefit the middle east by providing early information that will assist vaccine selection in countries to the west (Turkey, Iraq, Syria,...) was presented by Dr Geiger (FAO) and Dr Otorod (IVO). The former provided an overview of the FAO project (Appendix 13), and the latter illustrated how a knowledge of the animal populations and FMD incidence was being used to target FMDV surveillance, in particular aimed at collection of FMDV from animal mixing/marketing points that could provide an efficient means to determine if the FMDV types circulating presented a risk to break through the vaccines used in the region. Through this approach, a new and virulent type O strain had been detected which is currently spreading in Iran (Appendix 14).

Item 3 **Vaccination: selection and use in the region**

The Item was chaired by *Dr Khoury.*

Keith Sumption (FAO) presented an overview of key issues in vaccine selection, highlighting recent problems with FMD control in the region

which should provide lessons for selection by veterinary services (Appendix 15). He highlighted the need to predict which FMDV will provide the threat of outbreaks in the next 6-12 months, rather than using historic information. The ME region is much more complex than other regions, given the threats are from east (Asia-1) as well as south (sub-saharan Africa), and possibly in future from South America, as well as the regular type O and A strains within the region. In this uncertain situation, high potency vaccines are particularly important, as they generally confer a broader protection that low potency vaccines, albeit at higher price; this had probably been a major factor in the effective control of FMD in Thrace region of Turkey in 2006. The purity of FMD vaccines is important if countries are interested to develop export zones or FMD free zones where surveillance to demonstrate freedom from virus circulation is needed. The risk of virus escape, from non-OIE standard vaccines, or vaccine plants operating without adequate biosecurity, was mentioned; the latter should concern CVOs of countries with production facilities since the handling of exotic virus types could potentially lead to outbreaks of exotic virus strains to which the region has no immunity.

An overview of FMD vaccine selection in the MENA region, based on the responses to the questionnaire, was given by Dr Mustafa Hassan (Appendix 16). In general, FMD Serotype A is endemic in Afghanistan, Pakistan, Iran and Turkey while sporadic outbreaks occur in the southern Middle Eastern countries. [Vaccine matching tests revealed that the type A virus responsible for the 2005-6 epidemic is antigenically different to A Iran 96 and closer to A22; this new strain has been designated as A Iran 05. In contrast the type A strain responsible for outbreaks in Egypt in 2006 is closely antigenically matched to A Eritrea 98, and not to other type A vaccines used frequently in the MENA region such as A Iran 96 or A22.]

Five countries in region are known to produce FMD vaccine. They are Egypt, Jordan, Turkey, Iran and Morocco. Others are mostly importing their needs from external sources known to be recognized international vaccine manufacturers. From Africa, countries like: South Africa, Botswana, and Kenya (in early days) are the main sources of FMD vaccine. The vaccine imported is mainly trivalent (A, O, SAT1 serotypes) and quadrivalent (A, O, SAT1 and SAT2 serotypes) and rarely monovalent (A or O serotype). With few exceptions, vaccination strategy is either poorly planned or entirely lacking in most of countries. Thus, a scientifically backed up vaccination strategy is needed for the countries of the region. The diagnostic facilities for FMD are not well developed. This

justifies why most of the vaccine serotypes imported by the countries are not matching with the local serotypes. FMD contingency plans are not well developed in most countries of the region.

A Q&A session on the issues followed, including the questions:

Should purchasers check the suppliers claims before or after purchase? What level of vaccine purity is needed in the region? Is it safe to produce vaccine using viruses from outside of the region?

Priority antigens for use in vaccination programs in the MENA region

Dr Sumption introduced this paper. In Europe, a system is in place to guide decision makers, usually the CVO, on the choice of FMD antigen to hold in the emergency reserves. He suggested that the system could be adapted to provide guidance to the decision makers in the MENA countries on the priority antigens to be considered for their programs. The system in Europe involves the WRL producing a list every 6 months with a full review every 2 years; the review involves discussion with stakeholders and vaccine producers, since the strains listed should have a number of advantageous properties including extent of cross-protection to be expected.

