

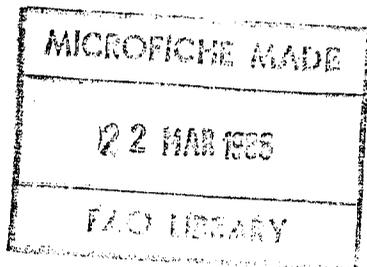
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TWENTY-SEVENTH SESSION
OF THE EUROPEAN COMMISSION FOR THE
CONTROL OF FOOT-AND-MOUTH DISEASE

Rome
21-24 April 1987



Meeting Report (AGA-701)

AGA: EUFMD

REPORT OF THE TWENTY-SEVENTH SESSION OF THE
EUROPEAN COMMISSION FOR THE CONTROL OF FOOT-AND-MOUTH DISEASE

Rome, 21-24 April 1987

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

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SUMMARY

The Twenty-seventh Session of the European Commission for the Control of Foot-and-Mouth Disease met in Rome from 21 to 24 April 1987. Delegates from twenty-five of the twenty-seven member countries attended, together with observers from non-member countries and international organizations. The Session reviewed information on the incidence of FMD in Europe and elsewhere in the world during the previous biennium, giving detailed consideration to the continuing epizootic in Italy. The progress of prophylactic campaigns undertaken by the Commission in association with FAO and the EEC was also considered.

CONCLUSIONS AND RECOMMENDATIONS

R1 With regard to the EEC proposal for an FMD Reference Laboratory, the Chairman emphasized the importance which the Commission attaches to having only a single Reference Laboratory designated in Europe. (2)

R2 FMD control-position in Europe during 1985 and 1986

The Commission agreed that Europe, facing a situation of relative disease freedom, should further strengthen the collaboration in FMD control between countries (2)

The importance of providing the World Reference Laboratory (WRL) with a comprehensive selection of reference virus strains was emphasized and all countries were invited to submit such samples to the WRL (3)

R3 Prophylaxis in Europe

With respect to vaccination of young animals, it was agreed that the time was not right for any common recommendation to be made and that problems must be referred to exporting and importing countries to discuss and agree a mutually acceptable and effective policy.

R4 FMD situation in Italy

It was recommended that:

- 1) Italy should implement a biannual mass vaccination of cattle and should ring vaccinate pigs in areas where necessary,
- 2) Despite the mass vaccination campaigns a total stamping out policy should be pursued whenever FMD was confirmed,
- 3) The additional measures recommended in the reports prepared by the Commission mission and by the experts who carried out the in-depth studies on epidemiological and cost-benefit factors should be taken, and in particular it was necessary to ensure central coordination of veterinary policies in affected regions,
- 4) Special note should be taken of the Chairman of the Research Group's recommendations with regard to the production of vaccine (3.2)

R5 Vaccination campaigns in southeastern Europe

It was agreed that a mission of the FAO/EEC/OIE FMD Group would meet the Turkish Veterinary Service to discuss and agree protocols for the Turkish vaccination zone, the possible relocation of that zone, and strategies for dealing with FMD outbreaks in Turkey.

The Commission also agreed unanimously that the buffer zone in southeastern Europe should be continued for a further two years. (3.3)

R6 Activities of Research Group

Identification of vaccine strains used in Europe

It was agreed that prior to attempting to harmonize vaccine strains in Europe, more efforts should be put into studies to define the antigenic relationship between currently used vaccine strains and recent field isolates (5)

It was recommended that the methodology for investigating the origin of infection in FMD outbreaks should be regarded as a guideline for the investigation of outbreaks by all member countries (5).

It was recommended that the Group study the feasibility of evaluating the level of immunity in vaccinated animals in the buffer zone through the use of serological tests.

R7 Regionalization of FMD vaccine production

With regard to the recommendations agreed at the meeting of the OIE Regional Commission for Europe, held in Berlin in September 1986, the observer from OIE stated that the text could not be changed until it had been discussed at the 55th General Session of OIE to be held in Paris in May 1987.

It was emphasized that the recommendation made in Berlin was agreed for implementation in the buffer zone in southeast Europe. (6)

R8 Vaccine bank

The relevance of the Bank in respect of policy changes which may be made as a result of the cost-benefit analysis of the FMD vaccination policy in Europe was emphasized. (7)

R9 Cost-benefit study on vaccination policy

The Guide prepared by the Working Group set up for this purpose was approved and accepted by the Commission. Member countries were invited to use the guide as they wished and could call on the expertise of the Commission for any assistance required in this respect. (8)

R10 Review of current policies of the Commission (a) Proposed conditions for importation of beef into Europe from countries where FMD is endemic and is caused by viruses not considered exotic to Europe, and

(b) Movement of slaughter stock and meat from areas where exotic strains of FMD virus have been reported or inactivated exotic vaccines have been applied

(a) The conditions as revised by the Commission at a meeting held in Paris in 1985 were amended and agreed with the proviso that these are minimum conditions which are valid for all countries whether they vaccinate or not.

(b) Delegates accepted the desirability of establishing a single set of recommendations. It was agreed that the subject should be discussed in Paris, and that the Executive Committee would then make a full proposal to the Commission. (9)

R11 Finance - increase in contributions

The Session agreed that member countries contributions be increased by 5% with effect from 1 January 1988 (10).

R12 Future policy of the Commission

The Session agreed on the programme of future activities (11).

R13 Membership of the Commission

In respect of Israel's wish to become a member of the Commission, Legal Counsel informed the meeting that since the present Constitution precluded such membership on the grounds of geographical location, it would be necessary to amend the Constitution accordingly. (14)

INTRODUCTION

The Twenty-seventh Session of the European Commission for the Control of Foot-and-Mouth Disease was held in Rome from 21 to 24 April 1987.

The Chairman, Prof. Dr. A. Rojahn (Federal Republic of Germany), welcomed delegates and invited Dr. C.H. Bonte-Friedheim, Assistant Director General, Agriculture Department, FAO, to open the meeting.

In his address, on behalf of the Director-General, Dr. Bonte-Friedheim welcomed delegates, experts and observers to the Twenty-seventh Session. He extended a special welcome to the representatives of OIE, EEC and PAHO, international organizations which share with FAO the responsibility for advising and supporting European Governments in improving their potential in animal production.

He then welcomed Albania and Czechoslovakia who since the last Session had joined the Commission as full members.

Twenty-seven European countries were now full members of the Commission. It was hoped that the remaining eastern European countries would soon apply for membership and thereby further strengthen the deliberations and decisions of this important Body.

Dr. Bonte-Friedheim emphasized the fact that FMD was still proving to be a serious menace to concrete and stable livestock development and trade on a worldwide basis, and the disastrous effects of repeated outbreaks had not ceased to be a cause for concern.

Statistical data for the period under review - 1985/1986 - was most disquieting. Italy, a country which had always played a leading role in the industrial development of vaccine and which for years has been in a position to successfully control, through a solid vaccination coverage and effective sanitary control measures, the spread of FMD epizootics, had been facing a protracted disease situation since November 1984.

FAO attributed great importance to the analysis of the Italian situation. If, as might be the case, the phenomena responsible for the present FMD situation in Italy were not specific to Italy, then other countries too might soon become involved in the same problems and the strategy of FMD prophylaxis and control in Europe might need to be reviewed. In referring to the buffer zone in southeastern Europe which has been successfully maintained now for 25 years, he stated that this was a constructive example of international collaboration in the implementation of control programmes in the field of FMD.

In concluding, Dr. Bonte-Friedheim stated that the advice and opinion of this highly qualified forum on the many technical subjects on the Agenda would be of great practical and scientific value to FAO. He then wished the participants success in their deliberations.

I. Adoption of Agenda

The following Agenda was adopted:-

1. Adoption of Agenda
2. Report of the Executive Committee on the Commission's activities during the last biennium
3. FMD position in Europe during 1985-86
 - Position and prophylaxis in Europe
 - FMD situation in Italy
 - Vaccination campaigns in southeastern Europe
 - FMD position in other regions of particular interest to Europe
4. Swine vesicular disease in Europe
5. Activities of the Research Group (Items referred to the Group by the Commission)
6. Regionalization of FMD vaccine production
7. Vaccine bank
8. Cost benefit study on vaccination policy in Europe
9. Review of current policies of the Commission
 - Importation of meat
 - Animal movement
10. Financial report and approval of budget
11. Future policy of the Commission
12. Adoption of the draft Report of the Session
13. Election of Chairman, Vice-Chairmen and members of the Executive Committee
14. Any other business

Item 2 - Report of the Executive Committee on the Commission's activities during the biennium 1985/1986

The Secretary introduced the report covering the period which had elapsed since the Twenty-sixth Session. (Appendix 1) The Chairman emphasized that most of the points mentioned by the Secretary would be discussed in greater detail at a later stage during the Session.

Following presentation of this document, some brief discussion took place on a number of the items referred to by the Secretary.

With regard to the EEC proposal for an FMD Reference Laboratory, the Chairman emphasized the importance which the Commission attaches to having only a single Reference Laboratory designated in Europe.

The EEC Delegate when invited to comment distinguished between two designations which were required by the EEC Directive on FMD.

1. to designate and describe the functions of a reference laboratory for the identification of FMD virus, and
2. to designate and describe the functions of a coordinating institution for FMD vaccines.

Both of these were still proposals which had not yet been submitted to the Council of Ministers.

A number of Delegates, however, felt that it was impracticable to differentiate between the two types of function, and that one laboratory should be designated for both purposes.

The Commission acknowledged the work carried out during the biennium under review, and agreed that Europe, facing a situation of relative disease freedom, should further strengthen the collaboration in FMD control between countries.

The Commission agreed that the period under review has been fundamental for the Commission and has further confirmed its importance as an international forum for the prevention, control and eradication of FMD in Europe through the concerted efforts of all member countries.

Item 3 - FMD position in Europe during 1985 and 1986

In introducing the relevant document the Secretary commented on the favourable situation throughout Europe with the exceptions of Italy and Turkey (Anatolia). (Appendix 2)

A single outbreak caused by A5 had also been confirmed in Spain in June 1986 but effective sanitary measures had prevented any spread.

Isolated outbreaks caused by type 0 and A₂₂ were reported in the USSR in 1985/1986.

The situation in Italy since November 1984 was illustrated by the Secretary, and it was noted that the highest monthly total of outbreaks was recorded in March 1987. Further discussion of this item was deferred to Item 3.2 of the Agenda, (FMD situation in Italy).

The Delegate from Turkey gave an account of outbreaks in his country during the biennium, emphasizing that the Thrace buffer zone had remained free of infection. Since 1978 disease due to O₁ and A₂₂ virus types had, however, continued in Anatolia, where 357 outbreaks had been confirmed in 1985 and 131 in 1986. Disease was seen as a mild infection in young cattle. In response to points raised by the Delegates he stated that the number of outbreaks recorded in Anatolia, particularly in cattle, had decreased in 1987. Production of vaccine had since increased at the new FMD vaccine production laboratory.

There was considerable discussion about the definition of an outbreak. The Chairman contended that this should apply, as normally, to a farm, whereas the Delegate from Turkey confirmed that in their interpretation it applied to an entire village.

Further discussion resolved the problem, as it became apparent that in Anatolia the type of husbandry was based on the village rather than on the individual farmstead. It was not possible to talk of farms in central and eastern Turkey. That description was relevant only to Turkish Thrace.

The Chairman then invited the observer from the USSR to describe the situation in his country. He stated that there were no outbreaks occurring at present and that regional vaccination programmes were used for prophylaxis. Trivalent vaccine, A₂₂/O₁ and C, was used in a thirty-km buffer zone along the southern part of the European border and a trivalent vaccine A₂₂/O₁/ASIA-1 was used in the Asian part of USSR. Cattle were vaccinated in the spring but pigs were not vaccinated in European Russia. They were, however, vaccinated in other parts of the country.

The representative of the FAO World Reference Laboratory (WRL) invited the observers from the USSR to submit samples of A₂₂ virus isolated in the USSR to the WRL. He emphasized the importance which the WRL attached to the receipt of a comprehensive selection of reference virus strains, and stressed that this invitation was addressed to all countries, and not to the USSR alone. The observers from the USSR undertook to refer the request for samples to the national authorities concerned. The Chairman offered the help of the Commission if this was needed.

The Delegate from Spain stated that no new outbreaks had been confirmed since June 1986. He confirmed that the origin of the Spanish outbreak had not been identified. The position in Spain remained favourable.

The Secretary underlined the importance of determining the origin of outbreaks wherever possible. Too many European outbreaks were now said to be of unknown origin and this was not a satisfactory situation since proper epidemiological investigations could not be made in the absence of such information.

Item 3.1 - Prophylaxis in Europe

The relevant document (Appendix 3) was introduced by the Secretary, who illustrated the prophylactic policies in different parts of Europe. In discussing tabulated information he emphasized that vaccination periods, potency tests, and vaccine strains all differed from one country to another. In response to questions raised by the Chairman some corrections were made to the tabulated information.

Following a point raised by the Delegate from Denmark about the size of vaccination zones and movement restrictions within those zones, the Delegate from Austria stated that vaccination was restricted to a single valley on the Italian border and that there was no frontier zone as such.

The Delegate from Hungary stated that the Hungarian vaccination zone was 40 to 50 kilometres broad, and that no movement at all was allowed within 21 days of vaccination.

Discussion then concentrated on the question of vaccination of young animals. The Research Group had advocated that calves should not be vaccinated when less than 4 months old but the FAO/EUFMD experts sent to

Italy had recommended the vaccination of imported calves at 3 months. Dr. van Bakkum, Chairman of the Research Group, said that the recommendations of the Research Group had been aimed particularly at the situation which pertained in Italy.

Since calves may come from vaccinating or non-vaccinating countries it was not possible to frame a rule which would be applicable to all calves. It was advisable that the matter be discussed between exporting and importing countries and desirable that the immune status of imported animals be assessed serologically. Having obtained such information it would be possible to base policy on the situation in exporting and recipient countries. The Secretary stated that the importing country should specify the type of vaccine to be used in animals intended for export.

The Delegate of Italy stated that Italy was willing to discuss the problem with each country individually. Italy imported 2 million animals each year, of which 700 000 were calves less than 1 month old. Eighty percent of these calves were imported from EEC countries and 20 percent from elsewhere. Most cases of FMD in Italy were found in young stock which had been vaccinated only once. The present policy was therefore to vaccinate calves at three months of age, for the first time, with a booster 3 to 6 weeks later at the place of destination. A new vaccination campaign, taking into account the recommendations of the FAO/EUFMD missions, will start in October 1987.

A number of Delegates pointed out that vaccination was forbidden in their countries under any circumstances. It was also pointed out that it may not be desirable to vaccinate calves immediately before transport since the stress of the journey could prevent the development of satisfactory immunity.

The Secretary suggested that young animals should be vaccinated at least 10 days before movement from countries which are willing to vaccinate before exporting, but that the only solution in the case of countries unwilling to vaccinate would be to set up quarantine stations in Italy, in which calves could be vaccinated on arrival and detained until immunity had developed.

The Delegate of Italy stated that he wished to avoid any misunderstanding. Italy was not asking for vaccination in the country of origin if such action was not acceptable to that country, but felt that it would be unreasonable for those countries to ask that unvaccinated animals sent by them to Italy be allowed to move freely in Italy until they had been vaccinated.

The Commission agreed that the time was not right for any common recommendation to be made and that problems must be referred to exporting and importing countries to discuss and agree a mutually acceptable and effective policy.

Item 3.2 - FMD situation in Italy

The FMD situation in Italy was discussed in depth. (Appendix 4) The Chairman introduced the subject stating that the Commission had been closely involved in assisting the Italian Veterinary Authorities in their efforts to control the FMD epizootics which had persisted on the national territory since 1984.

The report of the FAO/EUFMD mission (Appendix 5) carried out in October 1986 had been presented to the Italian authorities at the meeting

held at the Ministry of Health on 10 November 1986. (Appendix 5(a)) Following this meeting, at the request of the Italian Government, the Commission had agreed to send three experts to Italy to carry out an in-depth study in the fields of 1) vaccine production and control, 2) the epidemiology of the FMD epizootics, 3) the cost-benefit analysis of total or partial stamping out policies and sanitary measures applied in Italy. Copies of the resulting reports are attached. (Appendices 6 and 7)

The Secretary reviewed the situation in Italy since 1979 and introduced the report of the FAO/EUFMD mission. There had been few outbreaks in 1979, 1980 and 1981. No outbreaks had been reported in 1982 or 1983, but on 27 November 1984 an A₅ epizootic started which lasted until 31 August 1985.

This was followed by a C₁ epizootic commencing on 27 November 1985 and lasting until 23 April 1986, involving mainly pigs in large holdings.

Another A₅ epizootic started on 5 June 1986 and is still continuing, affecting mainly cattle but also some pigs. A single O₁ outbreak occurred in this latter period, without spread.

The regional distribution of each epizootic was presented and it was noted that in 1987 the regions of Lombardy and Emilia Romagna were particularly affected, with small numbers of outbreaks in other regions. The highest total number of outbreaks in any one month was reported in March 1987, while considerably fewer outbreaks were confirmed in April 1987.

The Secretary then presented the conclusions of the FAO/EUFMD mission, highlighting the following factors which were considered to be of major importance in the persistence of FMD in Italy.

- relaxation of vigilance
- large percentage of susceptible animals not protected by vaccination
- vaccination incorrectly applied
- annual vaccination not carried out systematically
- impracticability of always applying stamping out policy on intensive livestock holdings
- delay in diagnosis, especially in pigs
- delay in epizootiological investigations
- incorrect application of sanitary measures; lack of supervision of animal movement, transport of animals, supervision at market level
- absence of Task Force to cope with emergency animal disease situation

The Director of Veterinary Services in Italy had requested that the report be presented to interested regional bodies in Italy and reactions collected by the Secretary. As a result the Secretary had attended five meetings in Brescia, Rome, Naples, Sicily, and Sardinia. At these meetings the FAO/EUFMD Mission Report was widely accepted and the following important points were emphasized (Appendix 5(b)):

- a) lack of personnel at regional and local level, and inadequate payments for veterinarians who carry out vaccination.
- b) lack of personnel at the Institutes
- c) difficulty or impossibility from a practical viewpoint, of examining animals prior to movement (compulsory law of 25.9.86)
- d) lack of disinfection and washing equipment network for transport vehicles.
- e) lack of proper application of the Sanitary Reform by the Regions particularly as regards the necessary changes in and strengthening of the regional Veterinary Offices and even more of the USLs
- f) lack of uniformity at regional and at Unità Sanitaria Locale (USL) level in the application of the administrative and technical responsibility which has been delegated to the USL's, which should permit the latter to plan the necessary preliminary, intermediate, and final action to be taken promptly and efficiently, and at the same time to receive the collaboration of other local hygiene, sanitary and administrative services.
- g) it was unanimously requested that a clear definition be provided of the competence and authority conferred by the Sanitary Reform on the regional services and on the USL's, and means to effectively implement the activities be transferred to the Regions by the Sanitary Reform.

The Secretary concluded by saying that the present situation in Italy could not be justified. Something was clearly wrong. The law and rules were perfect but did not appear to work in practice, and it was important to decide whether this was purely a national problem, or whether it reflected changes in livestock production patterns in Europe generally. It was important to avoid a repetition of the Italian experience elsewhere in Europe.

In-depth study of the FMD epizootics and cost-benefit analysis of total/partial stamping out policy and sanitary measures applied in Italy

Dr. Davies introduced this document. (Appendix 6) He drew attention to the three distinct epidemics and identified the approximate direct costs of each. He reviewed the pattern of spread of each epidemic and drew attention to 12 factors which had particularly influenced the spread of infection. The most important were the differing slaughter policies pursued in different regions; inadequate surveillance caused by insufficient staff; inadequate control of the movement of infected and carrier animals; and population densities, particularly in the Po Valley which contains 75 percent of the Italian livestock population. In discussing slaughter practices he drew attention to the different virus excretion patterns which resulted from total or partial slaughter, particularly obvious when sequential partial slaughter occurred.

Dr. Davies identified four actions which would be particularly effective in controlling the spread of disease and indicated the cost where possible. The measures identified were: better reporting by farmers which could be encouraged by prompt payment of compensation; the adoption of a complete stamping out policy; increased surveillance around infected

premises; and improved movement control. He concluded by emphasizing the importance of the establishment of a regional team to supervise sanitation and of teams to give epidemiological advice.

In response, the Delegate from Italy expressed appreciation to the Commission for the assistance which had been given to his country and also offered thanks to the EEC, OIE, AVRI, and the United States Veterinary Services.

He considered that the epizootic in Italy had a special nature. The A5 virus was aggressive and spread easily. The animals affected were usually young and immunosuppressive factors were sometimes present. The most heavily affected areas were heavily stocked and much movement took place. All the reports had highlighted the problem of poor organization.

However, he stated that vaccination campaigns had been carried out effectively: 8 400 000 cattle had been vaccinated during the autumn/spring 1985 campaign, 8 945 000 during autumn 1985/spring 1986, and 7 045 000 during autumn 1986.

Pigs were also vaccinated using monovalent A₅ vaccine: 1 400 000 in 1984/85, 3 984 000 in 1985/86, and 2 543 000 between June-December 1986. In addition 1 500 000 pigs had been vaccinated in the first quarter of 1987. In his opinion the efficiency of surveillance had recovered during 1986, and the information system had improved.

