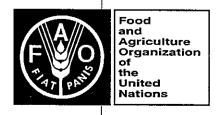
REPORT

Antalya, Turkey, 4-5 May 1998

European Commission for the Control of Foot-and-Mouth Disease

Sixty-first session of the Executive Committee



AGA: EUFMD/X/98/1

REPORT

of the

SIXTY-FIRST SESSION

of the

EXECUTIVE COMMITTEE

of the

EUROPEAN COMMISSION FOR THE CONTROL OF FOOT-AND-MOUTH DISEASE

held at

Talya Hotel, Antalya, Turkey

4 and 5 May 1998

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

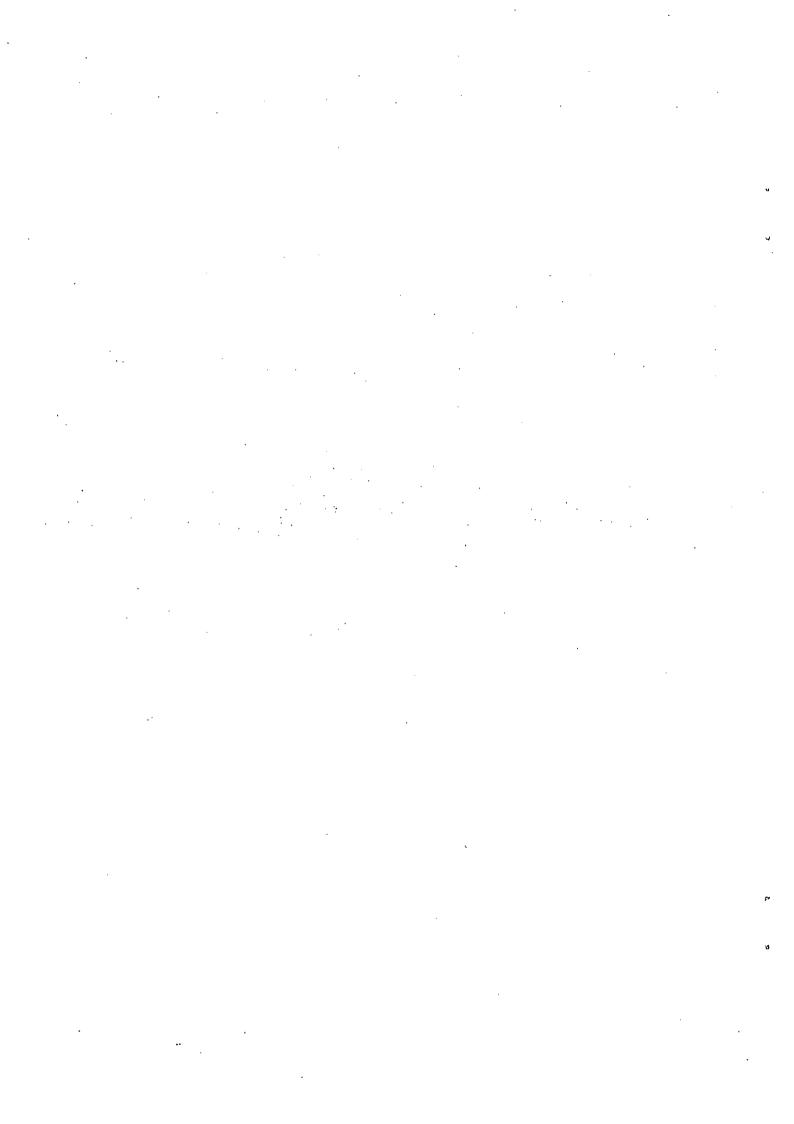
Rome, 1998

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Introduction

The Executive Committee of the European Commission for the Control of Footand-Mouth Disease (EUFMD) held its Sixty-first Session at the Talya Hotel, Antalya, Turkey, on 4 and 5 May 1998.

Members of the Committee present:

Dr R Marabelli, Italy, Chairman

Dr N. Voetz, Germany, First Vice Chairman

Dr L Celeda, Czech Republic, Second Vice Chairman

Dr G. Bakken, Norway

Dr. T. Balint, Hungary

Dr. D. Panagiotatos, Greece

Observers:

- Dr Nazif Aslan, Deputy Director General, Ministry of Agriculture and Rural Affairs, General Directorate of Protection & Control, Turkey
- Dr Mustafa Bahadir, Director of Section, MARA, GDPC, Turkey
- Dr Musa Arik, Director of Section, MARA, GDPC, Turkey
- Dr Mustafa Tufan, Epidemiologist, Animal Health Information Section, MARA, GDPC, Turkey
- Dr Memik Kibarkaya, Head of Department, MARA, GDPC, Turkey
- Dr Muhammet Aksin, Director, SAP Institute, Ankara, Turkey
- Dr Ismet Gürhan, Member of the Research Group, EUFMD, SAP Institute, Ankara, Turkey
- Dr Abdullah Kaya, Director of Agriculture, Antalya, Turkey
- Dr A.G.Özturk, Deputy Director of Agriculture, Antalya, Turkey
- Dr Cafer Tetik, Head, Animal Health Section, Antalya, Turkey
- Dr Monique Eloit, Ministère de l'Agriculture, Paris, France
- Dr M. Muthoo, FAO Representative, Ankara, Turkey
- Dr Y. Cheneau, Chief, Animal Health Service, FAO, Rome, Italy
- Dr K De Clercq, NIVR, Brussels, Belgium, Chairman, Research Group, EUFMD
- Dr A.I. Donaldson, WRL, UK
- Dr J.Westergaard, EC, Brussels, Belgium

Secretariat

- Dr Y. Leforban, Secretary, EUFMD, FAO, Rome
- Ms J. Raftery, Admin Assistant, EUFMD, FAO, Rome

On behalf of the Ministry of Agriculture and Rural Affairs, Turkey, Dr Nazif Aslan, Deputy General Director of Protection and Control, welcomed delegates and observers and stated that he was very pleased that the Sixty-first Session of the Executive Committee of the EUFMD, was being held in Antalya. He extended warm greetings to the participants and observers in the Session from Dr Celal Ozcan, Director General of Protection and Control.

In referring to the existing situation of FMD in the region, Dr Aslan underlined the role of the EUFMD as an important instrument for intercontinental cooperation and he appealed to the Commission to consider the position of Turkey, particularly in view of its location in such a critical and vulnerable zone for the protection of Europe.

He expressed the hope that the participants/observers would be able to spare some time to visit Antalya, one of the most beautiful touristic provinces of Turkey, and that on leaving they would carry with them very pleasant memories of their stay.

On behalf of the Director-General of FAO, Dr M.Muthoo, FAO Representative in Turkey, then welcomed the delegates/observers and wished them a successful meeting. He thanked the Government of Turkey, and particularly the General Directorate for Protection and Control for having offered to host this Session of the Committee in Antalya. Dr Muthoo briefly outlined the important role of the EUFMD and EC in their joint efforts to support the FMD control programme in Turkey through the provision of both technical advice and financial resources. In his capacity as FAO Representative in Turkey, he said that he wished to assure the Committee of FAO's high interest in the activities of the EUFMD and EC in Turkey and he looked forward to a close partnership in this joint endeavour. He wished the participants success in their deliberations and a pleasant stay in Antalya.

Before presenting the Agenda, Dr R. Marabelli, Chairman of the Commission, addressed the meeting. He welcomed Delegates and observers and expressed regret that Dr Vallat, France, was unable to attend.

On behalf of the Commission, he thanked the Turkish authorities for having offered to host the meeting and he wished the participants success in their discussions and an enjoyable stay in such beautiful surroundings.

Item 1 Adoption of the Agenda

The following agenda was proposed to and adopted by the Delegates:

- Item 1 -Adoption of the Agenda
- Item 2 -FMD situation in Europe and other regions -Results of the serosurvey in the Balkans
- Item 3 -Report on the FMD situation and control programme in Turkey -FMD control measures sponsored by EU
- Item 4 -Report on the occurrence of a new variant of type A virus in Iran and in Turkey
- Item 5 -Report of the Chairman of the Research Group on liaison with international organizations: European Pharmacopoeia, OIE, IAEA, OECD
- Item 6 -Report on the notification of Contingency Plans to the Secretariat by the Member countries
- Item 7 -Implementation of the new scale of contributions in 1998 and membership of the Commission
- Item 8 -Financial matters: accounts 1997 and budgets 1998 and 1999
- Item 9 -Review of the conclusions and recommendations of the Thirty-second Session and of the Sixtieth Session of the Executive Committee
- Item 10-Next Sessions: Agenda for the Sixty-second Session of the Executive Committee; date and agenda for the Thirty-third Session of the Commission
- Item 11-Any other business
- Item 12-Adoption of the draft report

Item 2 -FMD situation in Europe and other regions -Results of the serosurvey in the Balkans

The Secretary reported on the FMD situation in Europe in 1997 and 1998 (Appendix 1). He underlined the fact that no FMD outbreak had been reported since the end of October 1996.

With regard to the situation in CIS countries, FMD was reported in Georgia, Kirghistan and Turkmenistan in 1997. The situation in the transcaucasian regions was also discussed. Dr De Clercq, who visited Georgia in November 1997, stated that the countries in the region are interested in establishing trade with neighbouring countries (Ukraine, Bulgaria, Romania, Turkey). This new trade route could increase the risk of introduction of the disease into Europe. Dr Marabelli was of the opinion that there was a need to strengthen the national veterinary services in the region in a context of privatisation. It was agreed i) that there was a need for an evaluation mission of the buffer zone which has been requested by the countries of the region. ii) the countries concerned should present their programme for the buffer zone at the OIE Regional Meeting to be held in Prague in September 1998. FAO and OIE should take action in this respect.

Dr Muthoo informed the Committee that FAO is preparing a training programme between ten countries in the region funded by UNDP and other Organizations and he suggested that animal health be included as a major component of this programme.

Dr Marabelli suggested that for the benefit of other European countries, the membership of the Commission should also include countries of this region.

Dr Westergaard presented the results of the sero surveys carried out by Brescia IZS and Lindholm Laboratory at the end of 1997 in Albania and FYROM where evidence of previously infected sheep was found in both countries (Appendices 2 and 3).

Dr Donaldson reported briefly on the sero survey carried out by the WRL in Kosovo where no evidence of the circulation of virus was found.

Dr Panagiotatos queried the action to be taken in respect of the results of the survey and whether the Committee considered that there was a risk of recurrence of FMD in the countries mentioned above. Dr Dr Clercq stated that the results of the sero surveys are not easy to interpret as it was the first time that the new tests for detection of antibodies to non-structural proteins was used after epidemics. The conclusion of positivity to the tests is that the virus has been replicating but it does not indicate whether it is still circulating and represents a risk of spreading at the time of the serosurvey.

Dr Donaldson informed the meeting of serological results obtained from surveys in north Africa and Greece where low antibody prevalence rates (5-6%) among sheep were detected after epidemics had waned and disease was absent. The epidemiological significance of such antibody-positive sheep is an open question. He informed the Committee that the IAH Pirbright had started experimental work on this subject.

Item 3 -Report on the FMD situation and control programme in Turkey, FMD control measures sponsored by EU

A paper on the FMD status and the strategy to combat FMD in Turkey was presented by Dr Gürhan (Appendix 4). After recalling the legal measures taken for control of the disease in Turkey, Dr Gürhan presented the disease situation between 1997 and the beginning of 1998.