The draft WRL list for priorities for the MENA region was presented by Dr Ferris (Appendix 17).

He recommended that each country does its own risk assessment, but in doing so considers the high priority antigens on the list since they represent, according to the viruses detected internationally in 2005-6, the most appropriate antigens against the most prevalent viruses.

Where countries are affected by outbreaks, then specific advice from the WRL should be sought.

In discussion, the need to review the list by experts from the region was highlighted. In particular, Dr Otorod (IVO) questioned why A ran 87 was not listed as a priority. Dr Sumption thanked him for this comment since it highlighted the very high importance of the Reference laboratories such as the WRL receiving A Iran 87 isolates from recent outbreaks to test whether the priority type A vaccine strains provide sufficient protection. If they do not, this could justify raising A Iran 87 to high priority in the programs for the region.

Item 4 Preparing for emergency situations: the potential role of national FMDV vaccine or antigen banks

Dr Sumption opened this Item, and brought attention to the problems in the MENA region in the past year where commercial suppliers did not have stocks for immediate delivery to countries affected by the type A epidemics, but the EC was able to deliver 2.5 million doses of A/O/Asia-1 vaccine for emergency vaccination in Turkey from its antigen bank for immediate use. This highlighted the role of banks to provide an immediate response; these banks were little different from normal tenders, being a contract between a veterinary service and vaccine producer, that would ensure delivery of specific vaccine within days of demand from the CVO.

Dr van Aarle, (Intervet), presented a paper on this item (Appendix 18). He highlighted the fact that heptavalent (7 antigen) vaccines are used by some countries in the region; through using a antigen bank, several valencies could be potentially removed from the regular programs; in emergencies a monovalent vaccine could be rapidly made (5-10 days) for use in an emergency program. For most of the MENA countries, antigens banks could be a way to ensure they have access to vaccines for emergencies (exotic strains), when the antigen is not needed for the routine prevention (endemic strains). In addition, the formulation could be made specific to the problem, for example to make a high potency to counter a more antigenically divergent virus. He also illustrated the regulatory situation for FMD vaccines in Europe which was the most stringent in the world; together with the high purity this leads to a higher price, but also a more guaranteed result.

Item 5 Diagnostic laboratory performance and standardisation

This Item was Chaired by Dr al-Kuzaei (Bahrain).

Dr Ferris, WRL presented two talks (Appendix 19 and 20) on the subject of harmonising the performance of FMD diagnostic laboratories. Since the OIE prescribed tests for international trade, harmonisation of serology had been important for many years since otherwise disputes between countries arose through lack of recognition of laboratory results. Therefore FAO had supported the WRL to organise harmonisation studies (FAO Phase XIX, etc) , which involved sending panels of serum to participant laboratories to enable them to assess their own performance. This had become important in recent years for labs to reach or retain their accreditation (external quality assurance).

In the past year, FAO and the WRL had agreed to extend the harmonisation to virus diagnosis, in particular because many labs now wished to use RT-PCR methods and potentially there may be high variation between labs in their ability to detect FMD. This was a proven problem in the MENA region in 2005-6 since the new type A strains had led to low reactions in the ELISA tests, therefore diagnostic methods also need to be tuned.

The result obtained in 2006 will be further discussed between FAO and the WRL; the possibility to extend the panel to assist countries wishing to harmonise tests for post-vaccination monitoring will be considered.

Overall, the results clearly show that labs vary in their methods and in their results for the same samples; this could lead to serious problems. Commercially available test kits tend to be well standardised, but for FMD these are few, and for NSP ELISA the kits vary significantly in their performance.