One of the problems mentioned was that the clinical symptoms observed in pigs and cattle were often very slight. No more than 3.5 percent of cattle showed clinical symptoms on any holding and although the figure was higher in pigs it still did not exceed 15 percent. Italy had been vaccinating against foot-and-mouth disease for 20 years. There was no argument for total stamping out where there were large numbers of outbreaks, stock was fully vaccinated and few animals were affected. Farmers would not accept such a policy and the country could not afford to lose the genetic breeding lines. He wondered whether experts had considered this, and also challenged the reported vaccination costs. In his opinion the figures should be lower.

Although he fully endorsed the suggestions made by visiting experts, and wanted information about their findings to be publicized throughout the country, he still felt that something more was required. He was particularly concerned that animals which had been vaccinated before arrival with trivalent A₅/C₁/O₁ vaccine showed variable antibody responses when serologically tested on arrival. A satisfactory response was found to some, but never to all, the vaccine serotypes.

The Chairman thanked the Delegate of Italy for his comments and reiterated that the Commission's purpose was to offer help and advice when requested. He said that the important thing was to avoid further deterioration in the situation and suggested that a total stamping out policy, although expensive in the short term, would be cheaper in the end. He then invited comment from the meeting.

The Delegate from Austria commented that although cost was relevant, additional factors required consideration before the adoption of a total stamping out policy. It must be possible to destroy the carcasses of slaughtered animals. This was not possible in the Po Valley because of the large holding size and to adopt such a system in that area may prove more dangerous than partial stamping out.

The Delegate from Denmark believed that it had been a mistake to adopt a partial slaughter policy at the start of the epizootic. Total stamping out should always be carried out when outbreaks were first diagnosed. The importance of the education of the farming community should not be underestimated. If the majority of livestock owners do not cooperate voluntarily then rules cannot be enforced. The Secretary stated that there would be great problems in applying a stamping out policy in the Po Valley area. In that area he suggested mass vaccination of all susceptible animals using a monovalent A₅ vaccine. Elsewhere in Italy vaccination should be stopped and a total stamping out policy adopted. The Chairman could not support discontinuation of vaccination as the movement of animals made this inadvisable. He advocated biannual vaccination in the endemic regions and annual vaccination elsewhere, and reiterated that a total stamping out policy in all regions, although expensive, would be cheaper in the long run.

In response to these points the Delegate from Italy reminded the meeting that mass vaccination had been started by an Italian. There had been compulsory vaccination in the Po Valley, paid for by farmers, and the consequent reduction in outbreaks had convinced the Italian Government of the need to change to government-financed vaccination campaigns. It was not possible to envisage a change to total stamping out until the number of outbreaks had fallen to three or four per month. Therefore the Secretary's suggestions could be considered at a later date. The Italian Government was committed to carrying out two complete vaccination campaigns each year. One had already been completed, one was due in autumn 1987, and another planned in April/May 1988. Monovalent oil-adjuvant vaccine would also be used in pigs. In the longer term it was hoped to move to total stamping out for fattening stock, but it was felt that it would be difficult to apply the policy to breeding animals. Vaccination would certainly not be discontinued until there had been no outbreaks for a period of at least three years.

The OIE observer complimented the Italian authorities on the spirit of cooperation which had existed. He had met Italian Breeders' Associations at meetings organized by Dr. Bellani and found them very helpful. He had found that local veterinarians were often discouraged by a perceived lack of success and that breeders believed that vaccination was the only acceptable solution to the problem. This emphasized the importance of human factors and made it necessary to reassess priorities. It may be that rules which dealt successfully with outbreaks on small units 30 or 40 years ago are no longer applicable or acceptable on large industrial units. The effectiveness of vaccination had therefore become the central problem. The Italian situation was unique in Europe because of the large numbers of young animals imported and it was necessary to consider whether the vaccine now used was correct and appropriate for use in young herds. It would also be appropriate to look at the range of other veterinary medicines administered to cattle imported into Italy.

These remarks introduced a general discussion on aspects of vaccination and vaccination policy. The Chairman of the Research Group commented that although monovalent vaccine was slightly cheaper, and had the advantage of a larger production capacity, there was no evidence that the immunological response obtained from using monovalent vaccine was any better than that obtained with trivalent vaccine. What was important was the presence of sufficient antigen in the vaccine. He was supported by the observer from the Pan-American Health Organization (PAHO) who stated that his organization did not recommend the use of monovalent vaccine in South America, having found the response to trivalent vaccine to be perfectly acceptable.

A number of delegates commented about the vaccination of pigs. The Delegate from UK was pleased to note that Italy intended to increase pig vaccination and felt that this should reduce the possibility of recycling infection in waste food. He felt that to be effective it was necessary to vaccinate all pigs in a specific area in order to raise the general level of immunity in that area. The EEC observer informed the meeting that the European community had reviewed the vaccination of pigs and advised that vaccination should be completed in an area within a few days, and that during the vaccination campaign, and for a period of 15 days thereafter, there should be a complete standstill of movement.

The Chairman of the Research Group confirmed that to be effective it was necessary to vaccinate all pigs in a fairly large area. Vaccines presently in use provide good immunity levels in vaccinated stock; the problem lies in young pigs which are unprotected or only partially protected by maternal antibody. It was easy to achieve near 100 percent cover at first, but this level of cover dropped rapidly. He had no experience of continued, as opposed to short term, vaccination of pig populations. In reply to a question from the Secretary he confirmed that a pig epizootic can last for months independently of infection in cattle and, while he supported the EEC policy, he reminded the meeting that steps must be taken to prevent vaccination teams from spreading infection. In reply to a question from the Delegate from Italy he confirmed that vaccines which would protect pigs against laboratory challenge for more than six months were now available, and that pigs so vaccinated did not excrete virus for more than three weeks after infection.

In-depth study: Review of FMD vaccine production in Italy

The Chairman of the Research Group then introduced the report on his mission, which is summarized at Appendix 7. He expressed thanks to the staff of those laboratories which he had visited for their cooperation and for their helpful responses, and emphasized that in preparing his report he had had little opportunity to verify the information which he had received, nor had he considered economic factors.

He had concentrated his attention on various aspects of vaccine manufacture such as methods of antigen production, vaccine virus strains, vaccine formulation, inactivation, vaccine testing, and selection of challenge virus strains.

There are three producers and one controlling laboratory. Vaccine plants on the whole are well equipped although supporting laboratories sometimes appeared not quite adequately housed or instrumented. Formal security organizations are lacking.

Manufacturing plants vary in capacity, in production systems, and in a number of other aspects, but all use BHK cells. Virus is adsorbed to Al-hydroxyde or bentonite prior to inactivation. Virus inactivation is by formaldehyde, but at slightly different pH values and formaldehyde concentrations. In one instance innocuity tests were only done at the end of the production series; in another, on pooled batches of inactivated product. In-process control of inactivation was routinely done at only one institute. Vaccine manufacturers appeared to rely heavily on the final control carried out under the responsibility of the state controller, the Istituto Superiore di Sanità.

The recommendations made as a result of the study are included in Appendix 7.

The Delegate from Italy stated that tests to confirm innocuity were carried out at the Istituto Superiore di Sanità, Rome, in accordance with the methodology of the European Pharmacopoeia, and that infective virus had never been found in vaccine. Italian vaccine had been used in other countries with good results and had not caused outbreaks of FMD. The Chairman of the Research Group accepted that the testing carried out by Italian authorities is the best that can be done in present circumstances but found it difficult to believe that one test on 5 million doses was sufficient. He had not said that the Italian vaccine contained virus: he had said that innocuity testing should be increased.

Further discussion, in which delegates and observers from WRL, UK, Italy, France, Ireland, and Norway participated, concentrated on the socio-economic aspects of the problem, and on the question of education of the farmers and public. The Delegate from Italy re-emphasized his country's commitment to the control of the epizootic, one indication of this being that the Italian Government had now made 11 billion lire available to regions for the purchase of mobile disinfection units and to provide special means for transporting carcasses for disposal, and hoped to set aside 50 billion lire for compensation this year. Total slaughter would not yet be supported however, and he concluded by repeating some of the characteristics of Italian farming, particularly in the Po Valley, which mitigated against success.

The Chairman concluded the discussion by saying that recommendations must be made which would avoid the possibility of FMD remaining established in Italy for several years. He therefore recommended that:

- 1) Italy should implement a biannual mass vaccination of cattle and should ring vaccinate pigs in areas where necessary,
- 2) Despite the mass vaccination campaigns a total stamping out policy should be pursued whenever FMD was confirmed.
- 3) The additional measures recommended in the reports prepared by the Commission mission and by the experts who carried out the in-depth studies on epidemiological and cost-benefit factors should be taken, and in particular it was necessary to ensure central coordination of veterinary policies in affected regions.
- 4) Special note should be taken of the Chairman of the Research Group's recommendations with regard to the production of vaccine.

The meeting agreed this recommendation.

Item 3.3 - Vaccination campaigns in southeastern Europe

The Secretary introduced the relevant document and gave detailed information on the implementation of the vaccination campaigns in Greece, Turkey and Bulgaria in 1985, 1986 and arrangements for 1987. (Appendix 8) These had been implemented in conformity with the recommendations of the FAO/EEC/OIE FMD Group, as agreed at the meetings held in Vienna in 1984 and in Brussels in 1985 and 1986, taking due account of the requirements of the countries concerned with the buffer zone and of the epizootiological situation in Anatolia and in the Near East.

The Delegates from Turkey, Greece and Bulgaria, gave detailed accounts of progress of the campaigns in each country, and there was considerable

discussion on the use of ASIA-1 vaccine in Thrace. Many delegates expressed the opinion that the use of this vaccine strain would be more appropriate in eastern Turkey than in the Thrace buffer zone.

The relocation of the buffer zone was also discussed but the observer from the World Veterinary Association pointed out that logistical problems which would be encountered in Anatolia were virtually insuperable, whereas the Thrace area was susceptible to control provided that organization was good. It would be prudent to continue to concentrate efforts in the Thrace buffer zone area.

In summarizing the situation, the Chairman expressed the Commission's appreciation to the countries concerned, Greece, Bulgaria and Turkey, for their efforts in maintaining the buffer zone and referred to Turkey's newly developed ability to service its own vaccine requirements from the production plant in Ankara. He also referred to unresolved problems with the vaccine strains used in the Thrace buffer zone.

It was agreed that a mission of the FAO/EEC/OIE FMD Group would meet the Turkish Veterinary Service to discuss and agree protocols for the Turkish vaccination zone, the possible relocation of that zone, and strategies for dealing with FMD outbreaks in Turkey.

The Commission also agreed unanimously that the buffer zone in southeastern Europe should be continued for a further two years. It was noted that funds for this purpose were available in the relevant Trust Funds and would cover the period until 1989, provided that no emergency occurred in the meantime.

Item 3.4 - FMD in other regions of interest to Europe

The Secretary introduced the relevant document, and commented that FMD continued to be one of the major constraints to livestock development and international trade in large areas of the world, having a serious affect on the national economies of affected countries. He reviewed the situation in Africa, Asia, South America, the Middle and Far East, and noted the developing problem in the Middle East caused by a virtually unrestricted import policy. He drew attention to the table of virus types isolated from different countries by the World Reference Laboratory in 1985 and 1986 and praised the expertise of that Laboratory. (Appendix 9)

The Chief of the Animal Health Service, FAO, commented that the problems in the Middle East had been caused by lack of staff as well as by continuing conflict and civil war, but should improve with the assignment of a new epidemiologist to Baghdad and, in the longer term, the establishment of a Middle Eastern epidemiology centre.

The observer from Israel gave an account of FMD in his country. Israeli stock was always at risk because the disease was endemic in neighbouring countries. A computer-controlled vaccination programme was in operation, using trivalent A₂₂/ASIA-1/O₁ vaccine in cattle, and bivalent ASIA-1/O₁ vaccine in sheep and goats. Stamping out was practised in any initial outbreak which was suspected to be due to a virus strain not controlled by the vaccine which had been used.

Thirteen outbreaks caused by O₁ had been recorded in north-east Israel in 1985; 9 in cattle, 3 in sheep and 1 in goats. Infection seemed to be linked to disease in mountain gazelles in which species the O₁ virus caused

severe lesions and 50 percent mortality. The same virus produced mild symptoms and no mortality in affected cattle. The World Reference Laboratory had compared O₁ virus from Israeli outbreaks with earlier virus isolates from Jordanian cattle and found them to be similar. It had been necessary to cull gazelles and more than 1 400 had been killed during 1985, mainly in the southern Golan area. The culling was continued throughout 1986. Research workers had confirmed the exceptional susceptibility of gazelles to this virus type, and further dissemination studies were planned. No disease had occurred in Israel in 1986, but four outbreaks had been confirmed in sheep in Samaria, and in cattle and sheep in Yizreel, since 20 March 1987. Clinical symptoms were seen only in young stock, and the World Reference Laboratory had confirmed that the O₁ virus causing the outbreaks was closely related to that responsible for the 1985 outbreaks. The vaccine in current use seemed to provide adequate immunity.

The observer from PAHO gave an account of the situation in South America. Investigation of the Colombian outbreaks had shown that the problem had been caused by low vaccination coverage, only 20 percent of cattle having been vaccinated. A₂₄ vaccine had proved effective when used in revaccination, and no change in vaccination policy was recommended. It was fortunate that the Bogota Savannah, where disease had occurred, was an area to which stock was moved, rather than an area which sent animals to other areas, and this had helped in control. Venezuela, the last South American country to produce modified live virus FMD vaccines, had now stopped doing so. Argentina is the largest country which still permits the use of formalin inactivation, but the laboratories seem likely to change in the future to aziridine. The efficacy of oil-adjuvant vaccines had been demonstrated in Brasil, where no disease had occurred in two years in those areas of the State of Rio Grande do Sul where that vaccine was applied. Forty million doses of oil-adjuvant vaccine were used so far in South America, and this volume seems likely to rise considerably. The vaccine is given by deep intramuscular injection in the upper third of the neck, and no problems have been experienced. The practice in South America is that farmers are obliged to buy and administer the vaccine themselves.

The situation in Chile appeared to be under control. Disease had first been diagnosed in Chile on 12 March 1987. The main cause for concern was infection in the tenth region, which was an important cattle area. It was hoped that infection could be stamped out and the use of vaccine avoided.

The observer of the WRL then reported on recent work at the FAO World Reference Laboratory. His report is included as Appendix 9.

Item 4 - Swine Vesicular Disease

A very satisfactory situation existed, no disease having been reported in Europe in 1985 or 1986.

Five out of 23 samples received by the World Reference Laboratory from Hong Kong in 1985 were positive for SVD, but no outbreak was reported there in 1986.

Delegates from Denmark and Sweden reported on their experiences in screening using the ELISA test. 15 000 samples had been examined in Denmark in 1986 and all were negative. 2 000 samples taken from 80 herds producing boars had been examined in Sweden, and a small number of low titres had been disclosed.

SVD had been excluded as the cause of these titres and further refinement of the test to exclude low false positive readings was now taking place.

Item 5 - Activities of the Research Group

Dr. van Bekkum summarized the paper on the activities of the Research Group. (Appendix 10) The Group held two meetings in the last biennium, one in Rio de Janeiro, in 1985, and the second in Madrid in 1986. Participants had been the usual group members and representatives of the Pan American FMD Centre and the Plum Island Animal Disease Center.

At the meeting in Rio de Janeiro, staff from the PAFMD Centre presented valuable information on the situation of FMD in South America.

Much attention was paid to methods in use for evaluating vaccine potency. The target animal, the bovine, remains the system of reference. Alternative test methods are however considered useful, although for some virus strains further studies are needed for the establishment of significant correlations between data obtained in different tests. Future efforts should be directed towards inter-laboratory harmonization of standard methods especially as regards the more economical serological methods for the evaluation of the potency of vaccines.

For the characterization of virus strains monoclonal antibodies are finding more and more application. In addition molecular biology techniques such as polyacrylamide gel electrophoresis, T1 oligonucleotide finger printing, isoelectric focusing of viral proteins and, recently, rapid sequencing methods, provide means for FMDV strain characterization. Such analyses have demonstrated potential value, but the significance of the correlation of the results of biochemical and biological tests of numerous virus strains remains to be determined.

The Group was in favour of a scheme whereby in each country groups of vaccinated cattle should be identified for the assessment, by challenge infection, of the level of protection likely to be given by the available vaccines against new strains appearing in the field.

It further recommended national authorities to make use of the antisera from cattle and guinea pigs which are available from several laboratories under a scheme initiated by the International Association for Biological Standardisation (IABS) for assessing the value of available vaccines against field strains.

It was felt that, prior to a possible attempt to harmonize vaccine strains in Europe, more efforts should be put into studies to define antigenic relationships between currently used vaccine strains and recent field isolates.

At the meeting in Madrid, the first item discussed was the vaccination of young animals, a problem of great importance in the present FMD epizootic in Italy. The recommendations made by the Group in this respect had been discussed under Item 3.1 of the Agenda of the Twenty-seventh Session. Attention was paid to new observations on the use of monoclonal antibodies.

At the request of the Commission, the Group subsequently discussed the methodology for investigating the origin of infection in FMD outbreaks. A draft text prepared by Dr. Eskildsen was discussed and slightly amended by the Group. The finalized text was presented by Dr. Eskildsen to the Commission. (Appendix 11) It was recommended that this document should be regarded as a Guideline for the investigation of FMD outbreaks.

It was pointed out that for further progress on the next phase of the Collaborative Laboratory Study, funds would be necessary for the preparation of pools of standard sera. Drs. Mowat and Lombard agreed to make an estimate of short and long term costs and to present their data to the Secretary.

The Executive Committee had requested the Group to study the feasibility of evaluating the level of immunity in the vaccinated livestock in the buffer zones in southeastern Europe using serological tests. The Group felt that in order to make such an assessment it would be necessary to have more detailed information on the distribution of herds, herd composition, and stocking densities in the various countries.

At the request of the Commission, the matter of stocks of seed virus held at AVRI, Pirbright, was reassessed both at the meeting in Rio de Janeiro and in Madrid. It was finally concluded that these lots of virus, which were established in 1970, were no longer needed at the present time and could be destroyed.

The next meeting of the Group would be held at the Laboratoire National de Pathologie Bovine de Lyon, France, from 22 to 25 September 1987.

Item 6 - Regionalization of FMD vaccine production

The Secretary introduced the document on the regionalization of FMD vaccine production. The Chairman reminded the Delegates that, except for the emergency situation in Greece in 1984, the Commission had invariably followed OIE 1962/1965 policy in this respect.

The recommendations agreed at the meeting of the OIE Regional Commission for Europe, held in Berlin in September 1986, were discussed. The observer from OIE emphasized that the text adopted in Berlin could not be changed until it had been discussed in Paris in May 1987, but said that in the light of comments which had been received from various countries a revised text would be presented for discussion there, and it was hoped that final agreement would then be reached.

The recommendation made in Berlin that:

- 1) Precautions should be taken that Europe be protected against exotic FMD by vaccination and other measures. Vaccines should be used which are produced at suitable places under safe conditions, but they must not be produced on the European mainland.
- 2) The discussion of a modification or replacement of the 1965 OIE Resolution concerning the handling of exotic FMD virus should be brought to an end before long so that a generally valid new regulation can be agreed.

was agreed for implementation only in the buffer zone in southeast Europe.

Item 7 - International FMD vaccine bank

The Delegate from UK introduced a short paper on the International FMD vaccine bank established by seven participating countries and sited outside the security zone at AVRI, Pirbright. None of the participating countries vaccinate against FMD and the bank provides a relatively cheap insurance policy should any of them wish to do so in an emergency. Concentrated antigen is stored over liquid nitrogen and can be reconstituted within five days if required. The new diagnostic test used by the FAO World Reference Laboratory now enables the laboratory to give advice on the suitability of vaccine for a specific outbreak within this time limit.

In answer to questions from the Chairman, the Delegate from UK stated that the addition of ASIA-1 to the antigen strains already stored was still under discussion and that no final decision had yet been taken. Discussions with the American vaccine bank were also at a very early stage, only technical details having so far been reviewed.

The Delegate from Denmark stated that concentrated frozen antigen had been stored at Lindholm for eight years without loss of potency and the PAHO observer commented that oil adjuvant vaccine had been stored at -60°C for five years without loss of potency. He felt that this was a potentially useful method of storing reference vaccines, particularly in South American conditions.

The EEC Delegate commented that the FMD Directive provides authority to develop an EEC vaccine bank. The EEC intends to study the subject and hopes to make a proposal to the Council of Ministers by 1 January 1989.

The Chairman concluded the brief discussion by re-emphasizing the potential importance of a vaccine bank for countries which follow a stamping out policy and which do not vaccinate. The existence of the Bank also had relevance to policy changes which may be made as a result of the cost-benefit study of the vaccination policy in Europe.

Item 8 - Cost-benefit study on vaccination policy in Europe

Dr. Davies introduced the relevant study. (Appendix 12) He reminded the Delegates that the model had been approved at the last meeting of the Commission and that seven countries had volunteered to apply it to their situations.

Countries employing vaccination
Federal Republic of Germany
The Netherlands
Spain
Switzerland

Countries employing stamping out
United Kingdom
Ireland
Finland

A Working Group was set up for this purpose and representatives (veterinarians and economists) from these countries discussed their results at a meeting at the Pirbright Laboratory, UK, in October 1986. All were able to use the model (except for Spain which has a different epidemiological situation) and there was reasonable agreement on costs of national vaccination, costs of controlling an outbreak, and costs of ring vaccination.

There were three problem areas:

- (a) certain costs were regarded as insignificant e.g. vaccine banks
- (b) certain costs were difficult to calculate e.g. export effects
- (c) difficulties in handling variations in herd sizes and assessment of risks - the Dutch and Swiss workers had developed computer models to deal with this.