No FMD has been reported in Thrace since July 1996, 54 outbreaks were reported in Anatolia in 1997, 51 due to type O and 3 due to type A. 23 of the outbreaks (42%) were in the Western Buffer Zone (WBZ). In 1998, 18 outbreaks have been reported in Anatolia, out of which 7 in the WBZ.

The first round of vaccination for 1998 has been completed and the official figures provided by the Veterinary Service showed that the level of vaccination coverage throughout the country was lower than the 1997 level. In Thrace 59% of large ruminants and 47.5% of small ruminants were vaccinated. In Western Anatolia the coverage was

33% of large ruminants and 0.7% of small ruminants. Dr Aslan explained that MARA had tried to complete the first campaign of vaccination before the religious festival at the end of March and that some vaccination carried out by private veterinarians outside the control of MARA is not included in these statistics. Dr Balint expressed his concern regarding the absence of control by MARA of the distribution of FMD vaccine and the gap in reporting FMD vaccination by private veterinarians. The Committee expressed its preoccupation about the low vaccination coverage in Turkey for 1998 and requested that official control of vaccination be established in Turkey and that the control strategy in Anatolia be re-examined.

Dr Westergaard reported on EC Decision 98/64/EC which provides for a maximum assistance of ECU 227,360 for agreed priority activities in Turkey. He informed the Committee that in application of this decision a seminar on Cattle Identification in Turkey organized jointly by EC and EUFMD had been held at the end of March 1998 in Istanbul. He circulated a draft paper (Appendix 5) on vaccine control and requested comments from Turkey and from the Committee in order to prepare tenders for the control of A22 and 01 Middle East vaccine produced at the SAP and in the Community.

Item 4-Report on the occurrence of a new variant of type A virus in Iran and in Turkey

Dr Donaldson presented the background of the new type A variant in Iran and Turkey. He reminded the Committee of the history of previous epidemics in the region i.e. A22, ASIA 1, O1 Middle East, and indicated that in the absence of appropriate measures, as had occurred in the past, there is a high risk that the A Iran/96 strain may spread further west, including into Thrace.

The report of the ad hoc expert meeting held in Rome on 22 April 1998 was circulated to the participants (Appendix 6).

Dr Gürhan presented the situation of the new variant in Turkey and indicated that eight outbreaks had been reported up to April 1998 (see Appendix 4).

Dr Bakken was of the opinion that the occurrence of the new variant should not be over-estimated and that it could in part also be due to the low vaccination coverage in the WBZ.

Dr Panagiotatos supported the idea that the spread of the new variant to the West and to Thrace should not be considered as inevitable and was in favour of undertaking immediate vaccination in Thrace and in the WBZ with monovalent A/Iran/96 vaccine.

Dr Voetz strongly advocated immediate vaccination in Thrace, and the preparation of antigen to be included in the vaccine banks and the preparation of oil vaccine for Europe against the new variant.

The need for further experiments on the capability of the A22 vaccine to protect against the new variant was discussed in depth by the Committee and the agreement reached was that there was a need for further experimental work. However, considering the time/financial resources required to carry out this research (minimum 3-4 months at an approximate cost of US\$60,000) the Committee did not fully agree on the timing and the urgency of such an experiment i.e. the necessity to have the final results before vaccinating in Thrace and including the new variant in vaccine banks.

With reference to the proposals made by Professor Ahl during the meeting on 22.04.98, Dr Cheneau stated that he was in favour of experiments in animals to determine the cross-protection by A22 vaccines before deciding to vaccinate. He underlined the present lack of documented evidence about the breakdown of immunity in herds vaccinated with A22 vaccines, particularly in recent outbreaks of the new variant A in the Western Buffer Zone.

Dr Aslan stated that Turkey was ready to get involved in any kind of cooperation to combat the new variant. He agreed on the need to vaccinate first in Thrace and thereafter in the WBZ. He assured the Committee that as soon as the vaccine becomes available, its application will be implemented immediately.

Dr Muthoo on behalf of FAO renewed his support for promoting technical cooperation between Iran and Turkey in view of the threat represented by the new variant.

Recommendations for Items 3 & 4

- 1. The Committee endorsed the recommendations of the meeting held in Rome on 22 April i) for getting from Turkey more information on the epidemiology/origin and spread of the new strain ii) for the visit of an expert mission to Razi and SAP Institutes to advise on modern vaccine technology for the new variant.
- 2. The Committee endorsed the recommendation of the meeting held in Rome on 22 April and recommended that one round of emergency vaccination with Iran/96 strain be organised as quickly as possible in Thrace and that a letter should be written immediately by the Chairman to EC to investigate the possibility of covering the costs from TF911100 MTF/INT/003/EEC.
- 3. A round of vaccination of susceptible animals in the WBZ with Iran/96 strain should be organized as soon as possible and a trivalent vaccine including a valence protecting against the A/Iran/96 variant should be used for future preventive vaccination in Turkey.
- 4. The Government of Turkey is requested to prepare a plan for vaccination against the new variant in Thrace and in Anatolia and to forward it as a matter of urgency to EUFMD and EC.

- 5. A scientific trial to evaluate the capability of the existing Type A22 vaccine and of the new homologous vaccine should be organised as soon as possible with the objective of defining vaccine policy in certain parts of Europe in case of an emergency situation.
- 6. The Committee endorsed the recommendation of the Rome meeting that there is an urgent need to develop and produce an FMD vaccine to protect against the new variant in Europe.
- 7. The Committee expressed its concern on the high incidence of FMD in the WBZ and the Government of Turkey is encouraged, in close cooperation with the RG, to assess the FMD-data over the last two years with the aim to possibly explain why the incidence of FMD in the WBZ exceeds (5-6 times) the prevalence in the rest of Anatolia.
- 8. Technology transfer for diagnosis to SAP and Razi Institutes is encouraged and SAP Institute should prepare a proposal. The possibility of funding from FAO or other international organizations should be investigated.
- 9. The situation created by the new variant in Turkey should be given top priority when reviewing the next steps of the three-year EC funded programme started in 1998 under Commission Decision 98/64/EC.

Item 5 -Report of the Chairman of the Research Group on liaison with international organizations: European Pharmacopoeia, OIE, IAEA, OECD

This agenda Item was presented by Dr Kris De Clercq, Chairman of the Research Group (Appendix 7).

From 2 to 6 February 1998, a meeting on "The FAO/IAEA External Quality Assurance Programme (EQAP) and Movement towards a Generic Veterinary Diagnostic Testing Laboratory Accreditation Scheme" was held at the Vienna International Centre. Two documents were prepared on this subject.

- 1. Proposals for "Principles of Quality Management in Veterinary Diagnostic Testing Laboratories".
- 2. "Monitoring Compliance with the Principles of "Quality Management in Veterinary Diagnostic Testing Laboratories".

In the second document it was emphasised that OIE should be the seat of authority for the establishment and supervision of the monitoring programme.

These documents will be forwarded to the Secretariat of the OIE for consideration in the development of an international scheme for veterinary diagnostic laboratory accreditation.

The Session congratulated the Chairman of the Research Group on his clear presentation of this very useful information and on the work carried out during the past year.

Item 6 -Report on the notification of Contingency Plans to the Secretariat by the Member countries

The Secretary reported on the replies to the questionnaire sent to member countries on the progress of their Contingency Plans (Appendix 8). Thirty out of 33 countries had replied.

The Chairman reiterated the high interest for the Commission to continue to monitor the progress of Contingency Plans in member countries.

The conclusions regarding the collaboration between the EC Scientific Veterinary Group on Contingency Plans on FMD should be reinforced and that a small stock of non-perishable equipment should be kept by the Secretariat in Rome were endorsed by the Committee.

The Committee suggested that an analysis of the replies received should be presented to the Commission at the 33rd General Session to be held in Rome in April 1999.

Item 7 Implementation of the new scale of contributions in 1998 and membership of the Commission

The Secretary informed the Committee that the new scale of contributions has been implemented as of 01 January 1998, and that so far no difficulties have been encountered.

Item 8 Financial matters: accounts 1997 and budgets 1998 and 1999

The Secretary presented the accounts prepared by the Finance Division of FAO for TF's 904200/911100/909700 (Appendix 9). With regard to statements 2 and 3, he pointed out that the question of arrears for Yugoslavia has not yet been solved and FAO, due to the political nature of this issue, is not at the present time in a position to advise on the best course of action to be followed. He briefly explained the various items of expenditure under Statements 1, 4 and 5.

The Secretary then presented the approved budgets for TF904200 for 1998 and 1999. With regard to 1998, the Secretary informed the Committee that some revisions

were necessary to reflect actual expenditure under Component 2000 Duty travel (an increase of US\$6,000) and Component 5000 expendable equipment (an increase of US\$5,000 to provide reagents for Bulgaria).

With regard to the budgets for 1998 for TF's 911100 and 9097, the Secretary proposed that under TF911100 Component 5000 (vaccine) an additional provision of US\$400.000 (total US\$500,000) be included in case of need in Thrace to carry out emergency vaccination against the new FMD variant that Component 2000 Duty travel be increased by US\$50,000 to provide for non-staff travel and for travel to the Research Group meeting to be held in Pirbright in September. Under TF909700 an increase was proposed under Component 8000 Training & Workshops to offset expenditure for the Workshop which had been held in Pulawy, Poland, in March 1998.

Before proposing approval of the accounts and budgets, the Chairman asked the Committee if they were satisfied with the accounts/budgets as presented.

The accounts for 1997 and the budgets for 1998, including the proposed revisions, were then approved.

Item 9 Review of the conclusions and recommendations of the Thirty-second Session and of the Sixtieth Session of the Executive Committee

The Secretary presented the progress made in the implementation of the recommendations of the Thirty-third General Session and the Sixtieth Session of the Executive Committee.

He informed the Committee that Ireland had proposed to provide the services of an Associate Professional Officer and that the recruitment of possible candidates is in progress.

Regarding the Federal Republic of Yugoslavia, close technical contact has been maintained with the EUFMD in view of recent epidemics in the Region but due to the present legal situation no progress has been made in respect of their financial obligations to the Commission

Item 10 Next Sessions: Agenda for the Sixty-second Session of the Executive Committee; date and agenda for the Thirty-third Session of the Commission

The Committee proposed that a Tripartite FMD Group meeting be convened in the autumn before the Sixty-second Session. Dr Panagiotatos indicated that in line with the rotation between the three countries, Greece will host the next meeting.

The provisional agendas for the Sixty-second Session of the Executive Committee and the Thirty-third General Session were accepted and the Report of the autumn

Tripartite FMD Group meeting will be included on the agenda for the Sixty-second Session.

Dr Bakken circulated a questionnaire on the practical arrangements for the next Session of the Executive Committee and requested that the completed questionnaire be returned to him as soon as possible.

Item 11 Any other business

Regional Workshop in Greece

Dr Panagiotatis informed the Committee that it is the intention of Greece to organise a three-day workshop at its new FMD Laboratory in Athens with the participation of two representatives from the national laboratories of Turkey and Bulgaria. He stated that this Workshop should be bench orientated and the cost for travel and accommodation will be covered by Greece. The Committee fully supported his proposal which is in line with the objective for better technical cooperation of the countries in the region. Turkey expressed appreciation for the initiative of Greece and agreed to participate. The preliminary date for this workshop is 1-5 September 1998.