Discussion followed, which highlighted:

- the interest of the CVOs in the region to have an inspection of their laboratories by an expert, to develop an action plan that would assist to progress towards international standards;

- the issue of biosecurity, since very few national laboratories in the region are built to required OIE standards for FMD, and there is no separate category or derogation for laboratories in endemic countries to work under lower levels of biocontainment;

- the possibility that the new diagnostic methods, which do not require live virus, have advantages by not requiring expensive biocontainment

- the interest of labs to participate, and the question of whether the CVO should be sent the results before or after the laboratory has had a chance to comment on their own performance

Conclusions:

1- One of the major challenges facing vaccination against FMD is the prevalence of seven serotypes and more than 60 subtypes of FMDV which are quite distinct not enjoying common cross reactivity. Furthermore, frequent mutation adds to the complexity of vaccine selection in endemic regions.

2- It is essential to invest in research effort to develop vaccines which will provide wide protection against FMDV serotypes and subtypes and thereby reduce complexity and cost of regional FMD control through vaccination.

3- FMD vaccination is an essential tool in the control and eradication of FMD in the MENA region.

4- FMD vaccine producing countries in the region are few.

5- Joint efforts by the local, regional and international communities are needed to strengthen the existing vaccine production facilities to meet the demand of the region for quality vaccine meeting international standards.

6- Monitoring the circulating strains of FMDV (through reference labs) plays an essential role in the control of the disease through vaccination, and collected data should be analyzed in a regional reference centre, to improve of early warning and early control of the disease.

7- The recognition of the most prevalent serotypes in the region is very essential. Thus, national epidemio-surveillance campaigns, financially and technically supported by the international community, are needed in all countries.

8- Since the information available on FMD is limited in some areas of the region, training of personnel involved in disease investigation and control should be strengthened.

9- A science-based vaccination strategy is needed for the countries of the region.

10- Countries, supported by regional and international communities, need to develop and regularly update their national FMD contingency plans based on their FMD status.

11- Vaccine quality assurance is badly needed in the region, and establishment of a centre for undertaking independent trials on vaccines should be considered.

The Recommendations reached are as follows:

Considering that:

1. FMD remains a constant drain on the budget of veterinary services across the region, and that periodic devastating epidemics occur that spread rapidly across national and regional borders;

2. live animal movement, through regulated trade or by illegal movement, from regions not free of FMD is a feature of livestock trading patterns in the region, and contributes to the risk of FMD entry, and can be expected to continue in the future;

3. west Asia, and East Africa remain potential threats for countries in the eastern and central parts of the MENA region, and that virus submission to Reference Laboratories from these regions remains inadequate;

4. lack of information exchange between countries and to the international organisations has contributed to the scale of the type A epidemics experienced in the region in 2005-6.

5. The lack of immediate vaccines against the A Iran 05 and A Egypt 06 viruses contributed to the scale of the outbreaks.

6. the new serotype A virus (A Iran 2005) has continued to spread in 2006, circulating in Turkey and I.R. of Iran, and which has been detected in Pakistan and Saudi Arabia in 2006;

7. that further spread of the A Iran 2005 and possibly A Egypt 2006 viruses to countries in the Near-East is likely to occur unless effective preventive measures are taken;

8. the location and risk from other exotic viruses, should be kept under review by each country, including the continuous circulation of Asia-1 in south and east Asia;

9. the Type O remains endemic in the Near-East,

10. the dynamic disease situation requires continuous monitoring, not least because of first detection of new strains in the centre of countries rather than at the borders, and because of rapid animal trade movements;

11. that FMD vaccines can rarely contain all the required antigens to protect against the diversity of viruses expected in the region, and that priorities for each species are needed to reduce cost;

12. that antigen banks are an option for countries to hold sufficient stocks of antigen for immediate formulation in emergency situations, and which can reduce the need to vaccinate against some virus types;

13. that no country in the region currently maintains an antigen bank, and that only a few countries in the region have developed and formalised their contingency planning against FMD;