These uncertainties had been dealt with by three addenda to the Cost-benefit Guide.

The Chairman thanked the Working Group for its efforts. It was up to the individual countries to use the guide as they wished; the Commission would provide help if required. He pointed out that there were still great uncertainties in deciding policy and he referred to the prediction of the number of outbreaks over the last ten years in the study carried out by the Federal Republic of Germany.

The Delegate from France enquired whether the study had taken into account the socio-economic effects of loss of employment, both in vaccine production and for veterinarians. Dr. Davies replied that the limits of the study were set out in the guide and the Group was aware of these further effects.

The Delegate from UK asked whether the Group had drawn any general conclusions on the economic benefit or disbenefit of vaccination. Dr. Davies replied that the three countries using stamping out were even more certain after the exercise that their policies were correct for them. This was largely for geographical reasons. The representatives of the countries using routine vaccination appeared to be having second thoughts about their policies which might now seem less valid, partly because there was evidence that some of their outbreaks were due to vaccine virus, and partly because the risk of FMD had declined over the last 10-15 years.

The Delegate from Switzerland stated that the Swiss authorities had been under pressure to abandon vaccination but the Italian situation had relieved that pressure.

The Chairman, in closing the discussion, repeated that the Commission was willing to help countries that wanted to use the Cost-benefit Guide.

Item 9 - Review of the current policies of the Commission

- (a) Proposed conditions for importation of beef into Europe from countries where FMD is endemic and is caused by viruses not considered exotic to Europe

The Chairman introduced the relevant recommendation. It was confirmed that "any strain that is new to the region and against which the available vaccines do not show the acceptable standard of potency is to be considered as a potential threat and consequently to be regarded as exotic".

The proposed conditions which had been recommended by the Nineteenth Session of the Commission in Rome in 1972, and had subsequently been revised by the Commission at a meeting in Paris in 1985, were discussed, and were amended. The recommendation to adopt the amended conditions listed in Appendix 13 was then agreed, with the proviso that these are minimum conditions which are valid for all countries, whether they vaccinate or not.

- (b) Movement of slaughter stock and meat from areas where exotic strains of FMD virus have been reported or inactivated exotic vaccines have been applied

The Chairman drew attention to discrepancies in the policies adopted by FAO, OIE and EEC in this field. For example, in considering the duration of area freedom from disease before accepting slaughter stock or meat, OIE specifies 30 days freedom, FAO 6 months, and the EEC 12 months. There would be an opportunity to discuss the harmonization of conditions at a meeting to be held at OIE headquarters in Paris on the occasion of the OIE General Session in May 1987.

Delegates accepted the desirability of establishing a single set of recommendations. It was agreed that the subject should be discussed in Paris, and that the Executive Committee would then make a full proposal to the Commission.

Item 10 - Financial Report

The Administrative Assistant introduced the relevant working document and briefly outlined the information contained therein. (Appendix 14)

In referring to the arrears for 1986 (US\$ 32 102) she stated that the secretariat had been informed that the outstanding amount would be remitted to FAO in the near future by the countries concerned.

As regards the breakdown of expenditure for 1986, the Delegates were informed that the amount earmarked under Chapter II, Emergency expenditure, (US\$ 20 000) had been transferred to Item .20 Travel in order to meet additional expenses in connection with the missions undertaken to study the FMD situation in Italy.

The Administrative Budget for 1987, as agreed by the Forty-ninth Session of the Executive Committee, was presented. The Chairman pointed out that the amount of US\$ 4 000 set aside for temporary typing assistance (Personal Services, 03.) was necessary since FAO was for budgetary reasons unable at the present time to give such assistance to the secretariat.

Following some clarification of minor points raised by the Delegates, the Financial Report was approved as presented.

Increase in contributions

The Executive Committee at its Forty-ninth Session held in Switzerland from 10 to 13 February 1987, following review of the financial situation of the Commission, and taking into account the falling value of the dollar, felt that the time had come to increase the annual contributions of the member countries.

It was agreed that a proposal for an increase of 5% as of 1 January 1988 should be submitted for approval to the Twenty-seventh

Session. The Secretary, as requested by the Executive Committee, had informed Member Countries of this proposal prior to the Session.

This proposal was approved by the majority of the Delegates of the Member Countries. The new scale of contributions (Appendix 14) would become effective as of 1 January 1988.

Item 11 - Future policy of the Commission

The Forty-ninth Session of the Executive Committee of the Commission, which met in Berne in February 1987, had discussed the future policy of the Commission and had agreed that the following points should be given priority.

- 1) An in-depth analysis of the Italian FMD situation
- 2) Maintenance of the buffer zone to be continued
- 3) Cost-benefit analysis; following discussion and approval of the proposed model at the 27th Session, assistance to be provided by the Commission to those countries wishing to carry out the study
- 4) Setting up of guidelines for total or partial stamping out during FMD outbreaks, including disposal methods
- 5) Setting up of guidelines for hygienic standards on large holdings; the Secretary to collect relevant data from member countries
- 6) Compilation of a summary of Commission recommendations since its establishment
- 7) Focusing of efforts in the Near East area in the field of FMD and provision of technical advice through FAO if requested
- 8) Strengthening of technical collaboration with FAO in FMD programmes, including training courses/seminars

The Secretary reminded the meeting about a further point which had been discussed by the Executive Committee, and it was agreed that this should be included as the ninth point:-

- 9) The preparation of National Contingency plans for emergency action to be taken in case of an FMD outbreak, and preparedness of national veterinary services and other bodies concerned for prompt and efficient implementation of sanitary measures adequate to the case.

Particular support was expressed by Delegates for the concept of training exercises and seminars (Point 8), and it was felt that there would be especial value in holding such an exercise in the Mediterranean area. Delegates also stressed the importance of formal cooperation with OIE and the EEC. At present the formal relationship was confined to the buffer zone, and it was suggested that disease notification procedures should be a primary topic for future collaboration and standardization.

It was agreed that the nine points listed should be the main tasks in the future policy of the Commission.

Item 12 - Adoption of the draft report of the Twenty-seventh Session

Following discussion of the draft report, the Chairman called for its adoption, subject to the incorporation of the amendments agreed, and to any necessary editorial changes. This was agreed unanimously, and the report was adopted.

Item 13 - Election of the Chairman, Vice-Chairmen and members of the Executive Committee

The Chairman, quoting from the Constitution of the Commission, indicated the procedure to be followed for the election of Members of the Executive Committee. He then called for nominations for the offices of Chairman, two Vice-Chairmen and five members of the Executive Committee, and indicated that other commitments made it impossible for him to accept a further nomination for re-election as Chairman.

- a) Elected as Chairman of the Commission - Dr. W.H.G. Rees, UK
proposed by Dr. E. Stougaard, Denmark
seconded by Dr. R.G. Cullen, Ireland

- b) Elected as Vice-Chairmen
proposed by Dr. F. Walla, Austria
seconded by Dr. N. Tanev Belev, Bulgaria
 - Dr. A. Rojahn, Federal Republic of Germany

 - Dr. C.A.M. de Andrade Fontes, Portugalproposed by Dr. N. Tanev Belev, Bulgaria
seconded by Dr. M.A. Diaz Yubero, Spain

- c) The following delegates were elected to membership of the Executive Committee:
 - Dr. R. Berger (Finland) - proposed by Dr. B. Henricson (Sweden)
seconded by Dr. P. Gafner (Switzerland)

 - Dr. L. Perpere (France) - proposed by Dr. I. Fontaine (Belgium)
seconded by Dr. R. Frisch (Luxembourg)

 - Dr. N. Tanev Belev (Bulgaria) - proposed by Dr. J. Mazurek (Poland)
seconded by Dr. L. Perpere (France)

 - Dr. P. Gafner (Switzerland) - proposed by Dr. N. Tanev Belev (Bulgaria)
- seconded by Dr. L. Perpere (France)

 - Dr. E. Stougaard (Denmark) - proposed by Dr. R.G. Cullen (Ireland)
- seconded by Dr. B. Henricson (Sweden)

Membership of the Research Group of the Standing Technical Committee of the Commission was then considered. A suggestion that the size of the Group be reduced was discussed but, although supported by some delegates on the grounds of increased flexibility and effectiveness (the smaller group would have been able to co-opt other experts whenever necessary) it was agreed that no change should be made.

The Chairman then asked for nominations, emphasizing that only currently active experts could be appointed. The following nine experts were elected to serve (subject to Government clearance):

Dr. R. Strobbe (Belgium)
Dr. R. Hubik (Czechoslovakia)
Dr. M. Eskildsen (Denmark)
Dr. G. Dannacher (France)
Prof. Dr. G. Wittmann (Federal Republic of Germany)
Prof. G.F. Panina (Italy)
Dr. P. de Leeuw (Netherlands)
Dr. E. Domingo (Spain)
Dr. N. Mowat (UK)

The Commission proposed that Dr. M. Eskildsen would succeed Dr. J.G. van Bekkum, who was retiring, as Chairman of the Research Group.

The term of office of the present members of the Research Group expires on 31 July 1987.

According to FAO procedures the appointment of the newly elected members is subject to Government clearance and the two-year term of office would cover the period 31 July 1987 to 31 July 1989.

Item 14 - Any other business

Membership

The question of Israel's wish to join the Commission was discussed. The Legal Counsel of FAO was present to give an opinion on the interpretation of Article I of the Commission's Constitution relating to the States that were eligible to become a party to it. Having examined the travaux préparatoires of the Commission's Constitution, the Legal Counsel stated that it appeared that one of the essential conditions for becoming a party to it was that the State in question be geographically situated in Europe. The Secretary had transmitted Legal Counsel's opinion in this respect to the Permanent Representative of Israel to FAO in October 1986.

Following a discussion in which the majority of Delegates who spoke supported the principle of Israel's membership, the Legal Counsel confirmed that there were several possible ways in which the existing situation could be changed if that were the wish of members. For example if the Commission's members agreed unanimously that the term "European" had a political, rather than geographical connotation, that interpretation could be included in the report of the proceedings and become, for the future, the official interpretation of the provisions of the agreement.

Alternatively, there were procedures by which the Constitution of the Commission could be amended. To do so required a number of specific steps.

- 1) The amendment must be proposed by a member of the Commission in a communication addressed both to the Chairman of the Commission and to the Director-General of FAO at least 120 days before the opening of a Session of the Commission. In practice, it was desirable that the proposal be made as soon as possible.
- 2) In accordance with Article XIV, paragraph 2 of the Constitution the proposal would be communicated to all Members of the Commission.

- 3) The subject would then be placed on the Agenda to be discussed at the next Session of the Commission.
- 4) After discussion at that Session the proposal for the amendment would require approval by the Commission by a two-thirds majority of its membership.
- 5) If approved, the proposal would be submitted to the FAO Council, since the amendment could only become effective with the concurrence of the Council, in accordance with Article XIV, paragraph 4 of the Commission's Constitution.
- 6) After approval by the FAO Council, Israel would become eligible for membership of the Commission from the date of the decision of the Council and could then deposit an instrument of acceptance of the Constitution and thus become a member of the Commission.

According to this scenario, which had the advantage of avoiding any action which might be construed as unconstitutional, Israel could hope to achieve membership of the Commission.

The Chairman proposed that amendment of the Constitution was the preferred course of action, and the meeting so agreed.

Closing remarks

Dr. C.H. Bonte-Friedheim, Assistant Director-General of the Agriculture Department of FAO complimented the Commission for their work and for the way in which they had dealt with the many important items which had been discussed during the Session. He was sure that all would be pleased with the results of the endeavours, and concluded by thanking Dr. Rojam, on behalf of FAO, for his work in this important field during his term of office as Chairman.

On behalf of the Commission, Dr. Rees thanked the Chairman for his efficient conduct of the Session, and for his hard work during the previous four years.

The Chairman concluded the Session by thanking the Delegates and observers for their participation and for the contributions which they had made to the discussions, and to the draft report. He thanked the interpreters, secretariat, and rapporteur for their work, and wished Dr. Rees well during his term of office.

Report of the Executive Committee on the Commission's
activities during the biennium 1985-1986

General

This report covers the period which has elapsed since the Twenty-sixth Session which was held at FAO Headquarters, Rome, from 23 to 26 April 1985.

Since then the Executive Committee has held two regular Sessions: the Forty-eighth in Helsinki, Finland, from 15 to 18 April 1986, the Forty-ninth in Berne, Switzerland, from 10 to 13 February 1987, and an Ad hoc Session in Berlin, DDR, on 17 September 1986.

The Research Group of the Standing Technical Committee of the Commission held two Sessions during the reporting period: in Rio de Janeiro, Brazil, from 15 to 18 October 1985, and in Madrid, Spain, from 14 to 17 October 1986.

The relevant reports of the Sessions of the Executive Committee and of the Research Group contain full information on the activities carried out during the reporting period and have been distributed to all member countries of the Commission and to other interested governments and international agencies.

The activities of the Commission and its Secretariat during the period under review have followed the recommendations made by the Twenty-sixth Session of the Commission and the Forty-eighth and Forty-ninth Sessions of the Executive Committee. All activities of the Commission have been carried out in conformity with its Constitution.

The reporting period has been characterized by a favourable disease situation in Europe, with the exception of Italy.

FMD situation in Italy

A flare-up of FMD type A₅ in Modena in November 1984, followed by a second wave of type C₁ in November 1985, and the reappearance of A5 type in June 1986 lasting until 30 December 1986, caused much concern among Commission member countries and all efforts were directed towards monitoring the evolution of the disease.

The evolution of the disease and its persistence, especially among the pig population which is totally unprotected, was closely followed by the Secretary, and member countries have been kept informed of developments on a regular basis.

The Secretary visited the Italian Veterinary Services and the FMD Reference Laboratory for Italy in Brescia and discussed the disease situation and the sanitary measures applied for its control and eradication.

The Executive Committee at its Forty-seventh Session held in the Hague, Netherlands, from 5 to 8 March 1985, reviewed and discussed the FMD situation in Italy and recommended that strict and effective control

measures were essential to bring it under control. The Committee was of the opinion that a stamping out policy should have been applied immediately during the primary outbreaks.

During the Forty-seventh Session of the Executive Committee, the Director-General of Veterinary Services in Italy was contacted with a view to obtaining his views on the situation which had developed in Italy, and in order to inform him that the Commission wished to offer assistance in the form of expertise.

At the Twenty-sixth Session of the Commission, the FMD situation in Italy was further discussed and it was again strongly recommended that a stamping out policy should be applied for all outbreaks of FMD. This recommendation was not supported by Italy.

At the Forty-eighth Session of the Executive Committee held in Helsinki, Finland, from 15 to 18 April 1986, the matter was rediscussed. Particular attention was given to the report on the FMD situation submitted by the Director-General of Veterinary Services of Italy.

In August 1986, as the disease situation deteriorated, especially in northern Italy, the Secretary, on behalf of the Chairman of the Commission, addressed a letter to the Director-General of Veterinary Services in Italy in which he expressed the concern of the Commission regarding the evolving disease situation. He also stated that the Commission was ready to provide any type of assistance the Italian authorities considered opportune for the purpose of bringing the FMD situation under control.

In response to this letter, the Italian Veterinary Authorities officially requested an emergency meeting of the Commission to discuss the FMD situation in Italy, and a mission to Italy of a group of experts nominated by the Commission to examine the measures adopted by Italy against FMD and to advise on ways and means of controlling the disease.

Ad hoc meeting of the Executive Committee, Berlin, DDR, 17 September 1986

The Italian request was discussed at an Ad hoc meeting of the Executive Committee held on the occasion of the 12th OIE Regional Conference for Europe on 17 September 1986, in Berlin, DDR. At this Ad hoc meeting it was agreed:

- that the FMD outbreaks in Italy, which had started in 1984, had put at risk the European countries which were free from FMD
- that a Commission mission should visit Italy from 6 to 10 October 1986 to review and discuss the disease situation and make conclusions and recommendations for submission to the Italian Government
- that the conclusions/recommendations of the FAO/EUFMD mission should be further discussed with the Chairman of the Commission, those members of the Executive Committee who could attend, and the Italian Veterinary Authorities, at a meeting to be convened in Rome at a date to be decided as soon as possible following the mission's visit.

The Commission mission completed its task on the dates proposed by the Commission and its findings were presented by the Executive Committee of the Commission to the Director General of Veterinary Services at the Ministry of Health in Rome on 10 November 1986.

Following a request to the Commission by the Minister of Health, the Secretary of the Commission participated in meetings convened at regional level where the findings of the Mission in Italy were presented and discussed with the Regional Veterinary Authorities and representatives of the Veterinary and Farmers' associations.

Five meetings were convened: on 29 November in Brescia for the northern region, on 6 December in Rome for central regions, on 9 December in Palermo for Sicily, on 11 December in Naples for the southern region and on 12 December in Sassari for Sardegna.

The FAO/EUFMD mission report on FMD in Italy was given high consideration by the Ministry of Health and the Central Veterinary Services, as well as by all authorities who participated in the meetings at regional level.

The FAO/EUFMD mission report, the minutes of the meeting held on 10 November 1986, at the office of the Director General of Veterinary Services, Professor Bellani, and the minutes of the meetings convened at regional level, are presented under Appendix 5.

In evaluating these and in response to the request received from the Minister of Health, the Commission provided the services of three experts to undertake an in-depth study of the Italian FMD situation, especially in epidemiology, vaccine production and economic analysis of the sanitary measures applied and the reasons for the persistence of the disease.

The results of this study are presented as Appendices 6 and 7.

The close collaboration and valuable assistance provided by the Central and Regional Veterinary Authorities to the FAO/EUFMD Mission and the Commission experts in carrying out the difficult task entrusted to them is hereby acknowledged.

The Committee proposed that the recommendations made by the FAO/EUFMD Mission and the experts on the Italian FMD situation be given due consideration by the Italian Government in order to avoid repetition of such a disease situation which has seriously affected the national economy and has represented a risk for Europe.

The Committee is fully aware of the problems encountered by the Italian Veterinary Services in controlling the FMD epizootics which have occurred, and the efforts made to bring the disease under control. The Italian case should be borne in mind by all member countries and the insidiousness of the virus should not be underestimated; a favourable disease situation should not lead to undue relaxation of vigilance.

Maintenance of buffer zone in southeastern Europe

Implementation of vaccination campaigns in the buffer zone along the borders of Turkey, Bulgaria and Greece, was carried out in conformity with the recommendations of the Twenty-sixth Session of the Commission in April 1985, the Forty-seventh Session of the Executive Committee and those of the FAO/EEC/OIE Tripartite FMD Group. The requests of the countries concerned with the buffer zone expressed at the meetings held on 27 November 1985 in Alexandroupolis, Greece, were taken into account.

For 1987, Turkey will use vaccine produced at the FMD Institute, Ankara, for the implementation of the vaccination campaigns in the buffer zone Thrace (Turkish side) and in the Marmara area.

FMD position in other regions

This was continuously monitored by the Secretary of the Commission. Special attention was given to the Near East countries where the FMD situation continues to be a matter for concern since it constitutes a potential risk for Europe through the intensive traffic from this region into Europe. Detailed information on the epidemiology of the disease in the region is lacking. The Executive Committee at its Forty-eighth Session held in Helsinki, April 1986, recommended that the Commission be prepared to cooperate with FAO in organizing seminars or training courses on FMD control programmes and strengthening contacts with the Veterinary Services, international organizations, and FMD Commissions in other regions in the world.

The FMD situation in South America was given special attention. The Executive Committee noted with satisfaction the efforts made by Governments in supporting disease control programmes in the respective countries.

The good collaboration established between the Panamerican Center for FMD in Rio de Janeiro was further consolidated by the Session which the Research Group held at the Panamerican FMD Center in October 1985.

Visit to Israel

In response to an invitation received from Dr. Shimshony, Director of Veterinary Services of Israel, Dr. Rees, Vice-Chairman of the Commission and the Secretary visited Israel from 9 to 13 March 1986 to review and discuss the FMD position and control policy. At the Forty-eighth Session of the Executive Committee, Helsinki, April 1986, the Committee noted with satisfaction the information reported and comments made on the operation and effectiveness of the Israeli Veterinary Services in controlling FMD.

The Committee was informed of the wish of the Government of Israel to join the Commission and expressed its appreciation of the Israeli Authorities interest in and support of the Commission. It was regretted, however, that the Constitution of the Commission does not provide for membership of non-European states (Article I-Membership). This was confirmed by the Legal Counsel of FAO. The Committee recommended that in future Israel be invited to participate in Sessions of the Commission in an observer capacity.

Cost-benefit study on vaccination policy

As was recommended by the Commission at its Twenty-sixth Session held in Rome in April 1985, an exercise on cost-benefit analysis through application of the proposed model was carried out by the countries participating in the exercise. The results of the exercise were further discussed by the Working Group at a meeting held at AVRI, Pirbright, on 29-30 September 1986. The results of the exercise have been analyzed and discussed by the Working Group and are included in the model which was submitted to the Commission for consideration and approval.

Regionalization of FMD vaccine

The Executive Committee took all necessary action for the implementation of the recommendation made by the Commission at its Twenty-sixth Session. Detailed background information is included in the reports of the Forty-seventh and Forty-eighth Sessions of the Executive Committee.

Participation in FAO activities

The Commission participated through its Secretariat in all relevant FAO activities. The work carried out was related to the programmes of the Organization in the field of foot-and-mouth disease control. The main activities in which the Secretary was involved were: UNDP projects and TCP projects dealing with emergency assistance to countries facing FMD outbreaks, development of field programmes, recruitment of experts, advice on the planning, backstopping and evaluation of FMD projects and the setting-up of FMD laboratory facilities in different parts of the world (Bulgaria, Burma, India, Brazil, Sri Lanka) for which the Secretary acts as Technical Adviser. During the period under review the Secretary organized an FAO Seminar on current techniques for FMD virus diagnosis at the Istituto Zooprofilattico in Brescia, Italy, in September 1985.