Interpretation requirements at Sessions of the Executive Committee

The Committee confirmed its wish to maintain the bilingual (E/F) nature of the EUFMD. Documents for the General Session and for the Executive Committee should be produced in French and English and full interpretation facilities provided for the General Session.

Regarding Sessions of the Executive Committee, it was agreed that for budgetary reasons full interpretation cannot be provided at Sessions of the Executive Committee. The Commission therefore concurred with the proposal of the Forty-third Session of the Committee that host countries provide minimum support for interpretation as and when required.

This requirement should be included in the responsibilites outlined in the Director-General's letter to the host country.

Dr Celeda asked the Committee whether requirements for the importation of hair and wool into Europe had been agreed. Dr. Donaldson suggested that OIE code requirements should be followed.

Item 12 Adoption of the draft report

The draft report was adopted subject to agreed amendments.

The Chairman expressed the appreciation of the Committee to the Turkish colleagues, especially Drs Abdullah Kaya, A.G. Ozturk and Cafer Tetik, from the Province of Antalya, who had so efficiently and generously contributed to the success of the meeting. He extended special thanks for the warm hospitality offered and the very friendly atmosphere which had been established.

He thanked the secretriat for their work and dedication and before closing the meeting he invited Dr Voetz to take the floor. Dr. Voetz informed the Committee that after 24 years service and because of internal restructuring at the Ministry, he was taking early retirement. His departure was tinged with joy because he would be totally free to spend time with his family but also with sadness because he would miss his contacts especially the members of the Executive Committee with whom he had enjoyed working. On behalf of the Commission the Chairman thanked Dr. Voetz for his valuable contribution to the activities of the Commission and wished him a long and happy retirement.

The Chairman then closed the meeting.

Appendix 1

FMD situation in Europe and in other regions; results of the serosurvey in the Balkans

Yves Leforban

Secretary, European Commission for the Control of Foot-and-Mouth Disease

EUROPE

No FMD outbreaks have been reported in Europe since the end of October 1996. Bulgaria and Greece regained their OIE status of "FMD free countries without vaccination" in September 1997. The serosurvey organized by EC in the three Balkan countries which were infected by A type in 1996 has been completed in two countries namely FYRO Macedonia and the FR of Yugoslavia at the end of 1997 while the unstable political situation in Albania did not permit the collection of samples. 7,403 sera have been collected in the FYRO Macedonia and 6,202 in F.R. Yugoslavia. Sera have been tested respectively at the National FMD laboratory of Lindholm, Denmark, and at the WRL, Pirbright. In Macedonia, one cow was found positive for antibodies against FMD virus including the non-structural proteins. The conclusion of the National FMD Laboratory in Denmark which carried out the tests is that "the cow has with certainty been infected and the animal may be a potential carrier of FMD virus". There is evidence in 7 of the villages where testing was carried out that the virus had circulated also in a sheep. No evidence of past or present circulation of the virus has been detected in the FR of Yugoslavia.

Therefore, it can be assumed that Europe is presently free of Foot-and-Mouth Disease without vaccination with the exception of Turkish Thrace where preventive vaccination is still practised.

SITUATION IN NEIGHBOURING COUNTRIES Turkey

54 outbreaks have been reported in Anatolia, in 1997. 18 of them were located in Western Anatolia. 52 outbreaks were due to type O and 2 to type A (in Aksaray and Nigde Provinces in central Anatolia). A new programme for FMD control was started in Turkey in 1997 under the Authority of the Ministry of Agriculture and Rural Affairs. It includes a three-year intensive vaccination programme in Thrace with bivalent O, A type vaccines and the reinforcement of vaccination and of the control of animal movement in Anatolia. A new programme for the identification of cattle is also being initiated in Turkey. The EC DG VI is providing financial support to Turkey for the implementation of certain of these measures.

Between January and March 1998, 18 outbreaks have been reported, type O has been isolated in 8 Provinces, type A in five Provinces, including Kutahya Province in Western Anatolia.

CIS

FMD has been reported in Armenia, and Azerbaijan in 1996 and in Georgia, Armenia, Kirghistan and Turkmenistan in 1997. A request for support to reactivate the buffer zone of vaccination against FMD, which was formerly practised in the region under the Soviet Union.

has been sent by the countries in Trans-Caucasian and Asiatic regions and by the Federation of Russia to FAO and to OIE.

As indicated above, FMD probably due to type O was reported in Georgia at the end of 1997. Dr Kris De Clercq, Chairman of the EUFMD Research Group visited the Abkhazia region at the request of UNDP. The epidemic was over and no clinical case was observed. One of the conclusions of his mission was that, besides the FMD problem there is an urgent need for support to the veterinary service and animal production in the region. A project formulation mission has been sent to Abkhazia at the end of February 1998 with the participation of Dr Tony Garland, UK.

OTHER COUNTRIES Middle East

Disease continued to be endemic in most of the countries in the region in 1997. Control of the disease is difficult due to the importance of trade and movement of animals originating from different areas including Africa and Asia. A isolates from Iran and from Turkey were genetically and antigenically distinct from any other isolates in the WRL database. Type A continued to cause disease in cattle in Iran in January 1998

South East Asia

Taipei, China, reported to OIE on 8 January 1998, the occurrence in December 1997 of 9 outbreaks of FMD in pigs in 6 Prefectures. 324 of the 1,510 pigs present have been infected, 5 died and 489 have been destroyed. During the same period Swine Vesicular Disease has also been identified in Taiwan. During the initial epidemic which lasted from March to June 1997, 6,000 pig farms were affected and over 4 million pigs were slaughtered during the subsequent control programme. All susceptible livestock have been vaccinated.

Type O has also been found in cattle and pigs in Cambodia in January 1998

Africa

Serological surveillance in Morocco indicates that the country is now free of FMD. Virus of type A has been isolated from Senegal, Mali and Mauritania, at the WRL, Pirbright, during the last quarter of 1997 and first quarter of 1998. Two isolates from Senegal have been antigenically compared with a selection of the vaccine strains including A22 strain. None of them would be suitable for vaccination against the Senegalese strain. Biochemical characterization of the isolates also showed them to be different from other A strains. FMD due to Type O has been reported in Cote d'Ivoire and in Uganda in the first quarter of 1998. Antibodies to type A and SAT2 have been detected in sera from Eritrea.

Appendix 2

Serological survey for antibodies to FMDV in Albania: a preliminary analysis of results

A. Berlinzani and E. Brocchi Istituto Zooprofilattico Sperimentale della Lombardia e dell'Emilia (IZSLE), Brescia, Italy

Introduction

Foot-and-mouth disease (FMD) appeared in Albania at the beginning of May 1996. The laboratory diagnosis was confirmed by the Italian National Laboratory (Brescia) on 22 May. The isolate was identified as FMDV type A Albania 96, related to A 22. Outbreaks occurred in 10 villages in the Korcha district (southeast area of Albania). The disease was controlled by "stamping out" and vaccination. A total of 4,291 animals (cattle, sheep, goats and pigs) from infected villages were destroyed and a total of 266,048 and 285,263 animals (cattle, sheep, goats and pigs) were vaccinated in two rounds, respectively. No outbreaks of FMD have been reported since June 1996 and there have been no suspicions of clinical disease.

In July 1997, the Commission of the European Communities (CEC) passed a decision to assist with implementing a serological survey for antibody to FMD in the three countries that had been involved in the Balkan FMD epidemic of 1996, namely the FRY, the Former Yugoslav Republic of Macedonia (FYROM) and Albania. The objectives and workplan for the surveillance programme in the three countries were described in Commission Document VI/9036/96-EN Rev., which was accepted as Commission Decision 97/432/EC. The Istituto Zooprofilattico Sperimentale della Lombardia e dell'Emilia (IZSLE), Brescia, agreed to provide assistance to Albania and this report is a preliminary analysis of the results of the serological survey.

Objectives

- to assess the level and geographical distribution of antibodies linked to vaccines used and to field virus;
- to confirm that FMD is under control in selected areas of Albania;
- to validate a newly developed laboratory test designed to differentiate antibodies to FMD virus caused by field virus infection or as a result of vaccination.

Material and methods

Sampling strategies

The sampling strategy adopted was that proposed by the CEC mission which visited the region on 28 October 1996. A full description of the sampling protocol is given in Commission Document VI/8088/96 rev1. Briefly, the sampling epidemiological unit was taken as the village as all animals within a village were considered likely to have had contact. It was decided to sample 20 animals (5

cattle and 15 small ruminants) from each village, including bulls or rams and young animals (less than 12 months old).

For the sampling plan the following 12 districts were selected on the basis of geographical location, previous involvement in FMD infection or in the vaccination program:

- Korcha district: infected zone, protection zone and surveillance zone;
- Korcha, Pogradec, Devoll districts: ring vaccination area;
- Skrapar, Permet, Kolonje districts: FMD free area (around Korcha district);
- Tropoje, Has, Kukes, Diber, Bulqize districts: FMD free area (close to the Kosovo or Macedonia borders).

129 villages (within the 12 districts) were selected, 93 of them from FMD free areas and 36 from infected and ring vaccination areas.

Resampling strategy (in progress)

In addition to the sampling described in Commission Document VI/8088/96 rev1 it was decided to resample all animals found doubtful or seropositive to 3ABC ELISA test in the first round of sampling.

Implementation

Dr. Berlinzani of the IZSLE, Brescia visited the Albania from 27th November to 6th December 1997 to coordinate the collection and registration of sera. The equipment necessary for collection, separation, storage and dispatch of samples was supplied by the IZSLE to the National Veterinary Research Institute (IKV) at Tirana. Samples were collected by the veterinary service of the Albania according to the sampling schedule approved by EC in Commission Document VI/8088/96 rev1. Separation of sera, registration and collation of the relevant epidemiological data were carried out at the IKV of Tirana before despatching to the IZSLE, Brescia.

The first of the two consignements of serum samples (2500 sera) was received at Brescia on 30th January 1998 and the examination started immediately afterwards.

Analysis of data

Results were analysed using Microsoft Acces and Excel.

Examination of sera

All 2571 sera were examined for antibody to FMDV type A Albania 96 by a Mabs based liquid phase competitive ELISA (LPBE); end-point titres were calculated and positive sera were confirmed by VN test against FMDV A Albania 96.

All positive sera were also examined by 3ABC ELISA test to distinguish antibody induced by vaccination from those induced by infection.

Results

Of a total of 2571 serum samples examined for antibody to FMDV type A Albania 96, 336 sera were positive by ELISA and VNT. Out of them, 268 sera were from vaccinated animals; 200 more vaccinated animals did not raise FMDV antibody. Concerning the distribution of the 336 FMDV seropositive animals, the majority (n°= 309) was collected in infected and/or vaccinated districts; only 27 sera from non vaccinated districts reacted positive.

Antibody to 3ABC ELISA was detected in 51 out of the 336 seropositive samples. Forty-eight out of them and 5 3ABC doubtful sera were collected in the Korcha district, particularly in the villages where clinical evidence of FMD was recorded. Two 3ABC positive animals were found in the Pogradec district, contiguous to the Korcha district and included in the ring vaccination area. Both these animals came from the same unit.

Seropositivity against either structural and non-structural proteins was recorded from cattle, sheep and goats.