14. that there have been serious delays in diagnosis of the new type A viruses because diagnostic tests were not optimised for the type A infections;

15. that there is a need to build confidence in laboratory capacity in the region for early detection of new strains, and for monitoring of vaccination programs and sero-surveillance;

16. that most MENA countries have a national reference laboratory for FMD, but that there is significant variation in capacity, in bio-safety, and in standardisation of FMD tests, leading to lack of confidence in laboratory results, which affects trade prospects;

17. Progress has been made in the validation of NSP (non-structural protein) antibody tests for the major species, but that many countries lack the experience in design of surveillance in potential export or FMD free zones, or following FMD outbreaks,

Recommends that:

Relating to control of FMD in MENA region;

1. The whole of the Middle East and North Africa areas should be considered as one FMD epidemiological region, but with possible subregions reflecting different ecosystems for circulation of FMDV strains, requiring a set of co-coordinated prevention, control and eradication programs to be elaborated covering the entire region at risk;

2. Transparency in notification of FMD outbreaks should be strongly implemented within the region to assist an effective response and control of FMD;

3. FMD suspected samples to be sent to the international reference laboratories should be accompanied a comprehensive epidemiological report, including the geo-reference, to assist early warning and tracing the likely pattern of disease spread,

4. Coordinated action across borders and sanitary measures should be strengthened by imposing appropriate quarantine measures on animal movements whenever the disease is reported;

5. systematic vaccination campaigns of ruminants should be encouraged in all areas at risk, especially in border areas, that are designed to reach a population immunity that will effectively prevent FMD spread, using appropriate vaccines that meet international standards; Procurement of

vaccines should consider the recent FMDV antigenic subtypes in the countries of the region as well as the antigenic relationships to the virus isolates circulating in neighboring countries;

6. A strategy to achieve international recognized disease-free zones or FMD free country status must be developed in the region, within the framework of the progressive control of transboundary animal disease program (GF-TADs);

7. in support of the above, each country is encouraged to “map” their ruminant livestock population in the country, and consideration should be given to developing a standard format for livestock population mapping that is applicable across the region, and which will assist each country in planning disease control measures;

8. The countries of the region establish an FMDV network, co-coordinated by the Regional Animal Health Center (RAHC), to facilitate exchange of information and to respond rapidly to a emergence of any new serotype in the region;

9. Member Countries of the Middle East region are urged to develop, test and keep a regularly updated a national foot and mouth disease preparedness plan that will assist them to ensure a rapid and effective response to new epidemic events;

Relating to early warning of FMD risk in the MENA region;

1. the information flow to MENA countries on the change in FMD risk should be improved, with regular summaries of the situation and alerts with follow ups when major events occur that threaten parts of the region;

2. each country ensures that epidemiologically significant events are detected, acted upon and reported without delay; early recognition of these events can be helped by using DEFINITIONS of abnormal field and laboratory findings, such as increased incidence of FMD, the detection of a new subtype, or possible breakthrough of FMD in well vaccinated herds;

3. when threatening events of regional significance are identified, emergency meetings be rapidly convened by the RSC to assess the risk and necessary international response;

4. the Regional Steering Committee of GF-TADS organise regular roundtable meetings on FMD prevention and control, at least at yearly basis;

5. each country re-assesses the risk of entry of the prevalent epidemic viruses in the region, including the A Iran 05 virus type, and takes appropriate actions, including vaccination, to reduce risk of introduction and spread;

6. increased effort to collect and submit samples for virus typing is made by countries which have an epidemiological importance in the region, particularly Iran (as indicator for west Asia), Yemen (as an indicator for the Horn of Africa), and Sudan. For the Maghreb countries (North Africa), increased effort is mainly needed in the West African countries to the south of this region. International support from the FAO and/or OIE should be requested to reduce the cost of submission of samples that are of regional importance.