A Second FAO Seminar on simulation exercise on FMD control and eradication was organized and implemented in Bangkok, Thailand, in December 1986.

Missions carried out by the Secretary in 1985 and 1986

For FAO (travel costs met by the Organization)

- Jordan May 1985, to attend Ninth Executive Board Meeting of the Middle and Near East Regional Animal Production and Health Project (MINEADP)
- India June 1985, participation in a UNDP/FAO/Government, Tripartite meeting to discuss and finalize Prodoc IND/85/065 - "Establishment of a high security laboratory".
- Iraq June 1985, to visit the new FMD vaccine production centre at Dora, Baghdad, and discuss matters related to vaccine production and supply to the Region.
- Sri Lanka September 1985, review of FMD control policy in Sri Lanka
- Italy September 1985, to conduct the FAO Seminar on current techniques for foot-and-mouth disease virus diagnosis and identification
- United Kingdom October 1985, to attend the 60th Anniversary Meeting of the Animal Virus Research Institute, Pirbright, U.K.
- Brazil October 1985, to review and discuss project implementation (TCP/BRA/4403): production of oil adjuvant FMD vaccine at the Campinas laboratory

- Bulgaria May 1986, review and discuss project implementation BUL/84/002 FMD Centre, Sliven
- Albania June 1986, to review and discuss animal health programmes
- German Democratic Republic September 1986, to attend the XII OIE Regional Conference for Europe (travel paid by FAO)

For the Commission (travel costs met by the Commission)

- Turkey, Ankara January 1985, to review FMD situation and implementation of campaigns in the buffer zone (Chairman and Secretary)
- Bulgaria, Sofia February 1985, to review FMD situation and campaigns in the buffer zone (Chairman and Secretary)
- France, Paris May 1985, to attend the Ad Hoc Consultation on FMD in Europe held at the OIE, Paris, from 10 to 11 April 1985
- France, Paris May 1985, to attend the Fifty-third General Session of OIE
- Brazil, Rio de Janeiro October 1985, to conduct the Session of the Research Group of the Standing Technical Committee of the European Commission for the Control of Foot-and-Mouth Disease
- Greece, Alexandroupolis November 1985, to discuss FMD vaccination campaign policy in buffer zone area (Chairman and Secretary)
- Belgium, Brussels December 1985, EEC FAO/EEC/OIE FMD Group meeting to discuss FMD vaccination campaign policy in buffer zone area. (Chairman and Secretary)
- Italy, Brescia January 1986, to attend EEC meeting on monoclonal antibodies for the diagnosis of FMD virus.
- Israel, Tel Aviv March 1986, to review and discuss the foot-and-mouth disease (FMD) position in the country, control policy and plans for setting up an FMD vaccine production plant. Dr. Rees, CVO, U.K., and Vice-Chairman of the Commission participated.
- Finland, Helsinki April 1986, Forty-eighth Session of the Executive Committee of the European Commission for the Control of Foot-and-Mouth Disease
- France, Paris June 1986, to attend the Fifty-fourth General Session of OIE
- German Democratic Republic, Berlin September 1986, to attend the 12th OIE Regional Conference for Europe (travel paid by FAO/DSA paid by EUFMD) Ad hoc meeting of Executive Committee to discuss the FMD situation in Italy.

- United Kingdom, Pirbright September 1986, to discuss results of exercise for economic evaluation of foot-and-mouth disease control programme in Europe. (Working Group)
- Italy October 1986, FAO/EUFMD Mission to review the FMD situation in Italy
- Spain, Madrid October 1986, to conduct the Session of the Research Group of the Standing Technical Committee of the European Commission for the Control of FMD.
- Italy, Rome November 1986, Prof. Dr. A. Rojahn, Dr. W.H.G. Rees, and Dr. F. Walla - to present FAO/EUFMD mission report to the Italian Veterinary Services
- Turkey, Ankara November 1986, to review FMD situation and discuss implementation of campaigns in the buffer zone.
- Belgium, Brussels December 1986, meeting of FAO/EEC/OIE FMD Group to discuss FMD vaccination policy in southeastern Europe buffer zone in 1987. (Chairman and Secretary)
- Italy November-December 1986, to present and discuss the Report of the FAO/EUFMD mission on the FMD situation in Italy, Brescia, Rome, Palermo, Naples, and Sassari.

Membership of the Commission

Contacts were maintained with the European non-member countries of the Commission. Two new members joined the Commission: **Czechoslovakia in November 1985** and the **Socialist People's Republic of Albania in November 1986**, bringing the present membership to 27. It is hoped that the remaining countries will also consider applying for membership.

Fellowships

Three fellowships were financed by the Commission between 1985 and 1986.

Dr. O. Keszy from the FMD Laboratory in Poland undertook five months training in FMD vaccine production and control at the Istituto Zooprofilattico Sperimentale, Brescia, Italy from December 1984 to April 1985.

Dr. T. Soos and Dr. E. Mocsari from Hungary undertook 6 weeks training in FMD vaccine production at the Central Veterinary Institute, Lelystad, Netherlands from mid-November to 20 December 1986.

The Commission wishes to thank the Institutes for having accepted the fellowships and for the technical training provided to them.

Sessions of the Research Group

The Research Group held two Sessions during the biennium:

- a) the Session held at the Panamerican Center for FMD in Rio de Janeiro, Brazil, from 15 to 18 October 1985

- b) the Session held in Madrid, Spain, from 14 to 17 October 1986.

The work carried out by the Research Group under the chairmanship of Dr. J.G. van Bakkum and the advice given to the Commission on all matters referred to it for examination is highly appreciated by the Executive Committee. The relevant reports have been distributed to the member countries of the Commission.

Sessions of the Executive Committee

Since the Twenty-sixth Session of the Commission held in April 1985, the Executive Committee held two Sessions:

- 1) the Forty-eighth Session held in Helsinki, Finland, from 15 to 18 April 1986
- 2) the Forty-ninth Session held in Berne, Switzerland, from 11 to 13 February 1987.

The Agenda items discussed and conclusions and recommendations agreed in both Sessions are included in the relevant reports.

Forty-eighth Session, Helsinki, Finland, 15-18 April 1986

FMD position and prophylaxis in Europe

Special attention was given to the disease situation in Italy and its persistence since November 1984. The Committee expressed concern in respect of the difficulties encountered by the Italian Veterinary Services in the effective application of adequate sanitary measures in the primary outbreaks in order to avoid the spread of the disease of both A₅ and C₁ epizootics. The report on the FMD position in Italy presented to the Committee by the Director General of the Italian Veterinary Services was acknowledged. The Committee agreed that the methodology for investigating the origin of infection in FMD outbreaks needs to be studied and recommended that the matter be referred to the Research Group.

EEC proposal for FMD Reference Laboratory

The Committee, following examination of the various aspects of the EEC proposal, recommended that there should be only one FMD Reference Laboratory for Europe, both for EEC and non-EEC countries i.e. the existing FMD World Reference Laboratory, Pirbright, U.K.

The Commission's views in this respect have been presented to EEC by the Chairman and the Secretary of the Commission.

FMD prophylaxis in Europe

The Committee reaffirmed the Commission's position that the present prophylactic system in Europe gives satisfactory protection if national programmes for FMD prophylaxis and control including, stamping out, are properly implemented with regard to the continuation of the vaccination policy in Europe. The Committee requested that the Research Group study:

- the optimum age under different conditions for vaccination of young stock, especially if intended for export;

- identification of vaccine strains used in Europe and their serological relationship;

FMD campaigns in southeastern Europe

The difficulties encountered in observing the OIE policy related to the supply of exotic vaccine for the buffer zone in southeastern Europe was discussed. The Committee recommended that:

- vaccination campaigns in the buffer zone should be carried out with O/A₂₂/ASIA-1 trivalent vaccine for two years after the ASIA-1 outbreak reported in Greece in June 1984. The vaccination policy should be reviewed by the FAO/EEC/OIE FMD Group, in the light of the position of ASIA-1 virus in the Near East region and the epizootiological situation in this area.
- arrangements for the provision of vaccine for the maintenance of the buffer zone in southeastern Europe in 1987 should be made in accordance with the recommendations of the FAO/EEC/OIE FMD Group and the OIE policy unless this has been changed in the meantime.

The Research Group was requested to study, through serological tests, the feasibility of evaluating the level of immunity in vaccinated animals in the buffer zone.

Review of FMD position in other regions

The Committee recommended that the Commission continue to monitor the disease situation and efforts should be made to obtain prompt and reliable information on the FMD position in areas outside of Europe.

Swine vesicular disease (SVD)

It was recommended that countries should maintain vigilance against the reintroduction of SVD. Serological tests should be carried out in susceptible cases.

Activities of the Research Group

The Committee acknowledged the enormous and valuable amount of work carried out by the Research Group and noted with satisfaction the usefulness of the meeting held at the Panamerican FMD Center, Rio de Janeiro, Brazil, in October 1985 and in Madrid, Spain, in October 1986.

Cost-benefit study on vaccination policy

The Committee agreed that the results of the exercise on cost-benefit analysis through application of the proposed model be discussed and analyzed by the Working Group at the AVRI, Pirbright, U.K. in September 1986. The final model as modified by the Working Group at the meeting at Pirbright, will be submitted to the Commission for consideration and approval at its Twenty-seventh Session.

Review of the Commission's recommendations

a) Proposed conditions for importation of beef into Europe from countries where FMD is endemic and is caused by viruses not considered exotic to Europe (Nineteenth Session 1972). This was revised at a meeting convened

by the Secretary in Paris on 21 May 1985, on the occasion of the Fifty-third General Session of OIE. The revised text of this recommendation was approved by the Committee and it was agreed that the conditions outlined therein should be regarded as the minimum applicable for the purpose of this recommendation.

b) Movement of slaughter stock and meat from areas where exotic strains of FMD virus have been reported or inactivated exotic vaccines have been applied (Fourteenth Session 1969). In view of the different policies applied by the OIE, the EEC, and the FAO European Commission for the Control of Foot-and-Mouth Disease in this respect and particularly for the buffer zone areas in southeastern Europe, it is essential that this matter be reviewed and discussed with the aim of harmonizing the policies in Europe.

c) Seed virus stock. Regarding the stock of seed virus maintained at the World Reference Laboratory, Pirbright, U.K. the Committee agreed with the decision taken by the Research Group in this respect.

The implementation of the Commission's recommendations by the member countries has been monitored by the Secretary.

Strategic vaccine reserve for Europe

The Committee expressed appreciation to the countries who set up the vaccine bank and supported the work of the Bank.

Financial report and budget

The Committee approved the statement of accounts, breakdown of budget/actual expenditure for 1985 and the Administrative Budget for 1986.

Forty-ninth Session, Berne, Switzerland, 10-13 February 1987

The conclusions and recommendations of this Session are contained in the relevant report which has been circulated together with the working documents for the Twenty-seventh Session to all member countries.

Conclusions

Europe, facing a situation of disease freedom, should further strengthen the collaboration in FMD control between all countries and the recommendations adopted by the Commission in this respect should be strictly applied especially at the primary outbreaks.

Considering that the farming system has changed in Europe from dairy farming to large livestock fattening units which are mainly involved in national and international trade, the Committee is of the opinion that standards need to be established in respect of:

- emergency action to be taken in case of an FMD outbreak and preparedness of the national veterinary services and other bodies concerned for a prompt and effective implementation of the sanitary measures adequate to the case
- strengthening of the collaboration between farmers and veterinary authorities concerned with FMD prophylaxis and control

- minimum hygiene and management standards required for large livestock holdings taking into account animal species, size of holdings, distance from similar holdings and environmental conditions
- guideline for total or partial stamping out policy, taking into account the geological conditions of the areas where the holdings are located and environment protection
- rendering plants and means of transportation of slaughtered animals in infected areas.
- standardization of the FMD vaccine in Europe as far as vaccine virus strains, inactivation and potency tests are concerned

The Executive Committee would like to state that the period under review has been fundamental for the Commission and has further confirmed its importance as an international Commission for the prevention, control and eradication of foot-and-mouth disease through the concerted efforts of all member countries.

FMD position in Europe 1985-1986
(By country, number of outbreaks and virus type)

COUNTRIES	Jan.	Feb.	Mar.	Apr.	May	June	July	Aug.	Sept	Oct.	Nov.	Dec.	Total				
REMAINDER OF EUROPEAN COUNTRIES DISEASE FREE																	
ITALY	1985	33 A ₅	10 A ₅	22 A ₅	8 A ₅	19 A ₅	3 A ₅	2 A ₅	12 A ₅	--	--	3 C ₁	1 A* 17 C ₁	110 A ₅	20 C ₁	130	
	1986	17 C ₁	20 C ₁	9 C ₁	2 C ₁	--	11 A ₅	1 O ₁	25 A ₅	23 A ₅	9 A ₅	21 A ₅	10 A ₅	2 A ₅	48 C ₁	101 A ₅	1 O ₁
SPAIN	--	--	--	--	--	1 A ₅	--	--	--	--	--	--	--	1 A ₅		1	
TURKEY ANATOLIA	1985	21 A ₂₂ /O	30 A ₂₂ /O	61 A ₂₂ /O	29 A ₂₂ /O	33 A ₂₂ /O	30 A ₂₂ /O	83 A ₂₂ /O	25 A ₂₂ /O	29 A ₂₂ /O	18 A ₂₂ /O	20 A ₂₂ /O	38 A ₂₂ /O	417 A ₂₂ /O		417	
	1986	16 A ₂₂ /O	15 A ₂₂ /O	9 A ₂₂ /O	12 A ₂₂ /O	11 A ₂₂ /O	11 A ₂₂ /O	15 A ₂₂ /O	8 A ₂₂ /O	10 A ₂₂ /O	6 A ₂₂ /O	8 A ₂₂ /O	10 A ₂₂ /O	131 A ₂₂ /O		131	
USSR**	1985	--	--	--	1 A ₂₂	--	--	1 O ₁	1 O ₁	--	--	--	--	1 A ₂₂	2 O ₁	3	
	1986	--	--	--	--	--	1 A ₂₂	--	1 O ₁	--	1 A ₂₂	1 O ₁	--	2 O ₁	2 A ₂₂	4	

* A Verona/85 not closely related to A₅ Modena/85

** Southeastern provinces

-- No cases reported

... No information available

FMD Prophylaxis in Europe, 1985-1986

The FMD prophylaxis in Europe during 1985 and 1986 was implemented mainly on the continental area. A general vaccination programme was carried out in Belgium, France, the Federal Republic of Germany, Luxembourg, Malta, the Netherlands, Portugal, Spain, Switzerland, Italy, Czechoslovakia, the German Democratic Republic and in USSR.

An area vaccination programme was carried out in Bulgaria*, Greece*, (buffer zone in Thrace), Hungary and Romania, with conventional European vaccine of local production or imported.

In Turkey, the annual prophylactic and control programme has been implemented in Thrace buffer zone, in the east and southeast frontier areas in Anatolia and in the government farms in Anatolia. In Cyprus, the prophylactic vaccination programme was discontinued.

Details on FMD prophylaxis by country in Europe for 1985 and 1986 are given in Table 1.

In Italy, the annual prophylactic programme was supplemented by an emergency vaccination of all susceptible animals in the affected areas during the A₅, C₁, epizootics which began in November 1984.

Type C epizootic in pigs started in November 1985, making it necessary to vaccinate pigs in and around the affected areas. Vaccination was carried out with type C monovalent oil adjuvant vaccine produced at the Brescia FMD Institute. Over 3 million pigs have been vaccinated since November 1985 in the affected areas. In 1986, due to the FMD situation in Italy, the annual vaccination campaign which is normally carried out from 1 November to 30 January, was brought forward and implemented from 1 October to 30 November in the whole country with O₁, A₅, C₁ trivalent vaccine.

In the remainder of Europe, prophylactic vaccination is not practised; prophylaxis is based on strict import control of animals and animal products and on the sanitary measures and animal movement regulations in force in each country.

The favourable disease situation established in the greater part of Europe, the consequent tendency to relax the security measures in some countries and the movement towards a free market system may compromise the stability of the disease control system established so far, and at the same time, the capacity of the National Veterinary Services to face an emergency FMD situation may be reduced.

The recent FMD epizootics which occurred in Europe are clear evidence that complacency with regard to the FMD situation is dangerous; countries should continue to be alert to the insidiousness of the disease. National prophylactic programmes should in practice be properly implemented

* vaccination with O₁/A₂₂/ASIA-1 trivalent vaccine provided through FAO.

according to the rules existing in each country, and to the epizootiological situation in neighbouring countries or regions. This policy should be strictly applied especially in exporting countries.

Although the present prophylactic policy in Europe might not be the optimal, since vaccine coverage is applied only to the cattle population, if properly applied, it can guarantee a high percentage of protection among vaccinated animals. However, even in mass vaccination carried out under the best conditions, 15-20 percent of the cattle population still remains unprotected including young stock not vaccinated during the vaccination period or stock which did not react to vaccination as is frequently the case. These high risk animals are mainly found in national or international trade movement and their protection level against FMD especially against vaccine virus strains in use in the importing country is frequently a matter for discussion between exporting and importing countries.

It should also be considered that certain exporting countries use vaccines not produced and tested locally but imported and used on an ad hoc basis according to the exigencies of the market and the requirements of the importing country. As a consequence of this, there is a flow of animals of various origin in importing countries. These animals are vaccinated with vaccines containing virus strains different from those contained in the vaccine used in the importing country.

In countries where vaccination has been discontinued, exported animals are vaccinated only prior to export; this cannot guarantee an efficient level of protection especially among young stock. Revaccination of such animals upon arrival in the country of destination gives dubious results due to the stress of transportation and the treatment of these animals with antistress drugs and other vaccines against respiratory diseases which reduce the effect of vaccination against FMD. The risk these animals represent for the livestock in the importing country is obvious.

Therefore, it is essential that the vaccination of animals, especially those intended for export, be harmonized as far as the type of vaccine to be used in exported animals is concerned, and taking into account the requirements of the importing country in this respect. See Item 5 - Recommendation on immunity to FMD in young animals, Research Group, Session held in Madrid in October 1986.

In countries where an annual vaccination programme is carried out, standardization of vaccine formulation, inactivation (type of inactivant) and quality controls should be studied in order to achieve a good protection level among the vaccinated animals in those countries. This would minimize the risk of FMD through animal movement in national or international trade. The Research Group of the Commission as a follow-up of the Commission's recommendation adopted at its Twenty-sixth Session held in Rome in April 1985 discussed this matter at its Session held in Madrid in October 1986 and through a questionnaire sent out by the Secretary to all members of the Commission has collected updated information from the FMD Laboratories in Europe on the current FMD vaccine and challenge virus strains used in Europe.

In view of the possible outcome of the cost benefit analysis on the vaccination policy against FMD which all Commission member countries should carry out when the relevant model studied by the Commission is ready, the Commission should give high priority to this matter.

FMD PROPHYLAXIS IN EUROPE DURING 1985-86

Country	VACCINATION PROGRAMMES			VACCINES	
	Species vaccinated	Period of vaccination	Territory covered by vaccination	Valencies Cattle dose/cost	Potency required and results
Albania	No vaccination				
Austria	<p>Cattle, sheep, goats and pigs</p> <p><u>1985</u></p> <p>Cattle: 89 000 Sheep/goats: 4 000</p> <p><u>1986</u></p> <p>Cattle: 90 000 Sheep/goats: 4 200</p>	<p>A. Autumn</p> <p>B. Spring</p> <p>C. Animals for export as required</p>	<p>Around the FMD Institute (Vienna)</p> <p>Animals to be sent to mountain pastures.</p>	<p>Trivalent OAC (BHK) cattle 5 ml Sheep 3 ml (1)</p> <p>Animals for export vaccine charge 15 A.S.</p>	<p>Per type two groups of cattle (undil. and 1:4 dilution) are challenged intradermally with 10.000 ID₅₀</p> <p>Maximum number of generalizations admitted: 2</p>
Belgium	<p>All cattle above three months of age.</p> <p>The maximal interval between 2 consecutive vaccinations is 13 months.</p> <p><u>1985</u></p> <p>Cattle: 2 492 147</p> <p><u>1986</u></p> <p>Cattle: 2 401 141</p>	<p>From 1 Dec. to 31 March</p>	<p><u>the entire country since 1962</u></p>	<p>Triv. (0₁/A₅/C1) cattle: 10⁵ cc</p> <p>25 B. Fr. (2)</p> <p>Frenkel vaccine (sheep not vaccinated)</p>	<p>At least 5 cattle PD₅₀ the challenge being 10 000 ID₅₀ intradermally.</p>

Note: (1) vaccine and vaccination free of charge to owner
(2) provided by owners

Country	VACCINATION PROGRAMMES			VACCINES	
	Species vaccinated	Period of vaccination	Territory covered by vaccination	Valencies Cattle dose/cost	Potency required and results
Bulgaria	Cattle and sheep above 3 months <u>1985</u> Cattle: 183 000 <u>1986</u> Cattle: 200 646	Spring March/April	30 Km buffer zone along frontiers with Turkey and Greece and at frontier posts.	Triv 0 ₁ /A ₂₂ /ASIA-1 Provided through FAO	European Pharmacopoeia standards. Results satisfactory
Cyprus	No vaccination was carried out in 1985 and 1986				
Czechoslovakia	A. All cattle above 3 months Adult sheep, goats and pigs <u>1985</u> Cattle: 4 892 627 Sheep : 792 195 Pigs : 1 051 951 <u>1986</u> Cattle: 4 768 500 Sheep: 75 500 Goats: 25 000 Pigs: 990 000	During the whole year	<u>The entire country</u>	Trivalent OAC	Five cattle per type are challenged by rubbing a virus suspension on the tongue. One generalization tolerated.