Discussion

The analysis of the seropositivity specific for A Albania FMDV indicates that:

- In vaccinated districts the percentage of seropositive animals was higher than 40%. These animals could have become seropositive due to previous infection, previous vaccination or due to non-specific reactivity in the assays used:
- In non vaccinated districts, antibody against the whole FMD virus were found in a very low percentage of animals, random distributed in various districts. This percentage (1.4%, 27 sera out of 1871) is not epidemiologically relevant and could correspond to the level of false positive reactions recorded in the test used.

In fifty animals showing antibody to the whole virus also antibody to 3ABC, marker of previous FMD infection, were demonstrated.

A preliminary analysis of the distribution of such animals indicates that:

- The majority of animals with antibody to 3ABC was found in the Korcha district; within this district, seropositivity is distributed mainly in those villages which experienced outbreaks. However, there is not evidence that FMD virus is still circulating within susceptible population of the affected districts, since young animals (born after the occurrence of the outbreaks) were generally found negative against both structural proteins and 3ABC polypeptide.
- The absence of antibody to 3ABC in the 27 animals, which showed antibody to the whole virus, although collected in non vaccinated and clinically FMD free districts, suggest the absence of FMD infection in those districts and could confirm the non-specific reactivity of LPBE in same sera. In fact the VN titer of these sera has to be considered only doubtful according the evaluation reported in the OIE manual.

In conclusion, results of the serosurvey conducted in Albania demonstrate the presence of animals which have been infected with FMDV in any groups of animals examined, i.e. vaccinated or non-vaccinated cattle and small ruminants.

Appendix 3

Serological survey for antibody to FMDV in the Former Yugoslav Republic of Macedonia (FYROM): a technical Report in accordance with Commission Decision 97/432/EC of 02/07/97

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Introduction

In June and July 1996 a foot-and-mouth disease (FMD) epidemic occurred in FYROM affecting 18 villages in two districts, Skopje and Titov Veles. The first outbreak was diagnosed on the 23rd of June and the last on 13 th of July 1996. The disease was controlled by vaccination and by "stamping out". A total of 120,000 cattle were vaccinated, but the animals were not marked. A total of 4,500 cattle from infected villages were destroyed. Clinical disease was only observed in cattle. In July 1997 the Commission of the European Communities (CEC) passed a decision to assist with implementing a serological survey for antibody to FMDV in the three countries that had been involved in the Balkan FMD epidemic of 1996, namely Albania, the FYROM and the Federal Republic of Yugoslavia. The objectives and workplan for the surveillance programme in the three countries were described in Commission Document VI/9036/96-EN Rev. 1, which was accepted as Commission Decision 97/432/EC. The Danish Veterinary Institute for Virus Research, Lindholm, agreed to provide assistance to the FYROM and the results of the survey are summarised in this report.

Objective

- Assess the level and geographical distribution of antibodies linked to vaccines used and to field virus.
- Confirm that foot-and-mouth disease is under control in selected areas of FYROM.

Materials and methods

Sampling strategy

The sampling strategy adopted was that proposed by the CEC mission which visited the FYROM in October 1996. A description of the sampling protocol is given in Commission Document VI/8088/96/ rev. 1.

In brief, the epidemiological unit was the village, as all animals within the village were considered to have had contact, or a state farm. In the sampling plan adopted 22 animals were to be sampled from each epidemiological unit; 11 cattle including one bull, and 11 sheep including one ram. All epidemiological units in the infected zone were included and 10% in the vaccination and surveillance zones.

Implementation

Dr Sørensen of the DVIVR, Lindholm ,visited the FYROM 27-29 August 1997, to co-ordinate the collection and analysis of sera. The equipment necessary for

collection, separation, storage and dispatch of samples was supplied from the DVIVR to the Veterinary Institute in Skopje. Samples were collected by the veterinary service of FYROM according to the sampling schedule approved by the EC in Commission Document VI/8088/96 rev 1. Serum was separated and registration and collation of the relevant epidemiological data were carried out using Microsoft Access database at the Veterinary Institute in Skopje before despatch to the DVIVR, Lindholm. The last of the two consignments of serum samples were received at Lindholm Tuesday 9th December and the examination was started immediately afterwards.

Examination of sera

Sera were examined for antibody to FMDV type A Macedonia 96 at the DVIVR, Lindholm. Initial screening was performed using the whole virus blocking ELISA (ELISA A-Mac) at a dilution of 1:4 (Have and Jensen, 1983). Sera with ODp values of less than 55, i.e. showing more than 45% inhibition, were retested in the ELISA A-Mac and in addition tested for antibodies against the non-structural proteins 3D, 3AB and 3ABC at a dilution of 1:5 (Sørensen et al. 1998). Sera positive for antibodies against the NSP's 3AB or 3ABC were titrated.

A hundred sera from vaccinated animals were titrated in the whole virus blocking ELISA and 300 sera were also tested for antibodies against FMDV type O1-BFS.

Analysis of data

Results were analysed using Microsoft Access and Excel.

Results

Initial sampling

A total of 7,403 serum samples were screened initially for antibody to FMDV type A Macedonia in the ELISA A-Mac (Fig. 1). Of these 3,606 were sera of cattle, 3,263 sera of sheep and 511 sera of goats, while 23 samples had no species specification. A total of 2,381 samples had ODp values of less than 55 in the initial screening and were tested again in the ELISA A-Mac and in addition in the 3D, the 3AB and the 3ABC ELISA. Result profiles as shown in Fig. 2 were obtained with the ELISA A-Mac. The lines RS2 and RS3 indicate the results obtained with a low positive and a "cut off" standard serum produced by Pirbright Laboratory (sera with ODp values below 40 were considered positive, and sera with ODp values above 40 negative). Of the sera of cattle, sheep and goats 36%, 2% and 1%, respectively, were positive for antibodies against FMDV A-Macedonia. Of the 3,606 sera of cattle 2,582 were collected from cattle in the vaccination zone and 1,024 from cattle outside the vaccination zone (Fig. 3). Of the cattle from inside the vaccination zone 1,568 were older cattle, more than 12 months of age, and 1,003 were younger than 12 months of age, while 11 were of unknown age. Sixty-three percent of the older cattle were positive for antibodies in the ELISA A-Mac (ODp values below 40) and 24% of the younger cattle were also positive. As the latter were not vaccinated these antibodies probably represented remaining maternal antibodies. Of the cattle outside the vaccination zone 4% were positive probably due to movement of cattle between the zones.

On the retest of the 2,381 samples positive results were obtained in the 3D ELISA compatible with post vaccination antibodies on 40% of the samples. Only 1% and 0.8% were positive in the 3AB and the 3ABC ELISA, in total 22 samples (Fig 4). The

22 sera were titrated in the ELISA A-Mac, the 3D, the 3AB and the 3ABC ELISA (Table 1). Two sera (cattle sera) were low (borderline) positive in 3AB ELISA while negative in the 3ABC ELISA; one of these were also borderline in the 3D ELISA and the other was borderline in the ELISA A-Mac. Three of the sera were from cattle and the rest from sheep. One of the cattle and two sheep were less than 12 months of age. It appears from Table 1 that, with the exception of two of the cattle, which were borderline, the animals had medium to high titres, and some had very high titres. The animals originated from 10 villages. Detailed information on the animal population in the villages are given in annex 1 to 10.

Titres were determined on serum of 100 vaccinated cattle (Fig.5). It appears that 38% had titres of <8 and 53% had titres in the range 8-64.

Among the 2,381 sera mentioned above, that had been retested, 300 were also tested for antibodies against FMDV type O1-BFS. All but 5 sera were negative for antibodies against FMDV type O1-BFS. The 5 sera had low titres in the range 8 to 49 and were also positive for antibodies against FMDV type A-Holland and/or type C-Turup and were probably post vaccination sera of animals vaccinated previously with trivalent vaccine.

Second sampling

Resampling were carried out in the 10 villages mentioned in the Annexes 1 to 10. The number of samples collected per village appears from Table 2 and was the minimum required to achieve a 95% level of confidence at a prevalence of 5%. Serum samples of 18 sheep and 22 cattle were missing. In addition 33 serum samples could not be identified as the numbers were not recorded on the sample list. Twenty samples had numbers that were duplicate numbers and therefore not unequivocally identifiable. The sampling was carried out in March 1998 and the samples arrived to Lindholm early April. In order to monitor possible spread of infection from older animals infected during the outbreak in 1996 all age groups of cattle were sampled, whereas the sampled sheep and goats were born during spring 1997. To exclude maternal antibodies obtained by suckling FMDV antibody positive sheep/goats the animals should be more than 6 month of age. In addition, 53 samples of which 44 appeared to be from cattle and 9 from sheep/goats were of animals, which were also sampled during the initial round.

All samples were tested in the ELISA A-Mac, the 3D, the 3AB and the 3ABC ELISA. No evidence of infection with FMDV was found in the sera of cattle. All sera that were positive in the ELISA A-Mac and the 3D ELISA were negative in the 3AB and the 3ABC ELISA compatible with post vaccination antibodies. However, in sheep or goats indication of previous infection i.e. antibodies against 3AB and 3ABC were found in sera collected in 5 villages (Table 2). From the village Ljubanci 13 animals were positive in flocks belonging to 2 owners; 11 positive of 20 sampled and 2 positive of 3 sampled, respectively. In total 17 owners were recorded in Ljubanci of which 6 were sheep/goat owners. From Bulacani 16 animals were positive in flocks belonging to 7 different owners. In total 32 owners were recorded in Bulacani of which 8 were sheep/goat owners. The ratio of positive animals to numbers sampled belonging to each of the 7 owners were 4 to 9, 1 to 2, 1 to 5, 2 to 9, 1 to 9, 4 to 9 and 3 to 6, respectively. Thus a tendency of clustering of positive animals within the village on individual owners appeared. In Rastak and Kuceviste the 2 positive animals were also positive at the initial sampling. The 2 positive animals in Rastak had numbers 51138 and 51140, which were probably 5138 and 5140 in the initial sampling. They were the only samples collected from animals of the owners in

question. In Cerkezi 1 sample was positive among 38 samples from the same owner. The positive samples were titrated in the ELISA A-Mac, the 3D, the 3AB and the 3ABC ELISA and the results are shown in Table 3. All the samples except 2 from Bulacani were positive in all 4 assays. It appears that 2 additional samples of sheep from Bulacani were positive in the ELISA A-Mac and the 3D ELISA while negative in the 3AB and the 3ABC ELISA, indicating that they, if vaccination can be excluded, also had been infected. None of the 53 animals which had been sampled in both the initial and the second round had seroconverted during the time period between the 2 samplings. However, 6 of the 9 sheep/goats were positive on both occasions. One sample 46953 (Table 3) was not identifiable, but judged on the seize of the number it fitted in with the sheep from Bulacani.

Thus it appeared that the problems at present may be confined to sheep/goat flocks in the villages Bulacani and Liubanci.

Discussion

Infected cattle were destroyed after the outbreak in 1996. However a cow (Eartag no 6361) from the village Kisela Jabuka, where the cattle were vaccinated, was positive for antibodies against the NSP's 3AB and 3ABC in addition to the NSP 3D and the structural proteins with relatively high titres, showing that it had become infected with FMDV apparently without clinical disease being noticed. However five other cattle with the same owner were negative. Two cattle from other villages were low positive or borderline for antibodies against the NSP 3AB. One of the two cattle was less than one year old. Cattle can carry FMDV for two years or more, and there is field evidence that they can transmit the disease to susceptible cattle. However, none of the cattle sampled in March 1998 showed any serological evidence of infection with FMDV, and none of the 44 cattle which were sampled initially had seroconverted in the meantime.