Relating to improved control of epidemic FMD;

7. that each country develops and formalises a contingency plan for FMD that addresses the particular problem of entry of an exotic type of FMD virus to which the regular vaccination programs do not protect (see no. 11 above);

8. that each importing country that imports live animals from countries not free of FMD has in place a contingency plan to address the risk of virus entry from that region, that will assist to build confidence in animal trade with such countries and reduce restrictions, in full compliance with the OIE Animal Health Code

9. that each country considers establishing a national antigen bank to ensure rapid availability of potent FMD vaccines for use in emergencies;

Relating to priorities for inclusion in vaccination programs and in antigen banks;

10. each country re-examines its selection of FMD vaccines to ensure that the purchased vaccines meet or exceed OIE standards and the antigens are appropriate to the international risk situation;

11. that the WRL, through the OIE and FAO, is requested to produce a list of priority antigens for inclusion in vaccination schedules in the MENA countries on a regular basis; the list should be reviewed by the RSC or a task force nominated by this group, before being made publically available;

12. that the recommendations of the WRL to the 3rd Roundtable are noted by MENA countries, who should be aware of the elevated importance of A22 Iraq antigen (to protect against A Iran 05), and A Eritrea 98 (to protect against the A Egypt 06);

13. that efforts be made to address gaps in knowledge of vaccines to be used against the circulating virus types in parts of sub-Saharan Africa which provide a source of exotic FMD viruses to the MENA countries; the international organisations should provide support if the countries themselves are unable to do so;

14. that the RSC or a nominated task force develops guidance on the subjects

a. harmonisation of vaccination in the MENA region to ensure coverage against the most prevalent (priority) viruses;

b. vaccination of small ruminants;

Improving laboratory capacity and harmonisation of FMD laboratory test performance in the region

15. that member countries ensure that their national laboratories re-assess their methods and reagents to ensure that diagnostic tests are appropriate for detection of the current A (including A Iran 05, A Egypt 06), O, Asia-1 and SAT types expected in the MENA region;

16. that NRLs in the MENA region be encouraged by their national authorities to participate in the international FMD laboratory standardisation exercises organised by FAO through the WRL at Pirbright;

17. that participants in the Roundtable encourage or organise assessment missions to their NRLs for evaluation, and which will guide the potential establishment of a regional reference laboratory (RRL);

18. the RSC develop guidelines for biosecurity of laboratories that will assist compliance with OIE and are feasible throughout the region;

Epidemiological support for planning of FMD preventive and control measures;

19. that the RSC establish an epidemiology advisory group to assist in response to request from countries for technical support, for example

a. in the design of surveillance programs for establishment of export zones in the MENA region

b. in the design of sero-monitoring programs post-vaccination

20. that the RSC consider nominating one or more centres of expertise in the region to promote the application of modern epidemiological tools and methods to improve planning of FMD control measures; one such centre could be in Iran, making use of epidemiological capacity of the Iranian Veterinary Organisation and the support received from the FAO/EC and another one elsewhere in the MENA region, with the help of the international organisations.

Location and date of next meeting;

An offer was received from Jordan to host the next meeting; in approximately one year (November 2007).

Item 6 Endorsement of the Draft Report

The draft report was read and endorsed by the participants and their comments noted by the rapporteurs. It was agreed that the comments would be incorporated and draft circulated within 10 days of the close of the meeting.

Closure of the Meeting

Dr Khoury presided over the closure of the meeting, and Dr Yehia and Dr Sumption made short statements in closure. Dr Yehia thanked all the participants for their inputs which had lead to a successful meeting, and the sponsors of the lunches and evening events. He thanked the support staff of the OIE regional representation and of the FAO Headquarters for assistance.

A special vote of thanks was made to Dr Khoury and to the Ministry of Agriculture and Agrarian reform for the wonderful hospitality and excellent local arrangements.

Following the closure, Dr Zakharov (FGI-ARRIAH) made a presentation on their work on FMD vaccine production and recent results on vaccine potency (Appendix 21