Country	VACCINATION PROGRAMMES			VACCINES	
	Species vaccinated	Period of vaccination	Territory covered by vaccination	Valencies Cattle dose/cost	Potency required and results
Denmark	Total prohibition of vaccination as of 1 January 1977				
Finland	No vaccination				
France	<p>A. All cattle above 4 months</p> <p>B. All sheep and goats above 3 months</p> <p style="text-align: center;"><u>1985</u></p> <p>Cattle: 20 000 000 Sheep/goats: 700 000</p> <p style="text-align: center;"><u>1986</u></p> <p>Cattle: 20 000 000 Sheep/goats: 700 000</p>	<p>All year round</p> <p>Before transhumance</p>	<p>A. The <u>entire country</u> with the exception of Finistère</p> <p>B. The frontier departments of the Pyrennees Alpes de Hautes Provence, Hautes Alpes and Alpes MARITIMES</p>	<p>Trivalent OAC (1) (A Allier 1960 O Lausanne 1965 C Vosges 1960)</p> <p>Cattle 5 cc Sheep 2 cc</p> <p>Price: (triv. dose) 4.30 F.F. (Frankel) 3.80 F.F. (B.H.K.)</p>	<p>Principle: 85% protection rate in cattle against generalization by intradermolingual challenge</p> <p>Methods and minimums Index K (Lucan) = 1.2 Index C = 10² Index S = 10¹</p> <p>Vaccine used in France controlled by the L.N.P.B. Lyons</p>
Germany, Federal Republic of	<p>All cattle above four months</p> <p style="text-align: center;"><u>1985</u></p> <p>Same policy</p> <p style="text-align: center;"><u>1986</u></p> <p>Cattle: 13 000 000</p>	<p>Late in winter before going to pasture</p>	<p><u>The entire country</u> since 1965</p>	<p>Trivalent OAC (0₁/A₅/C) Dose: 5 cc Cost: DM 3.- (2)</p>	<p>Three cattle per type are challenged by rubbing a virus suspension on the tongue. No generalization admitted.</p>

Note: (1) associated or no with inactivated fixed rabies virus

(2) in some "Lander" vaccination is free of charge, in others the owner is charged 50% of cost

Country	VACCINATION PROGRAMMES			VACCINES	
	Species vaccinated	Period of vaccination	Territory covered by vaccination	Valencies Cattle dose/cost	Potency required and results
Greece	<p>Cattle, sheep and goats above 3 months of age</p> <p style="text-align: center;"><u>1985</u></p> <p>Cattle: 19 581 Sheep/goats: 67 126 Pigs: 215</p> <p style="text-align: center;"><u>1986</u></p> <p>Cattle: 14 875 Sheep/goats: 49 048</p>	Spring campaigns March/April	Frontier areas in Greek Thrace Buffer zone areas (84/548 EEC)	Trivalent 0 ₁ /A ₂₂ /ASIA-1) provided through FAO	<p>European Pharmacopoeia standards. Results satisfactory</p> <p><u>Vaccine production in FMD Lab. Athens.</u></p> <p>Conventional European strains. Stock reserve.</p>
Hungary	<p>Cattle and sheep above 2 months of age. Pigs not vaccinated.</p> <p style="text-align: center;"><u>1985</u></p> <p>Cattle: 477 000 Sheep : 1 080 000</p> <p style="text-align: center;"><u>1986</u></p> <p>Cattle: 467 500 Sheep: 239 800</p>	Two programmes: Spring and Autumn	Eastern border provinces	Trivalent OAC (1) Cattle dose: 5cc sheep dose : 3cc	
Iceland	No vaccintaion				
Ireland	No vaccination				

Note: (1) Vaccine and vaccination free of charge to owner

VACCINATION PROGRAMMES				VACCINES	
Country	Species vaccinated	Period of vaccination	Territory covered by vaccination	Valencies Cattle dose/cost	Potency required and results
Italy	A. All cattle above 3 months	A. From 1 October to 31 January	The entire country since 1968	Trivalent OAC (O ₁ /A ₅ /C) (1)	8 PD ₅₀ measured on cattle (3 groups of 5 cattle per valence - dilution 1:1; 1:4; 1:16 in <u>buffer</u>)
	B. Cattle, sheep and goats sent to alpine pastures	B. From 1 April to 30 June	Sheep and goats: the entire territory of Sicily	5 cc Cost: Lit. 480 per Triv. dose	
	<p><u>1985</u></p> <p>Cattle: 9 000 000 Sheep/goats: 2 800 000</p> <p>Sheep and goats over 3 months prior to transfer to mountain pastures</p> <p>Cattle not previously vaccinated which have attained 3 months of age</p> <p>Cattle which have only been vaccinated once</p> <p>All imported cattle</p> <p>Under special licence from the Ministry of Health vaccination of sheep and goats under 3 months when necessary of prophylaxis</p> <p>All pigs present in the surveillance and protected area</p> <p><u>1986</u></p> <p>Cattle: 9 000 000 Sheep/goats: 2 300 000 Pigs: 3 000 000</p>	<p>Emergency vaccination in affected provinces of all susceptible animals. Oil adjuvant type C vaccine for pigs.</p> <p>from</p> <p>1 April</p> <p>to</p> <p>30 June</p> <p>from 1 October to 30 September</p>		<p>Trivalent A₅, O₁, C₁</p> <p>A₅ Parma/62 O₁ Swiss/65 C₁ Brescia/64 5 cc Lit. 580 + Iva</p> <p>Monovalent in oil adjuvants: C₁ Brescia/64, A₅ Parma/82</p>	Vaccine for pigs should contain a quantity of FMD virus not lower than the minimal quantity of FMD virus with a bovine potency equal to 2 PD 50

Note: (1) vaccine and vaccination programme paid by Government

Country	VACCINATION PROGRAMMES			VACCINES	
	Species vaccinated	Period of vaccination	Territory covered by vaccination	Valencies Cattle dose/cost	Potency required and results
Luxembourg	All cattle above three months of age <u>1985</u> Cattle: 194 000 <u>1986</u> Cattle: 194 000	From 1 Dec. to 31 January.	<u>the entire country</u> since 1966	Trivalent OAC (O ₁ /A ₅ /C1) Cattle 5 cc Price 17 B. Fr. (1)	More than 7 cattle PD ₅₀ challenge being 10 000 ID ₅₀ intradermolingually.
Malta	Cattle, sheep and goats. <u>1985</u> Cattle: 10 586 Sheep 378 Goats: ---- <u>1986</u> Cattle: 11 116 Sheep 433 Goats: 4 122	Winter and Spring	entire country since 1978/79	OAC vaccine (Italy)	8 PD ₅₀ measured on cattle (3 groups of 5 cattle per valence - dilution 1:1: 1:4: 1:16 in <u>buffer</u>)

Note: (1) vaccine free of charge; vaccination cost 17 B.Fr. shared by the State (7 B.Fr.) and owner (10 B.Fr.)

Country	VACCINATION PROGRAMMES			VACCINES	
	Species vaccinated	Period of vaccination	Territory covered by vaccination	Valencies Cattle dose/cost	Potency required and results
Netherlands	All cattle above four months OAC vaccines <u>1985</u> Cattle: 4 200 000 <u>1986</u> Cattle: 4 000 000	From 1st Dec. to 1st March	<u>The entire country since 1953</u>	Triv. 0 ₁ /A ₁₀ /C (Frenkel) Vaccine plus injections: D. Fl. 5.5 (1) (5 cc)	At least 10 cattle PD ₅₀ . Resistance to generalization after intradermolingual challenge with 10 000 cattle PD ₅₀ . PD ₅₀ are calculated from three groups of 5 cattle
Norway	No vaccination				
Poland	No vaccination				
Portugal	Cattle: above 3 months Sheep/goats: above 3 months Pigs: above 3 months <u>1985</u> Cattle: 612 652 Pigs: 129 685 Sheep/goats: 3 513 <u>1986</u> Cattle: 584 550 Pigs: 101 587 Sheep/goats: 320	Once a year, when necessary twice a year	<u>The entire country</u>	Trivalent OAC Average 30 escudo per dose for cattle and 31 escudo for pigs	More than 3 PD ₅₀ per cattle dose

Note: (1) vaccine and vaccination costs borne by owner 50%

Country	VACCINATION PROGRAMMES			VACCINES	
	Species vaccinated	Period of vaccination	Territory covered by vaccination	Valencies Cattle dose/cost	Potency required and results
Spain	<p>A. All cattle above 4 months. Sheep and goats destined for transport.</p> <p>B. Pigs: compulsory for breeding stock. In case of outbreak all pigs.</p> <p style="text-align: center;"><u>1985</u></p> <p>Cattle: 4 037 000 Sheep: 4 000 000 Pigs: 4 917 000</p> <p style="text-align: center;"><u>1986</u></p> <p>Cattle: 3 100 000 Sheep: 7 200 000 Pigs: 5 200 000</p>	<p>A. Spring (and autumn) in border provinces.</p> <p>B. Twice yearly for breeding animals.</p>	<p><u>The entire country</u> for cattle & pigs sheep and goats</p>	<p>A. Trivalent OAC 35 Pst. per dose (1)</p>	<p>Potency testing based on the cattle PD₅₀ determination has been started, as reference. Routine: 2 vaccinated animals are challenged against field strains; both must remain protected. Results: very successful in pigs.</p>

Note: (1) The cost of vaccine free of charge for cattle and 50% in pigs and fattening cattle; vaccination paid by owner

Country	VACCINATION PROGRAMMES			VACCINES	
	Species vaccinated	Period of vaccination	Territory covered by vaccination	Valencies Cattle dose/cost	Potency required and results
Sweden	No vaccination				
Switzerland	All cattle born before 1 Jan. <u>1985</u> Cattle: 1 600 000 <u>1986</u> Cattle: 1 600 000	From 15 Feb. to 15 May Compulsory annual vaccination of all cattle born before January	<u>The entire country since 1966</u>	Trivalent OAC cost of vaccine SF. 1.6 (1) cost of injection SF. 1.7	Vaccines almost entirely imported from France

Country	VACCINATION PROGRAMMES			VACCINES	
	Species vaccinated	Period of vaccination	Territory covered by vaccination	Valencies Cattle dose/cost	Potency required and results
Turkey	Cattle, buffaloes, sheep and goats above 4 months of age	March in buffer zones ring vaccination all year round.	A. Turkish Thrace including Istanbul and Celibolu	0 ₁ /A ₂₂ /ASIA-1	9 cattle per batch (3 cattle per type are challenged intradermally; 6 controls).
	<u>1985</u>	Autumn - young stock in Thrace buffer zones	B. Frontier areas in eastern and southern Anatolia		Good results
	Cattle: 2 052 433 Sheep : 3 176 360 Pigs : 650		C. State and dairy farms, feedlots and other exposed areas		
	<u>1986</u>	Cattle: every six months	Thrace	0 ₁ /A ₂₂ /ASIA-1 Trivalent vaccine (FAO and local)	
	Cattle: 2 393 366 Sheep: 3 001 714 Pigs: -----	Sheep: once a year	Thrace		
		Cattle: every six months	20 km along eastern and south-eastern borders of Turkey (Anatolia)	0 ₁ /A ₂₂ Bivalent vaccine	
	Cattle: every six months	Government farms in Anatolia	0 ₁ /A ₂₂ /ASIA-1 Trivalent vaccine		
	Ring vaccination around the foci	Anatolia	0 ₁ /A ₂₂ Bivalent vaccine		

Country	VACCINATION PROGRAMMES			VACCINES	
	Species vaccinated	Period of vaccination	Territory covered by vaccination	Valencies Cattle dose/cost	Potency required and results
Yugoslavia	Cattle for export above 7 months <u>1985</u> Cattle: 97 781 <u>1986</u> Cattle: 40 637 Sheep: 18 462 Goats: 4 055	October 48 706 cattle exported during 1986 were vaccinated with same vaccine	Communes bordering on Italy	Trivalent OAC 5 ml doses	

NON-MEMBER COUNTRIES OF THE EUFMD

Democratic Republic of Germany	All cattle above 5 months <u>1985</u> Same policy <u>1986</u>	From 1 Oct. to 31 Dec.	<u>The entire country</u> since 1950	Trivalent OAC Dose 5 ml	
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Country	VACCINATION PROGRAMMES			VACCINES	
	Species vaccinated	Period of vaccination	Territory covered by vaccination	Valencies Cattle dose/cost	Potency required and results
Romania	Cattle and sheep above 6 months <u>1985</u> Cattle: 1 656 300 Sheep : 1 088 760 Pigs : 20 300 <u>1986</u> Cattle: 2 100 000 Sheep: 1 440 000	Twice a year (6 months inter- val); young cattle are revaccinated after 15-21 days	Frontier districts in the West. Frontier areas in the South and Southeast. Around sea and river ports and international airports	Monovalent vaccines produced against O ₁ , C, A ₅ . Cost per dose 13.54 lei.	The ordinary monovalent dose must contain 8 cattle PD ₅₀ . Current potency 18 PD ₅₀ /dose
U.S.S.R.	Cattle above 4 months Sheep and goats above 1 month, pigs above 2 months <u>1985</u> Cattle: 140 522 149 Sheep: 49 133 218 Pigs: 2 850 585 <u>1986</u> Cattle: 128 820 800 Sheep: 76 410 900 Pigs: 2 183 500	Early Spring and Autumn Compulsory slaughter is performed if foot-and-mouth disease occurs for the first time in a district previously free from the disease. The carcasses are destroyed. The products obtained from the animals, slaughtered within 3 months after recovery are used with restrictions. These restrictions are also applied to the animals having been exposed to contact within 3 months prior to slaughter. The number of the animals slaughtered under these provisions is not registered.	Republic of Transcaucasus Kazakhstan, Middle Asia with bordering regions of RSFSR and Ukraine	Mainly monovalent and trivalent vaccines. Cattle dose: 5 cc monovalent: 9 Kopecks trivalent 27 Kopecks	Required duration of immunity: 6 months

FMD situation in Italy

Introduction

After three years of freedom from FMD (last outbreak was reported in 1981) since November 1984 Italy has suffered a serious and widespread epizootic affecting a number of provinces in the entire country.

A₅ epizootic - 26 November 1984 to 31 August 1985

The first outbreak occurred on 26 November 1984 on a cattle farm in the town of San Prospero in the province of Modena. The herd was composed of 22 cows, 1 bull, 14 calves and 11 cattle out of which only one head of cattle and one bull were affected. Following the primary outbreak, the disease spread rapidly in the province of Modena, and to the adjacent provinces of Reggio Emilia and Bologna and subsequently to a number of provinces in the entire country, involving mainly cattle and pigs. The epizootic lasted until 31 August 1985, causing 154 outbreaks in cattle and pigs in 14 regions and 29 provinces. The most affected regions were Emilia Romagna, Lombardia, and Campania in southern Italy.

C₁ epizootic - 27 November 1985 to 23 April 1986

From the end of August to 27 November 1985 no outbreaks were reported in Italy and it was hoped that the disease situation had returned to normal. However, this disease silence was broken by a new epizootic, this time of virus type C₁ in pigs occurring on 27 November 1985 in the town of Campogalliano in the province of Modena. The disease, suspected on 18 November 1985, was confirmed on 27 November 1985. It spread rapidly within the province of Modena and to the adjacent provinces and subsequently to other provinces, involving pigs and cattle at a long distance from the primary outbreak in Modena. Seven regions and 16 provinces were affected with 68 outbreaks reported mainly in pigs where large holdings were infected.

A₅ epizootic - 5 June 1986 to 31 December 1986

A flare-up of the disease caused by the reappearance of type A₅ virus was reported on 5 June 1986 in the town of Borgo Forte in the province of Mantova on a farm of 4 267 pigs out of which 360 were infected. This epizootic followed the same pattern as the previous A₅ and C₁ epizootics involving pigs and cattle in a number of provinces in the entire country. The total number of outbreaks reported from 5 June 1986 to 31 December 1986, was 100 with 60 outbreaks in cattle and 40 in pigs. Although the number of outbreaks in pigs is smaller than in cattle, the number of pigs involved in this outbreak is superior due to the fact that most of the outbreaks occurred in large holdings.

During this epizootic, an outbreak of type O₁ was reported in cattle in the province of Perugia on 13 June 1986. Details on the disease evolution and number of animals involved, infected, slaughtered, died are given in Tables 1 and 2 and 3.

Disease diagnosis and virus identification

The laboratory confirmation of a suspected outbreak was carried out at the Regional Zooprophyllactic Institutes but in all cases this was confirmed by the National Reference FMD Laboratory at the Brescia Institute. Samples were also sent to the World Reference Laboratory, Pirbright, UK, for further investigation of the isolates.

The laboratory investigation carried out at the Brescia FMD Institute and at WRL, Pirbright showed that:-

- The type A₅ epizootics 1984-1985 and 1986 were identical to the vaccine virus strain A₅ Parma/62.
- The C₁ virus 1985/1986 epizootic was identical to the C₁ Brescia/64 vaccine virus strain and very different from C Argentina/84, C₁ Noville and C₃ Resende.
- The type O₁ isolate from Perugia (June 1986) was very similar to O₁ Swiss/65 (O₁ Lausanne) but different from O₁ BFS/67 and O₂ Brescia vaccine virus strain.

Immunological trials carried out in cattle vaccinated with O₁/A₅/C₁ trivalent vaccine and challenged with homologous A₅ Parma/62 virus and the new isolate A₅ Modena/84 virus showed a PB50 identical for both challenge viruses. This confirmed the suitability and efficacy of the Italian A₅ Parma/62 vaccine strain against the A₅ Modena/84 isolate.

The epizootiological investigations carried out by the Veterinary Services and the National Reference FMD Laboratory in Brescia have not shown any evidence as to the origin of the disease. Probang test carried out in imported cattle before the outbreak in Modena in 1984 resulted negative. However, an in-depth epizootiological investigation of the origin of the first outbreak reported during the three epizootics A₅, C₁, A₅ and the isolated O₁ outbreak has not been carried out by the Italian Veterinary Services and therefore the origin of the disease remains unknown.

Sanitary measures applied

The sanitary measures applied, including total or partial stamping out of animals in infected premises as well as ring vaccination of pigs within and around the outbreak, did not succeed in containing the disease at the primary outbreak. The problems encountered with the control of the A₅ epizootic in 1984-1985 were repeated again with the C₁ epizootic 1985-1986 and the reappearance of A₅ epizootic occurring since June 1986. This is the evidence that the sanitary control measures applied in the affected provinces were not sufficiently effective to prevent spread of the FMD virus to other regions. The reasons for this are closely indicated in the Report of the FAO/EUFMD Mission to Italy from 6-10 October 1986. The problems experienced by the Italian Veterinary Services in the control of the FMD situation, i.e. the conditions for a stamping-out of infected, in-contact and suspected, and remaining animals on infected premises, should be a matter for study by the Commission. (See Tables 1 and 2).

Vaccination policy

Following the Sanitary Reform of 1978 responsibility for the implementation of the vaccination programme carried out by the Central Veterinary Services from November to January was given to the regions.

This change caused some discontinuity in the implementation of the national norms for prophylaxis against FMD. This became more evident during the FMD epizootics in Italy where the regional and local sanitary authorities were experiencing difficulties in the application of effective prophylactic and control sanitary measures adequate to the cases. Despite the official confirmation of the number of animals vaccinated during the annual campaign and the emergency vaccination carried out in the affected provinces, the spread of FMD among vaccinated animals shows that the vaccination programme had not been properly implemented. Italy is a major importer of live animals. Despite the existing regulations on animal movement, imported animals had not been properly controlled and vaccinated on arrival, and having contracted the disease, were transferred to other regions and acted as carriers.

The two outbreaks reported on 24 January 1987 on heifer farms in the province of Modena and in the province of Cremona concerned animals which should have been vaccinated during the vaccination campaign (October-November 1986) and consequently protected against the current FMD virus occurring in Italy. Twenty seven out of 105 heifers present in the outbreak of Modena were infected while in the Cremona outbreak four heifers out of 161 were infected.

The official confirmation that the cattle population was vaccinated during the annual campaign and the emergency vaccination campaign carried out in the affected areas cannot be supported by the experts which show that disease spread among animals which should have been protected by vaccination.

The prophylaxis and control vaccination programme carried out in Italy during 1985 and 1986 is shown under Appendix 3.

Action taken by the Commission

The FMD situation in Italy was discussed at various Sessions of the FAO European Commission for the Control of Foot-and-Mouth Disease and it was closely followed by the Secretary. The action taken in assisting Italy to face the FMD situation was as follows:-

- At the request of the Italian Veterinary Services an ad hoc meeting of the Executive Committee was held on the occasion of the OIE Regional Commission for Europe held in Berlin in September 1986.
- An FAO/EUFMD mission visited Italy from 6 to 10 October 1986 to review/discuss the FMD situation.
- The mission Report was formally presented to the Director General of the Italian Veterinary Services at the Ministry of Health in Rome on 10 November 1986.
- The Secretary of the Commission presented the mission report in five meetings held at regional levels in Italy from 29 November to 12 December 1986.