Thus it appears likely that FMDV at present is absent from the cattle population in Macedonia.

No clinical signs of FMD were observed in sheep during the outbreak of FMD in 1996. However, sheep may show none or very mild symptoms and one or more sheep from the flocks of seven villages were positive for antibodies against the NSP's 3AB and 3ABC in addition to the NSP 3D and the structural proteins at the initial sampling, showing that the flocks had become infected with FMDV. One of the villages, Ljubanci, was outside the vaccination zone, but the cattle were apparently not affected. Sheep are not known to carry FMDV for more than about 9 months after infection, however the infection may be perpetuated by transferring the infection to susceptible offspring and other susceptible animals in endemically infected flocks. It was therefore important to test young animals born during spring 1997, i.e. about a year after the outbreak in 1996, but being more than 6 month of age in order to have lost maternal antibodies. Anticipating the sampled animals were between 6 and about 12 months of age indication of spread of infection was seen in the villages Bulacani and Ljubanci. Within the villages there was a tendency of clustering of the positive animals on individual owners, which may indicate a virus spread basically limited to very close contact such as possibly mother-offspring contact. In that respect it is also noteworthy that the cattle in the 2 villages apparently were free of infection with FMDV. Being the only 2 known villages with serological indication of multiplication of FMDV, the infection appears at present to be geographically confined in Macedonia and limited to sheep and goats. However, it should be noted that Ljubanci is situated outside the vaccination zone and that only 10% of the villages were sampled in the vaccination and the surveillance zones.

References

Have P and Jensen MH (1983) Detection of antibodies to FMDV type O by enzyme-linked immunosorbent assay (ELISA). Proceedings of the Session of the Research Group of the Standing Technical Committee of the European Commission for the Control of Foot-and-Mouth Disease, Lelystad, Netherlands, 20-22 Sept: Appendix VIII 44-51.

K.J. Sørensen, K.G. Madsen, E.S. Madsen, J.S. Salt, J. Nqindi, D.K.J. Mackay. (1998) Differentiation of infection from vaccination in foot-and-mouth disease by the detection of antibodies to the non-structural proteins 3D, 3AB and 3ABC in ELISA using antigens expressed in baculovirus. Archives of Virology. In press.

The FMD Status and the Strategy to combat FMD in Turkey

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1. Introductory comments

FMD is one of the most important disease causing significant economical loses. Vaccination, quarantine and control of animal movements are being applied to control the disease. Stamping out policy has been approved to be applied in the planned regions. FMD is endemic in Anatolia (types O and A). Thrace has been declared to be disease-free in 1991.

According to the Turkish Law 3285 Article 108, the scheduled disease has to be immediately notified to the veterinary authorities which undertake respectively supervise the necessary measures, such as outbreak investigation, taking of specimen for typing at the FMD Institute, Ankara, ordering movement restrictions to prevent further spread, quarantine, taken cordon, disinfection, compensation (destruction and stamping out), ring vaccination etc. Adjacent districts as well as neighboring provinces are immediately alerted.

Species	Thrace	Western Buffer Zone	Residual Anatolia	Total
Cattle	447,195	1,842,015	9,692,000	11,901,000
Buffaloes	7,230	32,820	365,500	405,550
Sheep	693,820	4,381,110	34,755,000	35,646,000
Goats	157,645	1,263,145	9,447,000	9,564,000

Table 1. Livestock population in Turkey in 1994*

2. Status of the Disease

2.1 The Trace Region

Trace was declared as FMD-free in 1991 (OIE Bulletin Vol.1 No.1, 4, January 1991). This zone composes in European part of Turkey with the following five provinces: European part of Istanbul, European part of Çanakkale, Tekirdağ, Kırklareli, Edirne.It has about 454,425 cattle and buffaloes as well as about 851,465 sheep and goats.

No vaccination has been carried out in Trace until the outbreak occurred in Ulukonak village of Kırklareli province, which was reported on 13.03.1995. In March 1995, all susceptible stock in a ten-kilometer radius of infected village was vaccinated with bivalent (A+O) FMD vaccine.

Two FMD outbreaks occurred in Kadıköy village of Keşan district and Ortakçı village of Lalapaşa district of Edirne province in Turkey on 27 May 1996 and 7 June 1996 respectively. Those outbreaks ended in 27 June 1996 and 5 July 1996 respectively.

^{*}SIS (State Institute of Statistic) Annual Report, 1994

All cattle were vaccinated against types O_1 and A_{22} three times and sheep and goats once in this region in 1997 in accordance with the established program. Strict measures have been taken and disease surveillance has been carried out within the Trace region continuously. No FMD outbreak was occurred in 1997.

Table 2. Vaccinations carried out in the Thrace in 1997 and 1998 (first round).

	Large ruminants		Small ruminants		
	Population	Vaccination ratio	Population	%	
round of vaccination	454.425		851.465	95	
2. round of vaccination	454.425	90			
3. round of vaccination	454.425	83.			
round of vaccination	454.425	59	851.465	47.5	

A contingency plan has been prepared to control the disease to react appropriately in the case of a FMD outbreak in Thrace. The legal regulations have been prepared for the application of the stamping out policy, which can be followed after the vaccination campains, if sufficient funds are available.

Cattle identification programme (ear tagging) was started in the beginning of 1997, but couldn't be completed because of some handicaps, which will be discussed later in chapter 4.

In 1998 first round vaccination has already been completed in Thrace as in the other parts of Turkey. 268.423 (59%) cattle and 404.683 (47,5%) sheep and goats were vaccinated in this period.

2.2 The Western Buffer Zone of Anatolia (WBZ)

This area includes 14 provinces: The Asian sides of Istanbul and Kocaeli, Adapazarı, Balıkesir, Bilecik, Bolu, Bursa, Çanakkale, Eskişehir, İzmir, Kütahya, Manisa, Uşak and Yalova. There are about 1.874.835 cattle and buffaloes as well as 5.644.255 sheep and goats.

According to the programme all of the cattle should be vaccinated twice a year and all the sheep and goats once a year in this region. However, neither in 1997 nor in spring campain of 1998 this could not to be achieved because of the financial problems and some other factors. In the first round of the vaccination 1997 1.345.415 (72%) Large ruminants and 1.663.668 (29%) small ruminants were vaccinated. In the first round vaccination in 1998, 622.578 (33%) cattle and 393.264 (0,7%) sheep were vaccinated only.

Outbreaks in this area are also dealt with, in accordance to the law no.3285, including temporary quarantine, transport restriction, ring vaccination, disinfection, etc.

There was a significant dicrease in the number of the outbreaks in WBZ during 1997 in comparison with 1996, 23 and 41 respectively. In 1998 in the first 3 months 7 FMD outbreaks occurred.

Table 3. Reported outbreaks in the Western Buffer Zone, 1996-98

Provinces in alphabetical order		•		Numbe	r of Outb	reaks in Y	ears	•	·
	1996			1997		1998(3 months)			
	Α	0	Total	A	0	Total	A	0	Total
Aydın		12	12	-	5	5	1	2	3
Balıkesir	_	7	7	-		-	-	2	2
Bilecik		2	2	-	2	2	 -		- -
Bolu			-	1-	10	10	 		 -
Bursa	-	2	2	-		<u> </u>	† <u> </u>		 -
Çanakkale	<u> </u>	1	1		-	-	 _ 		 -
Eski°ehir	_	3	3	1	2	3			 _
İstanbul	-	-	Ī-	1-		† <u>-</u>	† -	-	-
İzmir	-	 -		-	-	-	† <u> </u>	 -	
Kocaeli	- ,	4	4	-	-	<u> </u>	<u> </u>		 -
Kütahya	-	3	3	_	1	i.	1	1	2
Manisa	-	2	2	-	-	 -		- -	 -
Sakarya	-	-	-	_	1	$\frac{1}{1}$		1_	+
U°ak	-	3	3	Ī-	 - -	- -	_	 -	 -
Yalova	-	2	2	-	1	 	_	- - -	 -
TOTAL		41	41	1	22	23	2	5	7

There is a strong movement of beef cattle from the east of Turkey to the consumer centers in the western and central part of Anatolia. A number of control stations (Giresun-Center, Tokat-Reşadiye, Sivas-Center, Malatya-Karakavak, Kahramanmaraş-Pazarcık and Gaziantep-Nizip) have been set up at a northwest line stretching from Giresun to Gaziantep in order to check livestock transports coming from the east to the Western Buffer Zone. Some animals, moved from WBZ to Thrace region, must have stayed in WBZ at least 6 months.

2.3 The other provinces of Anatolia

There are about 10.057.500 cattle and buffaloes as well as about 44.202.000 sheep and goats in the remaining part of Anatolia. In accordance with vaccine vailability, vaccination was carried out in areas along the main east-west livestock transportation routs, in certain project areas, and in the case of private request of the farmers 6.716.423 (66%) large ruminants and 3.644.956 (8%) small ruminants were vaccinated in 1997. In 1998, spring vaccination campain, the figures are 1.584.163 (16%) for large ruminants and 556.017 (1%) for small ruminants.

The first round of 1998 vaccination has already been completed in all over the country.

FMD type O is widespread in Anatolia. Ring vaccination, strategic vaccination and quarantine measures are being applied in that area. Due to illegal movements from neighboring countries there is always the risk of new outbreaks.

It was planned that all cattle and buffaloes in the country would be vaccinated twice a year, all sheep and goats once a year in 1997, but the result came out to be unsuccessful.

2.4 Needs for vaccine and vaccination campaigns

All cattle will be vaccinated twice a year and small ruminants once a year between 1998-2000 in Turkey. On the base of this programme, the bivalent vaccine demand is 45.052.688 cattle doses/year.

Table 4. Vaccine requirement for 3 years vaccination campaigns

District	Bivalent cattle doses per year				
	1998	1999	2000		
Thrace	1.249.516	1.249.516	1.249.516		
WBZ	6.007.372	6.007.372	6.007.372		
Other provinces	37.795.800	37.795.800	37.795,800		
TOTAL	45.052.688	45.052.688	45.052.688		

3. Present status of FMD Institute and other laboratories

FMD Institute (Şap Enstitüsü) is the only laboratory for vaccine production and diagnosis of FMD in Turkey. It also carries out the epidemiological studies in the country. The annual production capacity is 30 million bivalent cattle doses.

The authorities have given permission to produce FMD vaccines to a private company, VETAL in Adıyaman. Production capacity of this plant should reach to 22 million bivalent cattle doses per year. However, in 1997 only 5 million doses produced.

There is no standard quantity for imported vaccines.

Table 5. Vaccine supplying companies

Sources	Years				
	1998	1999	2000		
Şap Institute	30.000.000	30.000.000	30.000,000		
National private company *	22.000.000	22.000.000	22.000.000		
EU bank	Unknown	Unknown	Unknown		
Imported	200.000 (first 4 months)	Irregular	Irregular		

^{*}maximum capacity

The Ministry of Agriculture and Rural Affairs (MARA) has already started to establish an independent vaccine control laboratory at Bornova, İzmir. Although it was planned to complete the building it will not, because of the financial insufficiency.

4. Presently applied methodology

The responsible ministry for livestock production and animal health is the General Directorate of Protection and Control (GDPC) in the Ministry of Agriculture and Rural Affairs (MARA). Animal Health Department is established in GDPC.

The transportation of the animals within the country requires a health certificate issued by the State Veterinary Officers after the inspection of the animals. If the province of the origin is under quarantine, no animals are allowed to leave the province.