- In addition to problems related to proper vaccination of animals of different ages, the factor of an immuno depressive effect of certain drugs or other vaccines used in intensive large livestock units and in imported young stock needs to be studied.
- An in-depth study of the FMD situation in Italy was carried out by three qualified experts from the Commission, with specific terms of reference, i.e. Dr. J.G van Bekkum, Netherlands (Chairman, Research Group) for FMD laboratories, vaccine production and control, from 19 to 27 January 1987, Dr. A. Donaldson, AVRI, Pirbright, UK for epidemiological investigation and Dr. G. Davies, Ministry of Agriculture, Fisheries and Food, UK, for cost benefit analysis of total/partial stamping out policy and sanitary measures applied in Italy, from 6 to 21 February 1987.

The collaboration and assistance provided by the Director General of the Italian Veterinary Services and the regional veterinary authorities for the successful implementation of the EUFMD missions in Italy was greatly appreciated.

Table 1

Cumulative data on FMD epizootics in Italy
from 26 November 1984 to 31 December 1986*

Place of first outbreak Duration of epizootic	Number of outbreaks - Virus type	Number of out- breaks per species of animals	Animals present in infected farms	Animals infected	Animals slaughtered	Deaths	Compensation paid to owners (x 000 I.it.)
<u>Modena</u> - 26.11.84 to 31.8.85	154 - A ₅	C: 139 S: 11 (C/S): 3 Sh: 1	C: 16 069 S: 28 071 Sh: 1 588	C: 2 173 S: 2 810 Sh: 642	C: 2 548 S: 8 114 Sh: 957	C: 12 S: 43 Sh: --	1 315 957
<u>Modena</u> - 27.11.85 to 23.4.86	69 - C ₁	C: 18 S: 51 Sh: --	C: 543 S: 114 916 Sh: 26	C: 50 S: 6 021 Sh: --	C: 80 S: 35 248 Sh: 18	C: 1 S: 472 Sh: --	5 556 057
<u>Mantova</u> - 5.6.86 to 31.12.86	100 - A ₅	C: 60 S: 40 Sh: --	C: 11 124 S: 179 471 Sh: 22	C: 396 S: 4 868 Sh: --	C: 1 769 S: 53 744 Sh: --	C: 4 S: 115 Sh: --	12 000 843
<u>Perugia</u> - 13.6.86	1 - O ₁	C: 1	C: 129	C: 11	C: 10	C: 1	
TOTAL	324	C: 218 S: 102 (C/S): 3 Sh: 1	C: 27 865 S: 322 458 Sh: 1 636	C: 2 630 S: 13 699 Sh: 642	C: 4 407 S: 97 156 Sh: 975	C: 18 S: 680 Sh: --	18 871 857

* Data provided by the Director-General of Veterinary Services, Italy

C - Cattle

S - Swine

Sh - Sheep

Table 2

FMD situation in Italy
(Regions and provinces affected from 1984 to 1986)

Region	Province	A ₅ epizootic 26.11.84 to 31.8.85	C ₁ epizootic 27.11.85 to 23.4.86	A ₅ epizootic 5.6.86 to 31.12.86
Emilia Romagna	Modena	+	+	+
	Reggio Emilia	+	+	+
	Bologna	+	+	-
	Ravenna	+	+	+
	Ferrara	+	+	-
	Forli	-	+	+
	Parma	-		+
Lombardia	Mantova	+	+	+
	Brescia	+	-	+
	Cremona	+	-	+
	Milan**	+	-	+
	Bergamo	-	-	+
Veneto	Verona	+	+	+
	Rovigo	-	+	-
	Padova	-	-	+
	Venezia	-	-	+
	Vicenza	-	-	+
Piemonte	Cuneo	+	-	+
	Torino	-	-	+
	Allessandria	-	-	+
Trento	Trento	+	-	-
Friuli	Pordenone	-	-	+
	Udine	-	-	+
Toscana	Florence	+	-	-
	Massa Carrara	+	-	-
	Pistoia	+	-	-
	Arezzo	-	-	+
Umbria	Perugia*	+	-	+
Lazio	Rieti	+	-	-
Abruzzo	Campobasso	+	-	-
Campania	Naples	+	+	-
	Avellino	+	+	-
	Benevento	+	+	+
	Caserta	+	-	-
	Salerno	+	+	-
Puglia	Bari	+	+	-
	Foggia	+	-	-
	Taranto	+	-	-
Calabria	Catanzaro	+	-	-
	Cosenza	+	+	+
Sicily	Ragusa	+	-	-
Total		154	69	101

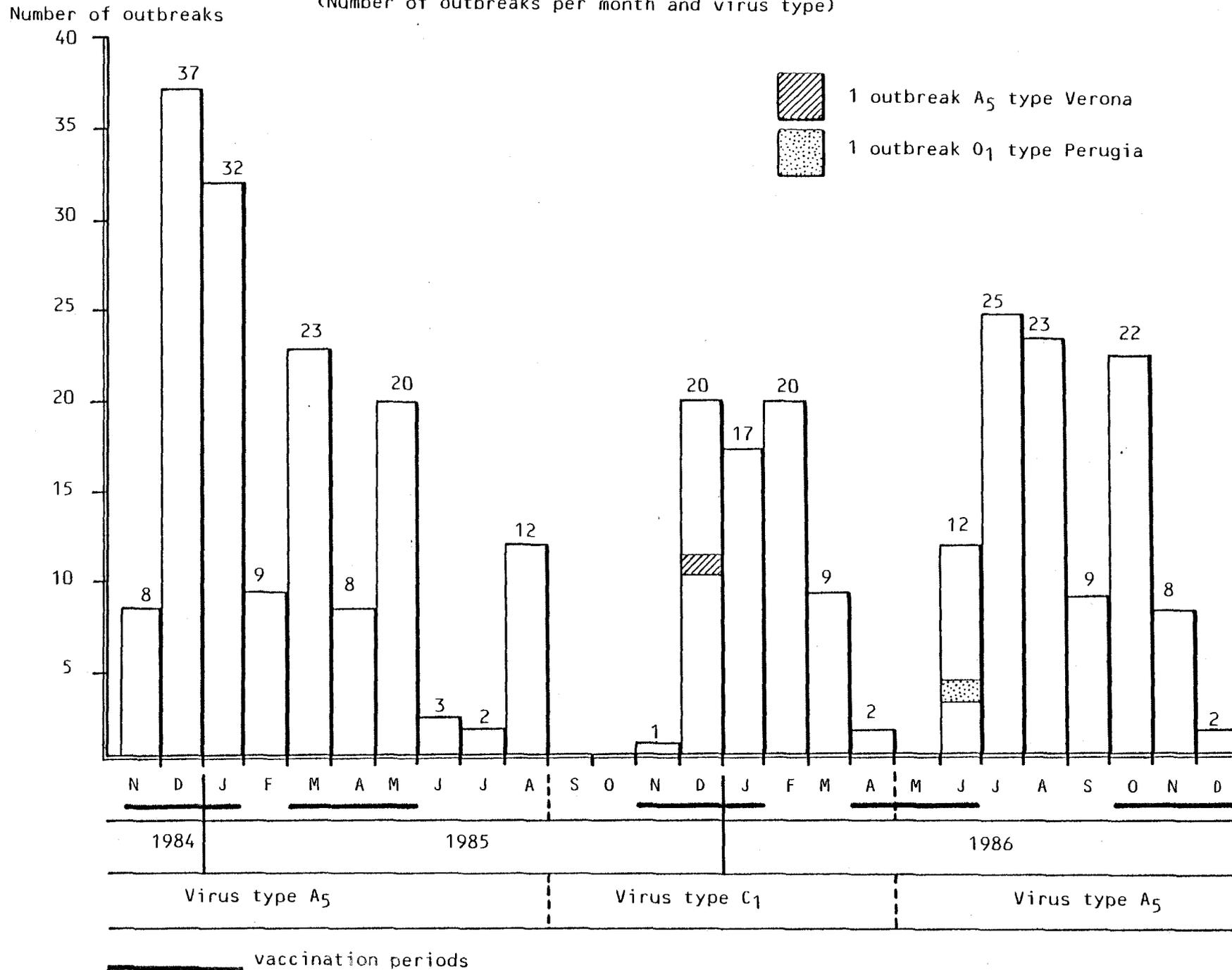
+ outbreak

- no outbreak

* outbreak type O₁

** outbreaks reported in January 1987

EVOLUTION OF FMD IN ITALY - from November 1984 to December 1986
 (Number of outbreaks per month and virus type)



Report on Mission to Review and Advise on the Foot-and-Mouth
Disease Situation in Italy 6 - 10 October 1986

CONCLUSIONS

RECOMMENDATIONS

- I. INTRODUCTION
- II. VISIT TO THE DIRECTOR GENERAL OF VETERINARY SERVICES, MINISTRY OF HEALTH, ROME, 6 OCTOBER 1986
- III. FIELD VISITS
- IV. FINDINGS OF THE MISSION
 1. Organization of the Veterinary Services in Italy
 2. Identification of Foot-and-Mouth Disease
 3. Eradication policy applied
 4. Epizootiological investigations
 5. Vaccine and vaccination
 6. Movement of animals

Acknowledgements

CONCLUSIONS

The Mission, having reviewed and examined all data obtained concluded that among the main reasons for the persistence of the FMD epizootics in Italy since November 1984, the following are of note:

- 1) Relaxation of vigilance and prophylaxis against foot-and-mouth disease because of the favourable disease situation in the period prior to the present epizootic.
- 2) High percentage of susceptible animals inadequately protected against foot-and-mouth disease despite official confirmation that the total cattle population (9 million head) had been vaccinated during the compulsory annual vaccination (November-January) 1984-85.
- 3) Vaccination not applied according to standard methods. Automatic guns/vaccination in different parts of the body used instead of the traditional method of vaccination previously in use which guaranteed prophylactic vaccination against FMD in a high percentage of the cattle population.
- 4) Possibility of incorrect shelf conservation of vaccine by the vaccinators which could have compromised its efficacy.
- 5) Delays in the implementation of the annual vaccination campaigns attributed to the non-availability of the vaccine on time in the field and to the uncontrolled use of the vaccine during the campaigns.
- 6) Stamping out policies, disinfection and sanitary measures not effectively applied to the infected and restricted areas.
- 7) Delays in payment of compensation to farmers for stamping out of animals. As a consequence of this, cooperation of farmers with the Veterinary Authorities responsible for the control of FMD had been unsatisfactory and farmers were reluctant to notify new outbreaks.
- 8) Lack of effective epizootiological investigation in the field and relaxation of sanitary vigilance by the authorities concerned resulted in some outbreaks being detected only following identification of the disease during veterinary inspection in the slaughter houses.
- 9) The sanitary measures applied with respect to animal movement and transport were not effectively implemented. Therefore animal movement from infected areas, means of transport and persons have been factors of major importance in the spread of the disease.
- 10) Following the Riforma Sanitaria, events show that the Regions and the respective USLs were not equipped to cope with the responsibilities entrusted to them. The result of such a situation is reflected in the persistence of FMD on the national territory.

Although the places visited by the Mission were limited to the most affected Regions of Emilia Romagna, to the Istituto Zooprofilattico Sperimentale della Lombardia e dell'Emilia in Brescia, and to the Istituto Zooprofilattico Sperimentale delle Venezie in Padova, this was sufficient for them to form an opinion of the FMD situation in Italy, to reach conclusions based on their findings, and to make recommendations accordingly.

The Mission is confident that the Italian Government will give due consideration to these recommendations.

RECOMMENDATIONS

1. Organization of the Veterinary Services in Italy

- It is essential that the animal health control policy be coordinated between the USLs within a Region, and between the Regions.
- A Central Unit should be set up to supervise activities at USL/Regional level.
- In case of an emergency at national level, coordination of action should be the responsibility of one Central National Veterinary Authority.

2. Identification of Foot-and-Mouth Disease

- The veterinary staff of the USL should be encouraged to submit material of all vesicular diseases to the laboratory concerned with FMD diagnosis.
- Good cooperation between the farmers and the veterinary staff of the USL is a prerequisite for rapid identification and notification of an outbreak of FMD and wherever possible should be improved.
- The National Reference Laboratory at Brescia should standardize the FMD diagnostic methods in order to harmonize diagnostic procedures in all national laboratories concerned with FMD diagnosis.
- In the near future when standardized ELISA techniques become available, these should be introduced for routine diagnosis of FMD in all laboratories concerned in the country.
- In view of the variable clinical picture of FMD in cattle as well as in swine, the veterinary staff of the USLs throughout Italy should be given the opportunity to attend courses on the clinical diagnosis of FMD, including epizootiological investigations, submission of specimens, and action to be taken in suspected cases pending laboratory confirmation.
- Biochemical studies to characterize outbreak strains should be regularly undertaken.

3. Eradication policy applied

- The stamping out policy should be strictly applied to all susceptible animals on the affected premises and at the primary outbreaks notwithstanding the size of the livestock unit infected, its structure and management.
- Vaccination on infected premises especially of pigs should be given careful consideration since the question of carriers before or following vaccination has not yet been clarified.
- Control of movement of animals and transport vehicles in restricted areas should be more effective and sound procedures in this respect should be established. Cooperation of other government bodies is essential.
- Disinfection of infected premises, cleansing and disinfection of means of transport, and clothing of persons involved in the infected premises, should be carefully implemented.

- The definition of infected and restricted areas should be clearly indicated and the quarantine measures applied to these areas should be strictly observed.

4. Epizootiological investigations

- Serum samples and probang samples should be collected from as many animals on an infected premise as is practicable and from a sample of animals on farms surrounding an infected premise. These animals should be clinically examined and the age of FMD lesions estimated.
- Questionnaires should be available to all veterinary staff investigating FMD outbreaks. These questionnaires should be standard for all regions and be prepared by an epidemiologist experienced in the investigation of FMD outbreaks.
- Possible contacts with the infected premises must be thoroughly investigated. If this involves premises in different regions the investigations should be coordinated by national authority.
- A Task Force should be set up at national level to cope with emergency animal disease situations especially FMD.
- Standard procedures for epizootiological investigations should be set up.
- Seminars on simulation exercises on emergency FMD outbreaks should be organized at regional levels in order to check the preparedness of the Veterinary Services to face emergency FMD situations.

5. Vaccine and vaccination

- Aziridin compounds should be used to replace formalin as an inactivant for FMD vaccine. This procedure would allow for innocuity testing of the inactivated virus prior to adsorption.
- More consideration should be given to prophylactic measures other than vaccination.
- Vaccine production methods, vaccine formulation, potency and innocuity controls should be harmonized. The same challenge virus strain should be used in the official controls for all vaccines produced in the country.
- All laboratories should be equipped with adequate disease security systems.
- Vaccine supply by the producing laboratories should be coordinated to ensure timely delivery to the field. Synchronization and monitoring of the vaccination programme was considered to be essential.

6. Movement of animals

- Strict control of all means of animal transport should be enforced; the cooperation of the police and other government services concerned should be strengthened.
- Operation of trade markets and fairs should be authorized with care and the origin and destination of animals from these places should be monitored and recorded.
- All movement of animals should be registered.

I. INTRODUCTION

On 13 September 1986, the Director-General of Veterinary Services in Italy, addressed a telex to the European Commission for the Control of Foot-and-Mouth Disease (EUFMD) requesting that a group of experts from member countries of the Commission visit Italy to examine the FMD situation which had persisted on the national territory since November 1984.

This request was discussed at an ad hoc meeting of the Executive Committee of the EUFMD held on 17 September 1986 during the 12th OIE Regional Conference for Europe which was held in Berlin, GDR, from 16 to 19 September. At this meeting the Executive Committee decided that a Mission should visit Italy from 6 to 10 October 1986 to investigate the FMD situation and make appropriate recommendations to the Government.

The Secretary of the EUFMD was instructed to make the necessary arrangements for the implementation of the Mission and subsequently to arrange for the Executive Committee to present the findings of the Commission to the Government at an ad hoc meeting to be convened at the Ministry of Health in Rome as soon as possible following the Mission.

The Mission was composed of:

Dr. F. Walla, Director of Veterinary Services, Austria
Dr. P. Gafner, Director of Veterinary Services, Switzerland
Dr. J. Westergaard, Head of Division, State Veterinary Service, Denmark
Prof. R. Ahl, Federal Research Institute for Animal Virus Diseases, Tübingen, FRG
Dr. R.P. Kitching, Animal Virus Research Institute, Pirbright, UK
Dr. P. Stouraitis, Secretary, EUFMD, FAO, Rome

During the four-day field trip the Mission was accompanied by Dr. F. Fabbrovich from the Directorate of Veterinary Services in the Ministry of Health.

The itinerary of the Mission was as follows:

- 1) Preliminary discussions with the Director General of Veterinary Services, Ministry of Health, Rome
- 2) Field visit to the region of Emilia Romagna
- 3) Visit to the Istituto Zooprofilattico Sperimentale delle Venezie, Padova
- 4) Final discussions/conclusions/recommendations at the Istituto Zooprofilattico Sperimentale della Lombardia e dell'Emilia, Brescia

II. VISIT TO THE DIRECTOR GENERAL OF VETERINARY SERVICES, MINISTRY OF HEALTH, ROME, 6 OCTOBER 1986

The Director General of Veterinary Services briefly outlined the history of FMD in Italy since 1951 and provided information on the FMD epizootics which had occurred on the national territory since November 1984.

The following significant points emerged:

- 1) In 1978 a Riforma Sanitaria modified the structure of the organization of the Veterinary Services.

- 2) Following the Riforma Sanitaria, responsibility for control and eradication of FMD was delegated to the Regions.
- 3) Control and implementation of the vaccination campaigns was delegated to the Regions.
- 4) The Ministry of Health limited itself to financing the provision of vaccine, providing a veterinary service at frontier areas, and compensating the breeders in case of stamping out. Control of the potency and safety of the vaccine remained the responsibility of the Ministry of Health.

The Director General of Veterinary Services pointed out that during these epizootics the disease had been characterized by:

- (a) persistence,
- (b) spread, and
- (c) dissemination over large areas.

Of note among the factors contributing to the present FMD situation were:-

- relaxation of vigilance and prophylaxis because of the favourable disease situation during the period 1981-1983,
- change in the breeding system, especially in the Po Valley, from small farms to intensive fattening lots, with animals imported from France, Federal Republic of Germany, Belgium, Denmark, Ireland and Eastern Europe,
- imported animals insufficiently protected by vaccination,
- sanitary police measures in respect of movement of imported animals not properly applied.

The Director General of Veterinary Services, in quoting the relevant figures in respect of animals slaughtered and destroyed, the mortality rate, and the situation in general stated that the number of outbreaks was insignificant but the large area involved was notable.

The action taken by the Italian authorities to control the disease was described. The Government had recently passed two Orders and one Emergency Law to strengthen the veterinary policy and the stamping out policy.

The Mission was requested inter alia to pay special attention to the following points:

- 1) efficiency and innocuity of vaccine
- 2) adequacy of one vaccination per year of cattle over four months to confer full protection
- 3) promptness and accuracy of diagnosis
- 4) emergency measures to be taken

The Director General of Veterinary Services thanked the Mission members for responding to the request for assistance by the Italian Government. He wished them success in their task and stated that his Government would give their conclusions and recommendations the highest consideration.

III. FIELD VISITS

The Mission visited the Region of Emilia Romagna where they had the opportunity to meet the regional veterinary authorities and the staff of some of the USLs (Local Sanitary Units) and other local authorities associated with prophylaxis control and eradication of FMD in the Region.

A visit was also paid to the Modena livestock market and to the organization for cleaning and disinfection in Modena.

The Mission also had the opportunity to visit an infected farm in the vicinity of Modena where the first outbreak of A₅ had occurred in June 1985 and where the stamping out policy had been applied.

Visits were made to the Istituto Zooprofilattico Sperimentale delle Venezie in Padova and to the Istituto Zooprofilattico Sperimentale della Lombardia e dell'Emilia in Brescia.

IV. FINDINGS OF THE MISSION

The Mission concentrated its attention on the following points:-

1. Organization of Veterinary Services in Italy.
2. Identification of foot-and-mouth disease
3. Eradication policy applied
4. Epizootiological investigations
5. Vaccines and vaccination
6. Movement of animals.

Findings regarded as being relevant to the six points are presented hereafter.

1. Organization of the Veterinary Services in Italy

Description

The present structure of the Veterinary Services is based on the Riforma Sanitaria of 1978. This reform delegated the authority to the Regions. Each Region has transferred this authority to the USLs within the Region. The Region is responsible for the work related to coordination and orientation of animal health programmes. Therefore, in practice the responsibility for animal health programmes lies with the USLs. In Italy there are at present 21 Regions and 670 USLs.

Observations

The Mission had the opportunity during the visit to the Region of Emilia Romagna to meet the Regional Veterinary Authorities and representatives of some of the USLs.

Following discussion, it was concluded that for effective implementation of the national animal health policy, activities of the USLs should be coordinated on a regional basis. In spite of the serious epizootic situation in the Region, (at the time of the visit a case of FMD had been detected about 20 km from the market), the Modena livestock market, which is the second largest in Europe, was in operation.

It was further noted that there was a lack of uniformity in the coordination of actions and measures adopted for an effective disease control policy both between the USLs within the Region and between Regions.

In view of the foregoing, the Mission concluded that it was extremely difficult to enforce the sanitary rules especially in the case of an emergency situation such as that existing at present.

From the information collected, it was evident that the Veterinary Services in the Regions and the USLs need to be strengthened in order to cope with all the responsibilities transferred to them following the Riforma Sanitaria.

Recommendations

- 1) It is essential that the animal health control policy be coordinated between the USLs within a Region, and between the Regions.
- 2) A Central Unit should be set up to supervise activities at USL/Regional level.
- 3) In case of an emergency at national level, coordination of action should be the responsibility of one Central National Veterinary Authority.

2. Identification of Foot-and-Mouth Disease

Description

The Mission was informed that the notification of an outbreak of FMD was in most cases by the farmer to the veterinary staff of the USL. In some cases the notification was through a private practitioner. The Veterinary Officer of the USL examines the suspect animals and collects samples for submission to the nearest Section of the Istituto Zooprofilattico for the Region concerned. The samples are either delivered by the Veterinary Officer himself or picked up by the Section for transmission to the Istituto Zooprofilattico.

All samples collected throughout the country, after a first typing at the Regional Istituti Zooprofilattici, are submitted to the National Reference Laboratory for FMD, Istituto Zooprofilattico Sperimentale della Lombardia e dell'Emilia, Brescia, for further investigation. Information and results are transmitted to the regional veterinary officer and to the Ministry of Health in Rome.

Observations

The detection of an outbreak is in most cases dependent on the notification of disease by the farmer to the USL veterinary staff, the experience of the veterinarian in FMD clinical diagnosis and the speed in delivery of the samples to the laboratory concerned for virus typing. This implies a good cooperation between the farming community and the USLs.

In the diagnosis sector the Mission was informed on the methods applied for FMD virus diagnosis at the Istituti Zooprofilattici in Padova and Brescia. The Mission considered that the methods in use at the

Institute in Brescia for field virus diagnosis and characterization are efficient and up-to-date. Results are always confirmed by the World Reference Laboratory, Pirbright, U.K. with which a good collaboration has been established.

In relation to sample collection, from suspected cases of FMD, the Mission underlined the importance of carrying this out correctly and promptly in order to guarantee maximum safety, and to avoid spread of the virus. Arrangements should be made for special delivery of the samples for diagnosis to the laboratory in special containers adequate for sample collection and dispatch. These containers should contain a buffer solution and should be readily available at all USLs.

The Mission was of the opinion that the National Reference Laboratory should have more authority to intervene on a national basis and to coordinate its activities with the other Istituti Zooprofilattici as regards methods for field sample collection and virus identification.

Recommendations

- 1) The veterinary staff of the USL should be encouraged to submit material of all vesicular diseases to the laboratory concerned with FMD diagnosis.
- 2) Good cooperation between the farmers and the veterinary staff of the USL is a prerequisite for rapid identification and notification of an outbreak of FMD and wherever possible should be improved.
- 3) The National Reference Laboratory at Brescia should standardize the FMD diagnostic methods in order to harmonize diagnostic procedures in all national laboratories concerned with FMD diagnosis.
- 4) In the near future when standardized ELISA techniques become available, these should be introduced for routine diagnosis of FMD in all laboratories concerned in the country.
- 5) In view of the variable clinical picture of FMD in cattle as well as in swine, the veterinary staff of the USLs throughout Italy should be given the opportunity to attend courses on the clinical diagnosis of FMD, including epizootiological investigations, submission of specimens, and action to be taken in suspected cases pending laboratory confirmation.
- 6) Biochemical studies to characterize outbreak strains should be regularly undertaken.

3. Eradication policy applied

Description

The strategies adopted in Italy to prevent the occurrence of FMD are based on an annual vaccination programme with a trivalent vaccine (O₁/A₂/C₁). The vaccination programme adopted for 1986 stipulates vaccination of all cattle (9 million) above the age of three months during the months of October and November (previously November-January) and vaccination during the period 1 April - 20 June of young cattle, sheep and goats sent to transhumance pastures.

In the case of an outbreak of FMD, in addition to the national regulations, the recommendations adopted by the European Commission for the Control of Foot-and-Mouth Disease and legislation adopted by the EEC outline the sanitary measures to be applied for the control and eradication of the disease.

Observations

The mission noted from discussions with veterinary authorities at central, regional, and local levels, that the stamping out policy had not been applied to all primary outbreaks occurring during 1984-1986.

Under certain circumstances total stamping out of animals had been replaced by partial stamping out of animals on infected farms. The Mission noted further that total or partial stamping out had been applied with some delay following confirmation of the disease by the laboratory. In most of the cases partial stamping out had been applied only to first detected infected animals on the infected premises. This occurred especially in the case of farms with large numbers of animals.

Although no information was available on the evolution of the disease in the remainder of the animals, vaccination was nevertheless applied on infected farms and in some cases these animals resulted infected at the time of the vaccination. Therefore the effectiveness of vaccination on infected premises was considered to be questionable.

The Mission noted the problems encountered with the application of the stamping out policy on farms of different sizes and the geological conformation of the site of location of the farm as well as the high concentration of the animal population in the affected areas. Lack of large-capacity rendering plants made such operations more difficult.

The Mission considered, however, that the stamping out policy was essential especially in the primary outbreaks in order to eliminate carriers and avoid the risk of further spread of the disease.

The Mission noted on a number of occasions that restrictions on movement of means of transport in the restricted areas had not been effective and as a result the disease had spread in various directions and over long distances.

Disinfection of infected premises, staff and means of transport had proved to be inadequate in many cases. In particular the cleaning and disinfection of vehicles had been generally left to the discretion of the driver and in the case of transport by train no disinfection had been allowed by the Railway Company. The Mission noted that the equipment for disinfection provided by a private agency in Modena was efficient; however, it was not clear whether or not such equipment was available elsewhere in the country.

The Mission considered that the level of collaboration established between farmers and Veterinary Services was of paramount importance for the prompt and effective application of sanitary measures. Administrative problems causing delays in payment of compensation to the farmers in the case of slaughter and stamping out had resulted in a negative attitude on the part of the farmers, a lack of collaboration in the application of the sanitary measures and the timely notification of the disease.

Recommendations

- 1) The stamping out policy should be strictly applied to all susceptible animals on the affected premises and at the primary outbreaks notwithstanding the size of the livestock unit infected, its structure and management.
- 2) Vaccination on infected premises especially of pigs should be given careful consideration since the question of carriers before or following vaccination has not yet been clarified.
- 3) Control of movement of animals and transport vehicles in restricted areas should be more effective and sound procedures in this respect should be established. Cooperation of other government bodies is essential.
- 4) Disinfection of infected premises, cleansing and disinfection of means of transport and clothing of persons involved, in the infected premises should be carefully implemented.
- 5) The definition of infected and restricted areas should be clearly indicated and the quarantine measures applied to these areas should be strictly observed.

4. Epizootiological investigations

Description

The first epizootiological investigation in the case of a suspected outbreak had been carried out by the veterinarians of the USL in collaboration with the staff of the Section of the Istituto Zooprofilattico responsible for diagnosis of the virus in the specimen submitted from the suspected case.

Observations

The Mission noted that an in-depth epizootiological investigation of the outbreak in the field and in the laboratory had not been carried out and therefore the primary outbreaks of A₅, C₁ and O₁ occurring since November 1984 still remain of unknown origin.

The large number of imported animals and the intensive animal movement within the country made such investigation a difficult operation especially at the check points at the frontier areas and at the points of final destination, including markets.

In addition, the Mission was informed that national rules in force until the end of July limited the activities of the Istituti Zooprofilattici to the provinces where the Institutes are located. This limitation applied also to the National Reference Laboratory.

The absence of a Task Force to cope with emergency situations was noted.

Laboratory investigations carried out at the National Reference Laboratory and the World Reference Laboratory showed:

- 1) The A₅ Modena 1984 isolate and a number of subsequent A₅ isolates from 1984; 1985 and 1986 outbreaks, were indistinguishable from the A₅ Parma 62 vaccine strain.
- 2) C₁ Modena 1985 isolates were closely related to the C₁ Brescia '64 vaccine virus strain.
- 3) The one outbreak of type 01 which had occurred had not been fully investigated.

From these laboratory findings the hypothesis that the virus had been introduced into Italy from abroad cannot be supported. However, the Mission had been informed that samples of Italian FMD vaccine strains had been occasionally provided on request to other European FMD laboratories.

The absence of an in-depth investigation of the outbreaks in the field can be demonstrated by the fact that a number of outbreaks had been first detected at the abattoirs during routine inspection following slaughter. Tongues taken from these animals and submitted to the laboratories had been found positive for FMD virus.

The Mission noted that a complete epizootiological survey based on serological tests and probang tests over extensive areas had not been carried out. It had been limited to a relatively small number of samples.

During discussions with persons contacted it became evident that the number of outbreaks reported may not have reflected the actual disease situation in certain areas of the country.

Recommendations

- 1) Serum samples and probang samples should be collected from as many animals on an infected premise as is practicable and from a sample of animals on farms surrounding an infected premise. These animals should be clinically examined and the age of FMD lesions estimated.
- 2) Questionnaires should be available to all veterinary staff investigating FMD outbreaks. These questionnaires should be standard for all regions and be prepared by an epidemiologist experienced in the investigation of FMD outbreaks.
- 3) Possible contacts with the infected premises must be thoroughly investigated. If this involves premises in different regions the investigations should be coordinated by national authority.
- 4) A Task Force should be set up at national level to cope with emergency animal disease situations especially FMD.
- 5) Standard procedures for epizootiological investigations should be set up.
- 6) Seminars on simulation exercises on emergency FMD outbreaks should be organized at regional levels in order to check the preparedness of the Veterinary Services to face emergency FMD situations.

5. Vaccine and vaccination

Description

In Italy FMD vaccine is produced at three Istituti Zooprofilattici located in Brescia, Padova and Perugia. FMD antigen production is based on BHK cells in suspension and monolayer, adsorption in aluminium hydroxide in Brescia and Perugia and in Bentonite in Padova. In all cases of vaccine production formalin is used as an inactivant. Vaccine potency test is carried out in cattle by using the PB₅₀ method - the potency shown was more than 7 PB₅₀ which met the standards of the European Pharmacopoeia and those of the European Commission for the Control of FMD.

Observations

The innocuity test carried out by the producer on different batches of vaccine and by the Istituto Superiore de Sanita, which is responsible for the official controls of all FMD vaccines to be used in Italy have always shown the vaccine to be safe. However, since recent observations made in European laboratories indicate that in some cases the formalin-inactivated vaccine could contain residuals of infective virus, the Mission was of the opinion that the use of a more effective inactivant such as Aziridin should be considered for the inactivation of FMD vaccine in Italy.

The Mission drew attention to the fact that vaccine adjuvants are different in the FMD vaccine production laboratories (bentonite adjuvants in use at the Padova Institute), with the result that FMD vaccine produced in Italy cannot be considered to be of homogeneous composition.

In addition, it appeared that in the three Institutes, the vaccine virus strains were not exactly of the same origin, and for the official controls of FMD vaccine a standard virus strain was not used for challenge (as is the case in other European FMD laboratories); but different challenge virus strains are provided by the production laboratories at the time of challenge.

Vaccine passed for use in the field is distributed by the production plants directly to the regional Veterinary Services who distribute it to the USLs.

Vaccination of cattle

As far as the vaccination programme is concerned, it was considered that with a vaccine as efficient as that used in Italy one vaccination per year should be sufficient to confer a good immunity against FMD in pluri-vaccinated animals.

In primo vaccinated animals a second vaccination is essential one month after the first vaccination. Regarding the vaccination of young stock with the probable presence of maternal antibodies, this should be carried out at the age of three or four months. Such animals however should be considered at high risk since a large percentage of the young stock has been shown to be without maternal antibodies, and a second vaccination at an interval of three or four weeks from the first is essential to confer adequate protection especially in animals intended for export.

The manner in which the vaccination is carried out, mode of inoculation, synchronization of vaccination campaigns on the national territory, careful registration of all operations carried out at the farm (date, number of animals, name of veterinarian, type of vaccine) was considered to be of great importance. The data collected by the Mission in this respect indicates that such operations have not been regularly and properly conducted and as a result a great number of cattle, especially young stock and those for fattening proved to be free of antibodies against FMD. This contrasts with the official information according to which the total cattle population in Italy (9 million head) is regularly vaccinated during the annual vaccination campaign (November-January).

Vaccination of pigs

The use of an FMD oil adjuvant vaccine provided adequate protection in pigs. The Mission expressed doubts as to the usefulness of the emergency vaccination carried out on pigs in the infected farms where only infected pigs were slaughtered. The findings of investigations in progress at the National Reference Laboratory on the persistence of eventual carriers on such farms may clarify the Mission's observations in this respect.

Recommendations

- 1) Aziridin compounds should be used to replace formalin as an inactivant for FMD vaccine. This procedure would allow for innocuity testing of the inactivated virus prior to adsorption.
- 2) More consideration should be given to prophylactic measures other than vaccination.
- 3) Vaccine production methods, vaccine formulation, potency and innocuity controls should be harmonized. The same challenge virus strain should be used in the official controls for all vaccines produced in the country.
- 4) All laboratories should be equipped with adequate disease security systems.
- 5) Vaccine supply by the producing laboratories should be coordinated to ensure timely delivery to the field. Synchronization and monitoring of the vaccination programme was considered to be essential.

6. Movement of animals

Description

Italy is one of the largest importers of live animals in Europe. Despite the strict sanitary regulations on animal movement in Europe, serological tests carried out in Italian laboratories showed that a number of imported animals had no antibodies to FMD on arrival. Imported animals are not vaccinated upon entry into the country but only during the annual vaccination programme. Once imported animals enter the country no records are kept of final destination. This makes it extremely difficult to trace them in case of disease emergency.

The Mission noted that there is intensive movement of animals within the country without strict sanitary control and the Mission was informed that illegal transfer of animals between transporters took place.

The Mission wishes to draw the attention of the national Veterinary Authorities to the disease risk linked to such operations. The cooperation of the police and other authorities concerned is of paramount importance in this respect.

Recommendations

- 1) Strict control of all means of animal transport should be enforced; the cooperation of the police and other government services concerned should be strengthened.
- 2) Operation of trade markets and fairs should be authorized with care and the origin and destination of animals from these places should be monitored and recorded.
- 3) All movement of animals should be registered.

Acknowledgements

The Mission nominated by the FAO European Commission for the Control of FMD to review and advise on the FMD situation in Italy greatly appreciated the valuable assistance given to them in the organization and implementation of their Mission by the Director General of Veterinary Services, Prof. L. Bellani, and by Dr. F. Fabbrovich of the Directorate of Veterinary Services who accompanied the Group during the Mission.

To all those who participated in and organized the field trips at Regional and USL level, and to the staff of the Istituti Zooprofilattici, special thanks is extended. Without their generous cooperation and assistance, it would not have been possible to complete the Mission's task in the limited time available.

Minutes of meeting held at Ministry of Health, Rome, on 10 November 1986
Presentation and discussion of FAO/EUFMD Mission
findings on the FMD situation in Italy

Present:-

Ministry of Health, Rome

- Professor L. Bellani, Director-General of Veterinary Services
- Professor A. Mattioli, Deputy Director-General of Veterinary Services
- Dr. G. Di Guardo, Directorate of Veterinary Services

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

- Professor Dr. A. Rojahn, Chairman
- Dr. W.H.G. Rees, Vice-Chairman
- Dr. F. Walla, member of the Executive Committee
- Dr. P. Stouraitis, Secretary, EUFMD
- Ms J. Raftery, Administrative Assistant, EUFMD

The Chairman of the European Commission for the Control of Foot-and-Mouth Disease, formally presented the report of the EUFMD Mission to the Director General of Veterinary Services. In doing so, he reiterated the willingness of the Commission to assist Italy in the implementation of the recommendations put forward by the group of experts who had undertaken the Mission.

In referring to the conclusions and recommendations contained in the Report, the Chairman underlined a number of points which were considered to be factors of major importance in the persistence of FMD in Italy i.e.

- relaxation of vigilance
- large percentage of susceptible animals not protected by vaccination
- vaccination incorrectly applied
- annual vaccination not carried out systematically
- impracticability of applying stamping out policy on intensive live-stock holdings
- delay in diagnosis, especially in pigs
- delay in epizootiological investigations
- incorrect application of sanitary measures; lack of supervision of animal movement, transport of animals, supervision at market level
- absence of Task Force to cope with emergency animal disease situation

The Chairman informed the Director General of Veterinary Services that it was the wish of the Executive Committee that the recommendations contained in the Report be discussed with him by the representatives of the Committee who were present for the purpose of reaching agreement on ways and means by which the Commission could support Italy in the implementation of the recommendations.

He also informed Professor Bellani that the Report would be discussed by the Executive Committee of the Commission at its Forty-ninth Session which will be held in Berne in February 1987, and thereafter at the General Session of the Commission (27th) which will be held in Rome in April 1987.

Before responding to the Chairman, Professor Bellani stated that he wished to hear the views of the Vice-Chairman, Dr. Rees, and those of Dr. Walla, and Dr. Stouraitis, who had participated in the Mission.

Dr. Rees stated that he felt the conclusions were sound. The situation called for the taking of rigorous measures especially if politicians were to be convinced that in the long term this would result in economic benefit at national level. He stressed the need to set up a Task Force to coordinate the action to be taken and strongly emphasized that such a Task Force should be set up under proper authority and power. He felt that the measures to be taken were extremely urgent since the situation was now such that the veterinary authorities were forced to deal with the disease as it appeared instead of being ahead of it; while partial slaughter was the only action possible in some cases, it could not resolve the problem.

Dr. Walla addressed the meeting briefly. He thanked the Director-General of Veterinary Services for the support given to the Mission. He stated that he considered the conclusions to be appropriate to this very difficult situation and that it would be impossible to eradicate the disease at this stage without a global fight at national level.

Dr. Stouraitis stated that, as Secretary of the FAO/EUFMD, he had followed closely the evolution of the FMD epizootics in Italy since 1984. He felt that it was essential that a Central Veterinary Authority should supervise the prompt and proper implementation of national sanitary rules at USL level, and that the USLs should be strengthened if the responsibilities entrusted to them following the Riforma Sanitaria were to be carried out effectively. As regards disease diagnosis, vaccine production and control, he stated that it was essential that these be harmonized through the National Reference Laboratory.

Professor Bellani expressed his appreciation for the prompt response of the Commission to the Italian Veterinary Authorities' request for assistance.

He stated that he had read the report of the Mission with great interest and had found the conclusions and recommendations contained therein to be concise, realistic, and a most valuable basis for future action. It was his intention to present the Report in its entirety to the Minister of Health and other political authorities concerned. In view of its importance and the validity of the recommendations put forward, it would be given maximum publicity at national level.

Referring to the Conclusions, Professor Bellani stated that he considered Point 10, the structure of the Italian Veterinary Services following the Riforma Sanitaria of 1978, to be of paramount importance.

The persistence of the epizootic, he stated, was due not only to the virus but also to the lack of veterinary infrastructure. Despite the existence of appropriate national laws and the efficacy of the vaccine and of the vaccination when carried out properly, FMD still persisted on the national territory. In theory everything was perfect but from a scientific point of view, and in practice, the system did not work.

The Director-General of Veterinary Services considered that the disease situation in Italy was a phenomena of such importance that it warranted special study by the Commission. He stated that if the

Commission were prepared to make a case study of the Italian situation, the Government would be prepared to accept the results of such a study and to give it maximum consideration.

In putting forward this proposal, Professor Bellani, emphasized that the objective of such a mission would be essentially to evaluate the present situation with a view to determining why a country which practises mass vaccination has been faced with such extensive epizootics of FMD. He was of the opinion that a three-man mission composed of a cost-benefit expert, a vaccine production expert and an epidemiologist would be necessary to undertake this task.

The Chairman of the Commission stated that in view of the benefit to be derived from such a study, not only for Italy but for the European Community in general, the Commission would do everything possible to arrange to carry it out as soon as possible. It was considered that it would not be necessary for the three experts to undertake the mission at the same time. The Secretary would be entrusted with the task of finding the appropriate experts and making the practical arrangements with the Italian Government.

Professor Bellani informed the meeting that this request would be formally addressed to the Director-General of FAO by the Minister of Health within the coming weeks. He also requested that the Secretary participate in meetings on a regional basis which would be organized to discuss the report of the Commission and ascertain reactions to its recommendations at regional level. It was agreed that the Secretary give priority to this task.

Following further discussion, it was agreed that:

- on receipt of the official request from the Italian Government arrangements would be made for qualified experts to undertake an in-depth study of the Italian case,
- the Secretary would participate in meetings convened by the Directorate of Veterinary Services at regional level,
- the findings of the Mission would be discussed at the Forty-ninth Session of the Executive Committee scheduled to be held in Berne in February 1987; at this meeting the Secretary would also present a report on the reaction at regional level in Italy to the findings of the Mission;
- the findings of the Mission, the Secretary's report on the meetings in Italy, and the study carried out by the three experts would be discussed at the Twenty-seventh General Session of the Commission to be held in Rome in April 1987.

Minutes of meetings held in Italy to present to and discuss with Regional and Local Authorities the Report of the FAO/EUFMD Mission on the FMD situation in Italy

As a follow-up to the recommendations made at the meeting held at the Ministry of Health, Rome, on 10 November 1986, regarding the presentation of the FAO/EUFMD mission report on the FMD situation in Italy, the Secretary participated in meetings which were organized by the Directorate of Veterinary Services to discuss the report of the mission and ascertain reactions to its conclusions and recommendations at regional level in Italy.

For this purpose five meetings were organized on 29 November in Brescia, for northern Italy, on 6 December in Rome for central Italy, on 9 December in Palermo for Sicily, on 10 December in Naples for southern Italy, and on 12 December in Sassari for Sardegna.

All meetings were attended by the Assesori Regionali for Health, a Representative of the Directorate of Veterinary Services, Ministry of Health, Rome, the regional and local sanitary units (USLs), the Istituti Zooprofilattici, and in Naples and Sassari, representatives of the respective Veterinary Faculties.