In the case of a FMD outbreak, where stamping-out measures will be applied, all the measures foreseen in the Turkish Law No.3285 (Article 41,108,etc.) are taken.

According to the Article 108, when FMD outbreaks occur, the Animal Health Control Commission should meet as soon as possible and measures should be taken based on the fourth part of chapter 1 of the Law 3285, guide.

The animal markets and stock exchange places that belong to the MARA and municipalities are under the control of State Veterinary Offices.

The regionalist approach for the country, with vaccination in Thrace, prophylactic mass vaccination in the WBZ, and vaccination in the rest of Anatolia has been explained already.

Apart from recording the outbreak situation and procedure on district and province level, the Animal Health Section at the GDPC is receiving these informations and compliance with an annual report.

Animals to be transported have to be vaccinated two weeks prior to their dispatch, and health and vaccination certificate has to be accompanying the animals. The increased vigilance at transport checkpoints was already mentioned in section 2.2.

Prerequisite of any meaningful disease control is the introduction of permanent identification of livestock because health certificates and other related matters are only controllable by individual identification. Following series of unsuccessful attempts done in the preceding years, pilot applications have been started in Thrace in 1997 by the support of EU project. Subsequently this work will be generalized in the country.

5. The knew A type virus outbreaks

FMD was continued to be endemic in Turkey in 1997 and only 3 of the outbreaks were A type, in March and August.

This year, 1998, 8 A type outbreaks were notified in 5 provinces (Ankara, Aydın, Burdur, Kütahya, Malatya) in the first 3 months.

The exact origin of those outbreaks has not been clarified. According to the information from the local authorities, disease cases were associated with the illegal movement of young and unvaccinated beef's cattle to and from Malatya, Kütahya, and Burdur and Afyon provinces by some dealers.

The outbreaks were controlled by disinfection, movement restrictions and ring vaccination of cattle with a bivalent vaccine (A_{22} Mahmatli + O_1 Manisa).

FMD Institute (Şap Inst.), Ankara have been informed about the circulation of new A type FMD virus strain in Iran by Dr.Paul Kitching and Dr.Sinan Aktaş at Pirbright Institute (IAH), U.K. However there was no suspicious situation in the field until the end of last year. The virus samples being sent to above mentioned Institute was identified as A₂₂.

This year, January 1998, some unusual FMD outbreaks appeared in the vaccinated animal populations in malatya and Kütahya provinces. Vesicular epithelium from these infected areas have been collected and tested at Şap Institute and in the mean time

they were sent to Pirbright Institute for further identification by molecular techniques. At the beginning of March the report of the tests at Pirbright Institute was sent which confirms the suspicious situation.

In February/1998 tissue culture adaptation studies were started at ^a ap Institute with A/Kütahya and A/Malatya virus strains. However, the titter is still low both in cell culture (FLK, IB-RS2 and BHK21) and ELISA. Recently (in the mid March) a new A type outbreak appeared in Burdur province. Cell culture (FLK) adaptation studies have also started with those fresh samples.

Since there is an urgent need to produce vaccine against new type A virus ^a ap Institute has got in touch with IFFA- MERIAL to obtain vaccine virus strain both as vesicular epithelium and tissue culture virus. No reply was received until now.

5.1 Planed future activities of Ankara FMD Institute

- *Vaccine production will start with the virus strain been received either from IFFA-MERIAL, France or Razi Institute Iran or another laboratory abroad;
- *Trivalent vaccine (A₂₂/Mahmatlı+A/Iran+O₁Manisa) will start to be produced at FMD Institute, Ankara.
- *To supply vaccine from European Vaccine Banks will accelerate the emergency vaccination programs in the infected and risky areas in the field;
- *Close collaboration with both Pirbright Institute, England and Razi Institute, Iran.

6.Major constrains & problems

- A. The animal health situation and other problems in some neighboring countries;
 - B. The difficulties in animal movement control;
 - C. Restriction of resources available to the Animal Health Services;
- D. The main animal production areas in Turkey are different from the main areas of consumption;
- E. On time official information of the outbreaks in the neighboring countries;
 - F. Recent initiatives for co-operation with donor agencies:
 - *Application for a FMD projects (EU);
- *Application for the upgrading of the Bornova Control Laboratory to a Quality Control Laboratory for Viral Vaccines (EU);
- *Application for experts to assess the feasibility of setting is revolving fund to compensate farmers' losses due to official combat measures against certain Epizooties.
- *Urgently preparation of a new project for improvement of the diagnostic laboratories at Şap Institute or to put the previously prepared project for collaboration with Pirbright (IAH) Laboratories on the agenda.

Quality assessment of FMD vaccines

Extract from EC Doc. VI/4848/98

1. Awarding authority

European Commission, DG VI – Agriculture "Veterinary and zootechnical legislation" (L-86 7/49), rue de la loi/wetstraat 200, B-1049 Bruxelles/Brussels.

2. Service category and designation

The Commission wishes to assess the quality of the European vaccine produced from the antigens which have been purchased for the European FMD vaccine bank under Commission Decision 97/348/EC. The sub-types of inactivated antigens of the FMD virus which have to be formulated into vaccine and tested are the following:

-A22 Iraq

-ASIA 1

Furthermore the Commission wishes to control the quality of the bivalent vaccine produced in Turkey and used in Turkish Thrace for mass vaccination in the buffer zone against foot-and-mouth disease virus Type A_{22} and 0_1 .

3. Quality assessment of the FMD vaccines produced in Turkey:

Quotation 5: Testing Turkish bivalent vacine type A_{22} and θ_1

Service description and technical criteria for testing

This vaccine is produced in the following laboratories:

- The SAP Institute in Ankara
- The VETAL Laboratory at Adiyaman

The vaccine is to be tested on its

- Safety
- Potency

The bottling and sampling of the vaccine shall be done under supervision of an expert of the testing laboratory.

The safety of the vaccine will be assessed by the control of the production and inactivation protocols of the manufacturer.

Representative samples of a batch of the above-mentioned vaccine produced in the SAP Institute and of a batch produced at VETAL, shall be tested using the liquid phase blocking ELISA after vaccination of cattle.

Selection criteria

The candidate laboratory has to be listed in Annex B of Council Directive 85/511/EC.

Minutes of Ad-hoc EUFMD/FAO/EC/OIE/Turkey/Iran, Meeting held at FAO HQ, Rome on 22 April 1998

Present:

EUFMD:

Dr. R. Marabelli, Chairman, EUFMD

Dr. K. De Clercq, Chairman, Research Group, EUFMD

Dr. Y. Leforban, Secretary, EUFMD, AGA

FAO

Dr. Y. Cheneau, Chief, Animal Health Service, AGA

Dr. P. Roeder, Animal Health Officer, EMPRES, AGA

EC

Dr. A.E Fuessel, European Commission DG VI.B.II.2

Pf. R. Ahl, Scientific Committee on Animal Health, EC Comission

OIE

Dr. Robert Reichard, Chief Scientific Division, OIE

WORLD REFERENCE LABORATORY FOR FMD

Dr. A.I. Donaldson, Head Pirbright Laboratory, IAH, U.K.

TURKEY

Dr. Musa Arik, MARA, Ankara

Dr. Muhammed Aksin, Director Sap Institute, Ankara

I. R. IRAN

Mr Mohammad Ali Yazdani, Permanent Representation of the I.R. of Iran to FAO, Rome

Dr. Cheneau welcomed the participants and wished them a successful meeting and a pleasant stay in Rome. He then reviewed the questions to be addressed by the meeting.

- 1- Does the vaccine currently available against type A in the vaccine banks protect against the new variant?
- 2- Is there a need to make a trial to estimate the protection of available vaccines against the new variant?
- 3- Is there a need to produce homologous vaccine against the new variant?
- 4- Recommendations to the vaccine banks.
- 5- Need to modify the policy of vaccination in Thrace, in the SVZ, in the rest of Turkey by including the new variant in the vaccine.

Dr Marabelli thanked the participants for attending this important meeting. He stated that in view of the new situation and in order to prevent spread of the strain into Europe rapid joint action should be taken by the European Commission for the Control of Foot-and-Mouth Disease, EC and the countries directly concerned.

Dr. Leforban, Secretary of the EUFMD, chaired the meeting and presented the following agenda/timetable which was adopted by all present.

Provisional agenda

- 1. Situation in the countries infected with the new variant In Iran, Mr Yazdani In Turkey, Dr M. Arek
- 2. Characterization of the new strain:

Razi Institute, Iran

Sap Institute, Turkey: Dr M. Aksin

World Reference Laboratory, Pirbright: Dr A.I. Donaldson

- 3. Need for further research and new vaccine:
 - -Iran,
 - -Turkey,
 - -other countries,
 - -Europe.
- 4. Conclusions and recommendations.

Situation in Iran:

Information on the situation in Iran was communicated through a written report provided by Dr A.A. Mottalebi, Head Veterinary Organisation of the IR of Iran who could not attend the meeting due to difficulties in obtaining a visa. The information from Iran was sent via the representation of the IR of Iran to FAO and was presented by Mr Yazdani.

The disease due to the new strain was discovered through a break down in vaccination using vaccines based on A 22-like viruses. It was first reported in the West Azerbaidjan Province in spring 1996 and the strain then spread progressively to 12 Provinces in 1997 and 1998. Mortality in lambs and calves was reported in the first outbreaks but later the pathogenicity of the strain was considered as being identical to other strains of A or O types both in small ruminants and in cattle.

Situation in Turkey

Dr Mussa Arik presented a document on the FMD situation in Turkey and he emphasized especially the situation related to the new variant A type, and the measures taken to control the disease. The new variant of virus was isolated from two outbreaks in Malatya Province in Central Anatolia at the end of December 1997, and in January 1998. The disease was observed in vaccinated animals. Three additional outbreaks due to the new variant were reported in January 1998 in Kutaya Province in the Strategic Vaccination Zone of Western Anatolia. The tracing of the origin of the Kutaya outbreaks indicated that animals had been transported from Malatya Province. The result of the characterization of the strain carried out at Pirbright was known at the end of March 1998 and since then the Sap Institute has been working actively on the new variant to adapt it for vaccine production.

The participants discussed the FMD situation in Turkey. Insufficient surveillance of the disease and the consequent lack of epidemiological information regarding the Eastern part of the country was underlined.

The representative of Turkey presented the current legal measures that are compulsory for controlling FMD outbreaks in Turkey. The meeting noticed that certain of these measures - such as the absence of stamping out of clinically infected animals associated with the short duration of quarantine - 15 days - are insufficient to effectively control the spread of infection.

Characterization of the new strain

Dr Donaldson presented tables and one dendrogram on the genomic characterization of the isolates from Iran and from Turkey. Isolates from Iran received by the WRL mainly originated from cattle. The first evidence of the occurrence of the new variant in Iran is related to one isolate from a sample collected in November 1996 in the west of the country.

Serological assays performed in the WRL, Pirbright, to compare antigenically four randomly selected isolates of type A virus from Iran and two isolates from Turkey with four different type A22 vaccine strains showed that the r1 values were <0.2 in all cases. These results indicate that none of these A22 vaccines would be likely to effectively protect against the A Iran 96 variant virus after one dose of vaccine.

Need for research and for vaccines

Iran has already adapted the new variant (called A/Iran/96) for vaccine production and since the middle of 1997 this new strain is included in the vaccine produced by the Razi Institute; a trivalent vaccine (A Mardabad, A/Iran/96, O1) is currently used in Iran.

Turkey informed the meeting that they are still in the process of adapting the new strain for vaccine production but they need technical support and/or the provision of the adapted strain from another manufacturer. They anticipate a delay of two months to produce the new vaccine after they have received the new cell-adapted vaccine strain.

Pf. Ahl proposed that a comparative evaluation of the vaccine protection of A 22 vaccines and of the new vaccine, including challenge tests, be organized. This evaluation should consist of vaccination of cattle with A 22 vaccine and the new variant type A, respectively and challenge with the new variant virus of three groups of 5 animals;

- one group receiving one injection of A 22 type vaccine
- a second group receiving one injection and one booster of A22 vaccine
- a third group receiving one injection of a new vaccine specific to the new strain.

The need for such an experiment was not clear to all participants. While approving the need for a challenge test some participants were of the opinion that such a trial should be carried out by the manufacturers of the vaccines. For Pf Ahl and others, an independent experiment with challenge is needed before taking a decision regarding the inclusion of the new strains in vaccine banks.

CONCLUSIONS

There is a need for more information on the epidemiology of FMD in Iran, Turkey and neighbouring countries in general and specifically with respect to the new type A variant.

Experimental and field observational data suggest that currently available type A vaccines can not be relied on to provide serviceable immunity against the new type A variant in emergency control situations.

There is an urgent need to develop new vaccines to provide protection against the newly-identified strain.

RECOMMENDATIONS

Prevention of movement of the new FMD type A to Europe

Based on historical precedents for the movement of FMD viruses from Asia to Europe and the particular antigenic character of the new virus strain, there is an urgent need to immunise all ruminants in Thrace with a vaccine of proven safety and potency (minimum 10 PD50) against the new variant Type A FMD virus and support this with seromonitoring of the response to vaccination.

Measures and legislation for the control of FMD outbreaks in Turkey should be modified to better prevent the spread of infection. Expertise from the WRL can be sought if needed to advise on the scientific bases for a new legislation.

The need for a new vaccine + cooperation and assistance

As there is an urgent need to develop and produce a new FMD vaccine to protect against the new variant, vaccine producers in Europe (or elsewhere) are encouraged urgently to initiate and expedite research work on the new strain and its adaptation to vaccine production conditions to produce an experimental homologous vaccine for efficacy testing.

There is a need for technical assistance to assist the development of vaccine production, using the new variant virus (possibly with provision of a candidate vaccine strain to Turkey), in the Sap Institute, Turkey, and the Razi Institute, Iran and to ensure that laboratory tests are optimised for FMD surveillance.

Cooperation between the Razi Institute in Iran and the Sap Institute in Turkey is encouraged in the field of surveillance and of vaccine production for the new FMD strain. This cooperation could include the exchange of reagents, virus strains (the new vaccine strain) and joint research of common interest for the two countries. An expert in vaccine production should visit the two Institutes and advise on modern technology of FMD vaccine production. This cooperation should be supported by international organisations.

Vaccine banks

An appropriate antigen to induce protection against the new variant type A virus should be included in European vaccine banks.

Provision of vaccine strain

The WRL-FMD is requested (and has agreed) to provide the new virus on request to any vaccine producer.

Diagnosis and serosurveillance

As the new variant is antigenically distinct from other type A viruses encountered in the region, FMD laboratories should use a mixture of polyclonal antisera (A_5 , A_{24} and A_{22}) in ELISA antigen detection tests, a procedure which has been demonstrated to work effectively. For serosurveillance there is a need for the WRL-FMD to check if the current LPBE reagents can detect animals convalescent after infection with the new variant virus and to produce a new reference serum. There is a need to produce novel monoclonal antibodies able to distinguish between the new variant and other type A strains from the region.

Strengthening disease surveillance and epidemiological understanding

There is a need to compile data on the events which have occurred in Iran, Turkey and neighbouring countries in order to attempt to clarify the origins and means of spread of the new type A FMD strain. FMD in small ruminants is often mild or subclinical and they probably play an important role in transmission; this requires clarification. Current collaborative studies between the WRL-FMD and the Sap Institute and Razi Institute should be supported and used as a model for other countries.

The meeting supported proposals presented by the Head of the Iran Veterinary Organisation in his report to the meeting and stressed the importance of support being provided for points # 4, 5 and 6 which read (paraphrased):

- diagnosis, epidemiology, immunology and vaccine manufacturing and control
- establishing an active disease surveillance system in Iran
- organising joint conventions with neighbouring and regional countries

The meeting also recommended that support should be provided to Turkey for strengthening of disease surveillance and epidemiological investigations of transboundary animal disease occurrence using the full capacity of the epidemiological expertise available within a co-ordinated national epidemiological structure.

Understanding livestock movements

Livestock movements in trade and transhumance are important determinants of the transboundary and intraboundary movement of epidemic diseases in Iran and Turkey and they need to be documented and monitored.

Additional sources of epidemiological information

The Secretary of the EUFMD is requested to seek from the Vladimir Institute, Russia, any information which might be relevant to the appearance of the new variant.

Future meeting

A further meeting between Turkey, Iran and FMD experts should be organised by OIE in Paris to review developments at the time of the OIE General Session in May 1998.

Movement Towards a Generic Veterinary Diagnostic Testing Laboratory Accreditation Scheme

Kris De Clercq²

From 2-6 February 1998, a Consultants' Meeting was organized by the Joint FAO/IAEA Division of Nuclear Techniques in Food and Agriculture and the FAO/IAEA Agriculture and Biotechnology Laboratory at the Vienna International Centre. The meeting was convened to consider the question of a generic quality assurance (QA) "accreditation" scheme for veterinary diagnostic testing laboratories that could be made available through international, regional, or national organizations as appropriate to the country of interest. This discussion was stimulated by the fact that few developed and no developing countries have nationally organized schemes to measure and recognize the QA systems and technical competence of veterinary diagnostic testing laboratories, but that such a scheme is of vital importance to the quality of policy decisions and actions taken on national animal health issues and the international trade of livestock and livestock commodities.

An emerging challenge to the international animal health community is to make the organization and operations of national-level veterinary services, including diagnostic testing laboratories, clear to outside observers so that the quality and comparability of animal health programmes and data can be evaluated. Traditionally, the OIE has been a focus of information gathering and dissemination for animal health and trade issues, but there has never been an agreed mechanism for assessing the value or reliability of the data reported to this organization. As international and regional trade agreements become more prevalent, the need for internationally harmonized principles of QA for veterinary diagnostic testing laboratories and a common method for monitoring compliance with these principles has never been greater.

A variety of processes have been developed worldwide to recognize QA systems in the manufacturing, production, and service sectors, as well as the technical competence of testing laboratories. In particular, the ISO/IEC Guide 25 (1) forms the basis for many national standards for recognition of the competence of calibration and testing laboratories while the OECD Principles of Good Laboratory Practice (OECD-GLP) (2) are used internationally as a basis for judging a laboratory's competence in the general area of safety studies. It is noted that some government laboratories in developed countries have achieved both the equivalent of ISO 25 Accreditation and OECD Compliance recognition.

Manuscript based on the Report of an FAO/IAEA Consultants Meeting at the Vienna Int. Centre, 2-6 Feb. 98
 Chairman of the Research Group of the Standing Technical Committee of the European Commission for the Control of FMD

The primary purpose of a veterinary diagnostic testing laboratory is to perform routine tests on biological samples. Properly conducted validation studies of routine assays, documentation of assay controls, and other QA elements are important to the operations of these laboratories. However, some of the metrological principles of the physical sciences embodied in ISO/IEC Guide 25 are not directly relevant or applicable to veterinary diagnostic testing laboratories, and efforts to comply with the interpretations of these principles can lead to substantial expenses of time and money without adding substantially to the QA effort. Similarly, the study-oriented approach of the OECD-GLP does not lend itself well to evaluating the quality management (QM), general operations, or technical competence of a veterinary diagnostic testing laboratory. Essentially, a veterinary diagnostic testing laboratory accreditation scheme based on either ISO 25 or OECD-GLP alone would either be too costly for the benefits obtained and/or not provide fully appropriate assurances of good quality management or technical competence to regulatory officials or trading partners for the range of activities conducted in this type of laboratory. Therefore, the most practical route to development of an accreditation scheme for veterinary diagnostic testing laboratories could be 1) to define the needs of the customers (primarily the national regulatory authorities and trading partners) with respect to the operation and output of a laboratory, 2) review ISO Guide 25 and OECD-GLP with an eye towards those management elements that are essential to meeting the needs defined above and which have practical application in veterinary diagnostic testing laboratories, and 3) define, based on this review, the QM principles and a monitoring process that are appropriate to international, regional, and/or national application.

Therefore two documents were prepared:

- 1. Proposals for "Principles of Quality Management in Veterinary Diagnostic Testing Laboratories"
- 2. "Monitoring Compliance with the Principles of Quality Management in Veterinary Diagnostic Testing Laboratories".

These documents will be forwarded to the Secretariat of the OIE for consideration in the development of an international scheme for veterinary diagnostic laboratory accreditation.

The first document: Proposals for "Principles of Quality Management in Veterinary Diagnostic Testing Laboratories" is based on ISO Guide 25 and the OECD-GLP and consists of 15 pages with following content:

- 1. Organisation and Management
- 2. Quality system
- 3. Document Control
- 4. Internal Audits
- 5. Quality Control
- 6. Proficiency Testing
- 7. Management Review
- 8. Staff

- 9. Accommodation and Testing Environment.
- 10. Equipment and Reference Materials
- 11. Assay Method Selection and Application
- 12. Consumables
- 13. Management of Material Submitted for Testing
- 14. Records
- 15. Test Reports
- 16. External Resources
- 17. Complaints

The second document: "Monitoring Compliance with the Principles of Quality Management in Veterinary Diagnostic Testing Laboratories" consists of 5 pages with following content:

I. General

An effective compliance monitoring process is based on the triangular relationship between:

- A. Technical/Scientific guidelines or standards for the performance of the assays, coupled with the appropriate quality control steps;
- B. A quality management system to ensure that the tests are adequately planned, performed, recorded and internally monitored;
- C. A quality management compliance monitoring system operated by a recognized authority.

II. Organization

A. Technical/Scientific standards

Refers to the OIE Manual of Standards for Diagnostic Tests and Vaccines.

B. Quality Management System

Refers to the first document: Proposals for "Principles of Quality Management in Veterinary Diagnostic Testing Laboratories"

C. Compliance Monitoring

The OIE should be the seat of authority for the establishment and oversight of the monitoring programme. A comprehensive set of "Inspection Guidelines" should be established by the OIE.

The OIE should delegate the practical requirement for monitoring to appropriate international, regional, or national bodies. They should report to the OIE in order to assure impartiality and harmonisation.

The monitoring process should be self-financing.

Agreements relating to mutual acceptance of data between countries should be handled through the auspices of the OIE.

III. Process

The monitoring process should include the following:

- 1. A period for collection of information required for inspection purposes.
- 2. The appointment of inspector(s) delegated to perform a specific inspection.
- 3. Agreement by the laboratory to accept the inspectors.
- 4. A physical inspection of the laboratory facility and quality documentation.

- 5. An analysis and evaluation (review) of all information relevant to the inspected laboratory.
- 6. A decision to accept or reject the laboratory's request for compliance recognition.

References

- 1. International Standards Organization (1990). ISO/IEC Guide 25.
- 2. Organization for Economic Cooperation and Development. OECD Principles of Good Laboratory Practice (1997 revision). OECD, Paris, 1998.

List of Participants at the Vienna meeting

R. Bokma

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Report on the notification of Contingency Plans to the Secretariat by the Member Countries.

The Thirty-second Session of the Commission held in Rome, Italy, 2-4 April 1997, proposed that the Secretariat of the Commission be officially informed of the status of the Contingency Plans in member countries and that a follow-up of the situation be carried out by the Executive Committee.

In line with this recommendation, a questionnaire in English/French, aimed at assessing progress in the implementation of Contingency Plans, was addressed to member countries on 20 August 1997. CVO's were requested to reply by 15 September 1997. CVOs were also requested to attach a copy of the Plan, and/or a summary, in one of the official languages of the Commission.

30 of the 33 member countries replied to the questionnaire and 21 out of 30 enclosed a copy of their Plan or a summary in English.

CONCLUSIONS

- 1. The details of the results will be presented at the 33rd Session
- 2. As agreed by the 60th Session of the Executive Committee it is suggested that a small stock of equipment be kept at the Secretariat in Rome. It should be restricted to non-perishable equipment i.e. equipment without an expiry date.
- 3. Only 16 of the 29 countries have organized simulation exercises to date. This should be a priority for all member countries to validate the existing contingency plans.
- 4. In 19 of the 29 countries, no suspicion of vesicular disease has been reported over a 3-year period. This absence of any suspicion of vesicular disease must be interpreted as an indicator of a low level of surveillance. This assumption is confirmed by the fact that during the same period the countries with a high level of awareness regarding FMD and vesicular diseases had suspicions reported.
- 5. A joint EUFMD/FAO/EC Workshop on Contingency Planning and Emergency Preparedness for FMD, CSF, and other Exotic Diseases has been held in Pulawy, Poland from 15 to 22 March 1998, with the participation of 13 countries of Central and Central-eastern Europe. This workshop included simulation exercises on CSF and FMD. It is expected that this workshop will develop the level of awareness in the 13 participating countries of Central and Central-eastern Europe and specially in those which have not yet prepared their CP.
- 6. The requirements for contingency plans are under review within the EU. The EC Commission has set up 5 working groups to review the Community regulations on FMD. One of these groups concentrates on contingency planning and actual time alert exercises. It is suggested that cooperation be developed between this group and the EUFMD Commission. The information collected by EUFMD through the questionnaire could be made available to the EC group and the EUFMD could participate in the activities of the group to prepare new guidelines for CPs in Europe.

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

EUROPEAN COMMISSION FOR THE CONTROL OF FOOT-AND-MOUTH DISEASE

The European Commission for the Control of Foot-and-Mouth Disease is a body established under Article XIV of the Organization's Constitution for the purpose of promoting and coordinating national and international action for the control of foot-and-mouth disease in Europe and its final eradication. Its funds are handled as a Trust Fund under Financial Regulation 6.7, with the symbol MTF/INT/011/MUL.

FUNDS

The Organization does not maintain separate bank accounts for each Trust Fund, but instead manages and invests Trust Fund monies combined in pooled bank accounts. The balance of funds held by the Organization on behalf of the European Commission for the Control of Foot-and-Mouth Disease as at 31 December 1997 amounted to US\$136,103.

INCOME AND EXPENDITURE

Contributions to the Commission's Trust Fund amounting to US\$273,696 were received from Member countries of the Commission in 1997. Contributions for 1997 amounted to US\$266,508, contributions paid in advance for 1998 amounted to US\$1,950 and contributions received in arrears for earlier years amounted to US\$5,238. The Commission's Trust Fund was credited with interest earned during 1997 amounting to US\$12,652 Administrative costs for 1997 amounted to US\$300,726.

SERVICES PROVIDED BY THE ORGANIZATION

During 1997 the Organization made available without charge the use of accommodation and facilities, to a total estimated value of \$50,000.

Plato M. Kastanias Chief, Accounting and Financial Service Finance Division

MTF/INT/011/MUL - TF number 904200

EUROPEAN COMMISSION FOR THE CONTROL OF FOOT-AND-MOUTH DISEASE

Financial Report as at 31 December 1997

	US\$	US\$
Balance as at 1 January 1997	·	150,481
Interest received (average rate 7.42%) Contribution from member countries (As per statement 2)	12,652 <u>273,696</u>	286,348
<u>Expenditure</u>		. •
Commission Secretary	126,005	
Consultant	2,500	
Admin. Support Personnel	88,297	
Duty Travel	19,183	
Contracts	49,000	
General Operating Expenses	14,274	
Expendable Equipment	3,967	
Non-Expendable Equipment	<u>(2,500</u>)	
Total Expenditure		(300,726)
Balance as at 31 December 1997		<u>136,103</u>

TRUST FUND No. 9042.00 - MTF/INT/011/MUL -Inter—Regional European Commission for the Control of Foot—and—Mouth Disease

Status of Contributions as at 31 December 1997 (expressed in US\$)

Member	Outstanding	Contribution	Received up to	Outstanding
Governments	31/12/1996	<u>due for 1997</u>	31/12/1997	31/12/1997
ALBANIA	1,322.86	1,300.01	2,601.87	21.00
AUSTRIA	0.00	7,800.71	7,800.71	0.00
BELGIUM	0.00	13,000.40	13,000.40	0.00
BULGARIA	15,264.90	3,900.09	7,800.00	11,364.99
CYPRUS	0.00	1,300.01	1,300.01	0.00
CROATIA	1,300.01	1,300.01	1,300.01	1,300.01
CZECH REPUBLIC 1		7,800.71	0.00	1.42
DENMARK 1		13,000.40	13,000.00	0.40
FINLAND	0.00	7,800.71	7,800.71	0.00
FRANCE	0.00	26,000.83	26,000.83	0.00
GERMANY 1	0.00	26,000.83	26,000.00	0.83
GREECE	36.24	3,900.09	3,936.33	0.00
HUNGARY	0.00	7,800.71	7,800.71	0.00
ICELAND	0.00	1,300.01	1,300.01	0.00
IRELAND	0.00	3,900.09	3,900.09	0.00
ISRAEL	0.00	3,900.09	3,900.09	0.00
ITALY	0.00	26,000.83	26,000.83	0.00
LITHUANIA	0.00	3,900.09	3,900.09	. 0.00
LUXEMBOURG	0.00	1,300.01	1,300.01	0.00
MACEDONIA, Fed. Y. Rep. of	0.00	0.00	0.00	0.00
MALTA	. 0.00	1,300.01	1,300.01	0.00
NETHERLANDS	0.00	13,000.40	13,000.40	0.00
NORWAY	0.00	3,900.09	3,900.09	0.00
POLAND	0.00	13,000.40	13,000.40	0.00
PORTUGAL	0.00	3,900.09	0.00	3,900.09
ROMANIA 1,		7,800.71	7,800.00	0.71
SLOVENIA 2	•	1,300.01	3,250.02	(1,950.01)
SPAIN	0.00	13,000.40	13,000.40	0.00
SWEDEN	0.00	13,000.40	13,000.40	0.00
SWITZERLAND	0.00	13,000.40	13,000.40	0.00
TURKEY	0.00	7,800.71	7,800.71	0.00
UNITED KINGDOM	0.00	26,000.83	26,000.83	0.00
FED. REP. OF YUGOSLAVIA /	44,460.59	7,800.71	0.00	52,261.30
TOTALS	54,585.31	286,011.79	273,696.36	66,900.74

^{/1} o/s amounts under \$10 are not to be called as they are assumed to be differences on exchange

STATEMENT 3

Summary of Contributions Received in Arrears in 1997

Received in arrears for earlier Years	US\$
ALBANIA BULGARIA GREECE	1,301.86 3,899.91 <u>36.24</u>
	<u>5,238.01</u>

^{/2} US\$1950.01 paid in advance for 1998 /3 o/s amount not to be called

MTF/INT/004/MUL - TF number 909700

FOOT AND MOUTH DESEASE - EMERGENCY AID PROGRAMME

Financial Report as at 31 December 1997

Balance as at 1 January 1997

Interest received (first semester rate 7.42%)

Expenditure

Expendable Equipment

(500)

Total Expenditure

Balance as at 31 December 1997

STATEMENT 5

MTF/INT/003/EEC - TF number 911100

FOOT AND MOUTH DISEASE

Financial Report as at 31 December 1997

	US\$	US\$
Balance as at 1 January 1997		1,077,653
Interest received (first semester 7.42%)		69,595
Contribution received		175,125
Expenditure		
Consultancy	9,476	
Duty Travel	38,922	
General Operating Expenses	(8,575)	
Expendable Equipment	2,740	
Non-Expendable Equipment	2,500	
Support Costs 6% (on all items except expendable equipment)	<u>2,540</u>	
Less: Total Expenditure		(47,603)
Balance as at 31 December 1997		<u>1,274,770</u>

TF 904200 MTF/INT/O11/MUL - EUFMD

Budgets <u>approved</u> for 1998 & 1999 by Sixtieth Session of Executive Committee Approved revision of 1998 budget by 61st Session of Executive Committee

US\$

US\$

325,000

325,000

101,500

325,000

742

750

73,343

325,000

Pledges 1998-1999

1998

1999

Budget components	Approved Budget 1998 - US\$	Revised Budget 1998 - US\$	Approved Budget 1999 - US\$
1101 Secretary	142,943	142,943	152,949
1300 Admin Assist	79,815	79,815	82,208
Overtime	2,500	· -	1,500
33rd Session - support staff	-	-	15,000
Sub-total	225,257	222,758	251,657
2000 Duty travel secretariat/NST's	30,000	36,000	35,000
3000 Contracts	•		
Annual WRL	30,000	30,000	30,000
Coll Lab Study	9,000	9,000	6,343
Workshop	20,000	20,000	-
4000 GOE/hosp.	500	500	500
5000 Exp equipment	1,000	6,000	750

3,500

94,000

5,743

325,000

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6000 Non-exp equip

Sub-total

balance

Total

Reserve/unalloc

Budgets 1998 for Trust Funds 911100/909700 as approved by Thirty-second Session and revised by Sixty-first Session of the Executive Committee

TF911100 MTF/INT	/003/EEC		
Component	1 1110 1110111		
1151 – Consultants	US\$	50,000	
2000 - Duty travel	US\$	70,000	·
4000 – General operating expenses	US\$	2,500	
5000 - Expendable equipment (vaccine)	US\$	500,000	
9100 – Support costs (6% except on vaccine)	US\$	7,350	<u> </u>
Total	US\$	629,850	
Balance 31 December 1997	US\$	1, 274,770	-
Balance less projected expenditure	US\$	644,920	<u> </u>

TF909700 MTF/INT	/004/MUL		• • • • • • • • • • • • • • • • • • • •
Component	Allotment		
1151 - Consultants	US\$	20,000	
2000 - Duty travel	US\$	5,000	
5000 - Expendable equipment (vaccine)	US\$	25,000	
6000 - Non-expendable equipment	US\$	5,000	
8000 - Training (Workshop Pulawy)	US\$	5,000	
9100 - Support costs (6% except on vaccine)	US\$	2,100	
Total	US\$	62,100	
Balance 31 December 1997	US\$	63,905	_
Balance less projected expenditure	US\$	1,805	

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