During the meetings, the Secretary of the FAO European Commission for the Control of Foot-and-Mouth Disease, presented the report of the FAO/EUFMD mission to Italy which took place from 6 to 10 October 1986, and clearly outlined the present FMD situation in Italy.

As regards the reasons for the persistence of the disease in Italy for more than two years, the findings of the mission can be summarized as follows:-

The report of the FAO/EUFMD mission to Italy which took place from 6 to 10 October 1986 with the participation of Dr. Stouraitis, Secretary of the Commission, Dr. Walla, CVO, Austria, Dr. Gafner, CVO, Switzerland, Dr. Westergaard, Danish Veterinary Services, Professor Ahl, Federal Research Institute for Animal Virus Diseases, Tubingen, FRG, and Dr. Kitching, Animal Virus Research Institute, Pirbright, UK, was presented to and discussed with the competent authorities of the Region and of the USL's (local sanitary units) at five meetings held between 29 November and 12 December 1986 at the Zooprophyllactic Institutes of Brescia, Rome, Palermo, Naples, Sassari and Sardegna.

During the meetings, the Secretary of the EUFMD presented the report and clearly outlined the present FMD situation in Italy. While taking into account the fact that the A₅ and O₁ virus strains isolated during the epizootic were found to be closely related with the homologous Italian vaccine virus strains (A5 Parma 1962, C1 Brescia 1984) it nevertheless appeared evident that the widely held supposition that the disease had been introduced from abroad was unfounded.

As regards the reasons for the presence of the disease in Italy for more than 20 months, the findings of the mission can be summarized as follows:-

- 1) Organization of the Veterinary Services Two points emerged regarding the Sanitary Reform -
 - the first refers to the lack of coordination, also with respect to control, between central and regional authorities;
 - the second concerns the implementation of the programme which proved defective because of the lack of staff at regional and local level
- 2) Type of Livestock Breeding Unit The progressive tendency of the Italian livestock breeding units - especially cattle breeding units - to become fattening units has led to a series of problems which have not always been solved or in some cases cannot be solved, as well as the necessity to continuously introduce young animals, mostly imported, on the farms. These young animals are frequently not immune to FMD.
- 3) Epizootiological investigations In the majority of cases it has not been possible to identify the origin of the infection; this leads one to conclude that the epizootiological investigations have not been sufficiently thorough or that certain outbreaks have not been reported.
- 4) Vaccination The compulsory cattle vaccination campaigns have not been properly implemented; animals have been found to be without antibodies. Special attention should be paid to the problem of young animals which have not always acquired the necessary maternal antibodies and which even if vaccinated once, still constitute a high risk. Such animals should be revaccinated 3-4 weeks after the first vaccination. As regards pigs, problems may be encountered with emergency vaccination in the infected premises.
- 5) Vaccine Innocuity, efficacy and potency testing of Italian vaccine indicate that it is of high quality. However, notwithstanding this, two factors emerge:
 - the vaccine produced by the three Institutes in Italy (Brescia, Padova and Perugia) is not identical at least as far as the adsorption method is concerned: Brescia and Perugia use aluminium hydroxide while Padova uses Bentonite
 - as far as inactivation is concerned it is considered that arizidin will give better results than formalin
- 6) Animal movement Serious gaps exist as regards animal inspection prior to movement, hygiene and disinfection of means of transport.
- 7) Stamping out Partial stamping out on infected premises is a cause for concern. In addition, delays in payment of compensation to the farms acts as a deterrent to the farmers' cooperation which is vital to effective control of the disease.

Following presentation of the mission report by the Secretary of the Commission all participants actively commented on the mission's findings.

The Report was formally accepted during the five meetings and favourably commented upon for its realistic analysis of the FMD situation in Italy and the problems encountered in the country following the Sanitary

Reform in 1978 which transferred veterinary authority from the Central Veterinary Services to the Regions and to the Local Sanitary Units (USL's).

The following important points were emphasized:

- a) lack of personnel at regional and local level and inadequate compensation for vaccination
- b) lack of personnel at the Institutes
- c) difficulty, or impossibility from a practical viewpoint, to examine the animals prior to movement (compulsory law of 25.9.86)
- d) lack of disinfection and washing equipment network for transport vehicles.
- e) lack of proper application of the Sanitary Reform by the Regions particularly as regards the necessary changes in and strengthening of the regional Veterinary Offices and even more of the USLs
- f) lack of uniformity at regional level of the administrative and technical authority of the USL's which would permit the latter to plan the necessary preliminary, intermediate and final action to be taken promptly and efficiently while at the same time availing of the collaboration of other local services (hygiene/sanitary/administrative).
- g) it was unanimously requested that a clear definition be provided of the competence and authority conferred by the Sanitary Reform to the regional services and to the USL's and the consequent availability of means to effectively implement the activities transferred to the Regions by the Sanitary Reform.

During the meetings it was strongly requested that sheep and goats be included in the compulsory vaccination campaigns.

Summary of report on the in-depth study of the FMD epizootics and
cost-benefit analysis of total/partial stamping out policy
and sanitary measures applied in Italy

SUMMARY

1. There have been three distinct epidemics of FMD in Italy over the last three years. The 334 outbreaks (to 31/1/87) have between them cost circa 40,000,000,000 lire in direct public cost and possibly 15,000,000,000 lire in direct private costs. (see point 1)
2. All three epidemics have been characterized by initial spread in the lower Po Valley with subsequent spread to other parts of Italy. (see point 3)
3. Virus isolated from field outbreaks in the early stages of the epidemics are similar to the vaccine strains used in Italy. (see point 3)
4. Twelve epidemiological factors have been identified as hindering the control of the epidemics. Measures to counteract these are outlined together with the cost of such action. The most important measures are probably better disease reporting, total stamping out, increased surveillance around outbreaks, and strict movement control. Two of these, better reporting and increased surveillance can be undertaken at relatively little cost. (see point 4)
5. National vaccination has cost 15,000,000,000 lire per annum and this cost will probably increase to circa 40,000,000,000 lire p.a. as the recent changes in vaccination policy are implemented. Both changes, 6 monthly vaccination of adult cattle and double vaccination of young animals will improve protection of the national cattle herd. (see point 5)
6. A trained task force should be set up in each region to take responsibility for sanitation and immediate movement control at an infected premises. In addition the regional authorities should have access to an epidemiological team. (see point 6)
7. The present epidemic can be contained and eventually extinguished if firm measures are taken. If they are not the recurrent direct public costs of circa 60,000,000,000 lire p.a. will continue. (see point 7)

1. Description of epidemics

The foot-and-mouth disease outbreaks that have occurred in Italy since 1984 can be divided into three distinct epidemics.

- (a) November 1984 - August 1985 Type "A" 153 outbreaks
- (b) November 1985 - April 1986 Type "C" 69 outbreaks
- (c) June 1986 to date Type "A" 112 outbreaks (to 31/1/87)

2. The direct cost of the epidemics

The approximate cost of these epidemics is:

	Direct public costs+	Direct private costs*
	'000 lire	'000 lire
"A" 1984/85	5,500,000	3,000,000 - 5,000,000
"C" 1985/86	11,000,000	3,000,000 - 5,000,000
"A" 1986/77 (to 31/1/87)	20,000,000	5,000,000 - 7,000,000

+ the direct public costs include:

- (a) compensation for slaughtered animals
- (b) sanitary measures on farms
- (c) local administrative costs (including surveillance)
- (d) vaccination around outbreaks

* The direct private costs are: estimates based on British and German estimates of lost production in infected herds.

3. The pattern of spread of the epidemics

The pattern of the three epidemics is similar:-

- (a) An origin in the lower Po Valley (also infection near Perugia in the 1986/87 epidemic). Infection discovered on several farms within a few days.
- (b) Rapid spread over a period of 60 days (Type A 84/85) to 90 days (type C 85/86) within the lower Po Valley.
- (c) Later clusters of outbreaks in other parts of Italy. Up to 20 clusters were evident in the type A 84/85 epidemic and up to six clusters with the type C 85/86 epidemic. These clusters have mainly occurred in areas where the density of animal population is far less than in the Po Valley and they have all been controlled fairly quickly.
- (d) The epidemic dying out in the Po Valley 60-90 days after commencement but with isolated outbreaks occurring during the period 100-140 days after commencement.

The 1986/87 epidemic is still continuing 300 days after the commencement.

4. The origin of the epidemics

Type A, 1984-1985 - Oldest disease in sheep (San Prospero) and cattle (Campo Galliano) in Modena indicates infection in that province in early November, possibly October 1984. Most vaccine was used from December

onwards. Isolates from late November, early December and January were all indistinguishable from A₅ Parma/62 virus - the Italian vaccine strain.

Type C, 1985-1986 - First reported outbreak in pigs (Campo Galliano, Modena) is unlikely to have been primary. An isolate from Rubiera (Modena) (3/12/85) indistinguishable from Brescia/64 by TI mapping at Pirbright laboratory but differed on heat lability tests at Brescia laboratory. Primary focus unknown.

Type A, 1986-1987 - First outbreaks reported simultaneously 6 June 1985 in pig farms at Mantova and Perugia; possibly linked by transport. Pirbright and Brescia laboratories agree that isolates from this epidemic are undistinguishable from A₅ Parma/62 strain.

5. Factors influencing spread of infection

(a) Reporting of disease

Reporting by farmers is late or not at all. This allows infection to spread widely within herds and also between herds before it is detected.

(b) Diagnosis

Mild disease in cattle and confusion with SVD has resulted in some delays in recognizing disease in the field. Laboratory diagnosis is generally satisfactory.

(c) Slaughter policies

Policies differ between regions. Where complete slaughter has been used most often, as in Piemonte region, the disease has been contained. Guidelines for partial or complete slaughter are not strictly followed. Partial slaughter in some cases means repeated, fragmented slaughter. Complete slaughter is usually the last resort when morbidity is evidently high.

(d) Disinfection

Disinfection cannot be carried out adequately where only part of a herd is slaughtered. Truck movements linked to spread suggest improper cleansing and disinfection. Delay in the disposal of carcasses is evident in very large units.

(e) Surveillance

Surveillance around infected premises is neither systematic nor sufficiently intensive. The area covered by patrols may not be large enough as infection is often occurring outside the 2 km zone. There is little coordination of manpower between the USLs.

(f) Movement of animals

Spread of infection within the Po Valley and spread to other parts of Italy indicate lack of control of movement of infected (and possibly carrier) animals. There is inadequate support from the policy in closing roads and markets. Unofficial markets have developed.

(g) Airborne spread

The density of animals in the Po Valley and temperature inversions during winter months suggests that some airborne spread is occurring. One pig holding visited during the mission had almost ideal precautions to prevent access but infection spread to it probably from an infected premise 3 km distant.

(h) Spread by personnel

Spread of infection has been associated with veterinarians (unknowingly contaminated) who have carried out A.I. and embryo transplant procedures. Spread is also being associated with rodent exterminators visiting farms.

(i) Population densities

The Po Valley has one of the highest densities of pig and cattle populations in Europe. The close proximity of large commercial pig herds and veal calf units has aided disease dissemination and made decontamination and the disposal of carcasses and effluent difficult.

(j) Vaccination

Vaccination cover was originally less than complete but it has now improved. The cattle population now includes a large proportion of young animals many of which are imported. These imported animals frequently have inadequate levels of maternal antibody and young stock as a whole provide a large pool of susceptible animals. Although imported animals should be identified for vaccination, breakdowns of communications between USLs mean that the calves are not traced and vaccinated. Lack of restraint on farms encourages the use of jet applicators for vaccination.

(k) Imported animals

There is no evidence that the 2 million cattle imported annually from other European countries have carried FMD. The young animals do however provide a pool of susceptible stock (see above).

(l) Slaughter houses

Infected animals are undoubtedly still reaching slaughterhouses due to partial slaughter policies and improper movement control.

6. Action suggested to control the spread of disease and the cost of such action

(a) Better reporting by farmers

Reporting of disease by farmers is likely to remain poor until such time as a policy of fair and prompt compensation is brought into operation. Farmers are paid up to a maximum of 80% of value determined by central government data and these values are said to be below market rates. The farmers' greatest cause for complaint is that payment is frequently delayed over one year after slaughter.

COST of prompt payment (within 60 days) of compensation for slaughter in an average outbreak (125 million lire) at 10% p.a. = 12,500,000 lire.

Farmers failing to report disease should be prosecuted.

(b) Slaughter of all susceptible stock on a holding

A policy of complete "stamping-out" will reduce the spread of infection and should be followed on all infected premises irrespective of the apparent weight of infection, the vaccine status of the animals or the arrangements of the buildings.

COST - The direct public cost of recent (86/87) outbreaks under the present policy of partial slaughter is estimated at 178,289,000 lire (per outbreak). The cost if all stock are slaughtered is estimated at 537,235,000 lire.

Therefore the extra cost of total slaughter (per outbreak) is:

$$\begin{array}{r} 537,235,000 \\ - 178,289,000 \\ \hline 358,946,000 \text{ lire} \end{array}$$

This is the extra public cost. In addition there is substantial extra private cost due to loss of production.

(c) Increased surveillance around infected premises

Increased and systematic surveillance around infected premises is required so as to identify foci of disease. Two actions are necessary -

(a) Increased manpower. It is estimated that circa 40 man days, per outbreak are spent at the infected premises, in local surveillance and in office duties. If total slaughter were introduced the manpower at the infected premises would be reduced (say by 10 man days). A further 40 man days per outbreak should be devoted to surveillance.

(b) Cooperation between USLs (and Regions) in providing manpower. There is little or no cooperation at present. Specific Regional task forces could be created for this purpose (see later).

COST - Each man day (Veterinary Officer) costs circa 250,000 lire. An extra 40 man days per outbreak would cost 10,000,000 lire.

(d) Movement control

Police cooperation for movement control must be obtained from the time of first suspicion of disease on a farm and thereafter maintained until a negative laboratory result is obtained or, if positive, until all stamping out, disinfection, ring vaccination and surveillance activities have been completed. Roads in the infected area should be manned and closed and all markets and slaughterhouses closed completely.

Movement in and out of an infected area should not be permitted unless authorized by a veterinary certification. Movement records of animals must be maintained at all times,

COST - The cost of these measures cannot be estimated.

(e) Vaccination

All cattle should be vaccinated at the age of 3 months and revaccinated one month later. Vaccination should be by syringe and needle only and random serological checks should be carried out for verification. In view of the current weight of infection in the country all cattle over three months of age should be vaccinated at six monthly intervals. Vaccination of pigs should be limited to infected zones and no vaccination of animals should be carried out on premises where disease has been confirmed. Used vaccine bottles are being stored. They should be discarded.

COST - The cost of vaccination of the national herd is:
1984 - 11,150,000,000 lire (official data)
1985 - 15,192,000,000 lire (official data)

The number of doses produced in 1986 was 19,500,000 (Brescia: 12 million cattle doses, 2 million pig doses; Padua: 3,500,000; Perugia circa 2,000,000).

The likely cost of national vaccination is:
1986 - 27,300,000,000 lire

If all adult animals are vaccinated every six months and all young stock are given an extra dose the likely cost is:
1987 - 40,000,000,000 lire

These costs include the cost of the vaccine and the cost of administering it.

(f) Diagnosis and epidemiological investigations

In all cases of vesicular disease samples should be collected and submitted without delay to an appropriate diagnostic laboratory. The Brescia laboratory should compare selected field isolates with vaccine strains by T mapping to investigate more extensively the involvement of vaccine virus in the initiation of outbreaks. the use of primary bovine thyroid cells would improve the sensitivity of the isolation of virus.

A formal system of reporting should be instituted. This would include telephoned and written reports from suspect infected premises to USL and from USL to regional and national authorities. Standard epidemiological questionnaires should be used.

7. The creation of task forces

Skilled task forces should be established at regional level. They would be responsible for:

- The slaughter and disposal of animals
- The cleansing and disinfection of infected premises
- The disposal of waste products
- The establishment and maintenance of farm and road disinfection
- Check-points
- The posting of warning notices
- The disinfection of any essential vehicles leaving or entering
- The prevention of entry or exit of unauthorized personnel

A task force which has carried out these duties (in-part) has been used in the Piemonte region.

In addition epidemiological teams should be created to support regional authorities. They would include veterinary virologists and technicians from the national FMD laboratory, and meteorologists familiar with the operation of computer systems for analyzing and predicting the airborne spread of FMD. In the event of an outbreak the epidemiological team would be sent to infected premises without delay. It would be responsible for the following:

- (a) determination of the extent and pattern of disease on the premises
- (b) determining the source of infection
- (c) assess probability of secondary spread
- (d) advise veterinarian in charge of control procedures on risks to other premises

The team should be equipped with specialist vehicles and radio-phones.

8. Prospects for control of the present FMD epidemic

We have heard it said that the FMD situation in Italy is now "endemic". If by this it is meant that the presence of disease is taken for granted and that it cannot be eliminated in the foreseeable future we do not agree.

If firm measures are taken as outlined in para 6. above the present epidemic could be contained within the 1987/88 financial year, particularly in view of the recent intensification of national vaccination. The infection could be completely extinguished if total stamping out is applied, particularly when the epidemic is in its declining phases. Thereafter the maintenance of intensive vaccination for some years, in the absence of active disease, should eliminate any possible carrier animals.

For the ultimate future, the authorities should consider their national vaccination policy in view of the risk of live vaccine virus, the cost of national vaccination, and the fact that there appears to be no evidence of infection in imported stock.

The cost of the control measures detailed in para 7. can be set against:

The direct public and private costs of the present epidemic - circa 25,000,000,000 lire p.a.. The cost of the national vaccination campaign - circa 30-40,000,000,000 lire p.a. In addition there are effects on Italy's domestic and export trade in livestock products.

If little or no action is taken then these costs will recur annually and possibly increase.

Summary of report and recommendations on the study of
FMD vaccine production in Italy

Facilities

FMD vaccines used in Italy are manufactured in three Zooprophyllactic Institutes in Brescia, Padua and Perugia. Apart from details, these premises meet international standards. The production installations are, on the whole, modern and well designed. Production figures per Institute were given as 1.5 to 8 million trivalent doses per year. In two Institutes, the supporting laboratories lacked adequate floor space and/or instrumentation; they were also under-staffed. Separate isolation facilities for animals, including cattle, exist in Teramo, Perugia and Brescia.

The official controller is the Istituto Superiore di Sanità. This Institute possesses an isolation laboratory, but no large animal facilities.

There is no formal security organization in any of the production laboratories.

Diagnosis

Laboratory diagnosis of suspected field samples is done by most of the Zooprophyllactic Institutes, which possess small protected laboratories for this purpose. Some of these Institutes only occasionally receive samples of suspect material. Lack of routine may result in delayed diagnosis. The CF-test is routinely applied using self-prepared immune sera or sera obtained from other Italian laboratories.

The Brescia Institute is the official National Reference Centre. It acts as a training centre and distributes reference sera, but cannot enforce the use of standardized techniques or ingredients. It is responsible for confirmation of diagnosis of regional laboratories and for subtyping of field isolates.

Vaccine production

Vaccine production is based on BHK-cell cultures, either in suspension or as monolayer. Virus production is mostly, but not completely, in closed systems. Production methods vary in details, such as cell line and medium used, virus or cell passage level considered acceptable, time of harvesting cells or virus, and treatment of virus harvests. Virus batches vary in volume from 600 to 3,200 litres. Virus yields are mainly estimated on the basis of infectivity. Chloroform treatment is used to control possible contaminants; sterile filtration is omitted.

Virus is concentrated by adsorption to Al(OH) or bentonite prior to inactivation. Three to 20 mls of virus suspension are available per dose of monovalent vaccine.

All manufacturers use the same virus strains for vaccine production, i.e., A₅Parma, O₁Lausanne and C₁Brescia. Inactivation is by formaldehyde at 25-26°C for 48 hours, pH ranges from 7.9 to 8.5. Formaldehyde concentrations were given as 0.4 to 0.5 o/oo.

One manufacturer carried out inactivation of small lots of virus several times a week, another stored virus for several weeks prior to inactivation of large volumes. Manufacturers stressed the need for prolonged storage of vaccines prior to use in the field. Inactivation apparently is done as a two-step process; the second phase, at refrigerator temperature, is not properly defined or controlled.

Testing

The most important vaccine tests are innocuity and potency tests.

Proper innocuity testing involves in-process testing and, thus, can only be done by the manufacturer. However, only one manufacturer reported routinely making virus inactivation curves. The two other manufacturers did only innocuity tests on pooled batches of inactivated virus; in one laboratory, a single test on the total annual production was considered sufficient.

Innocuity tests included an elution and concentration procedure applied to volumes of vaccine varying from hundreds of mls to several litres. The procedure, however, had only been validated in one laboratory.

Manufacturer's potency tests are restricted to guinea pig tests done on some or all lots of monovalent vaccine. Cattle tests, in practice, are done only within the framework of the official vaccine control programme.

The State Controller draws his samples from representative 1% volumes of each manufacturer's production. Annually, four series of tests are run on 1.5 to 5.0 million-dose batches of trivalent final product. Tests include inoculation of three susceptible cattle and an elution/concentration procedure for innocuity, as well as a cattle PD₅₀ test for each type for potency. The cattle tests are done in the isolation facilities mentioned before. An observed 7 PD₅₀ per type and dose is the minimum accepted.

Vaccines have an official shelf life of 12 months from the date of sampling by the Controller.

Recommendations

1. If the present spread of production of vaccine over three Zooprophy-lactic Institutes is to be maintained, the staffing must be ensured at each laboratory in order to scientifically support vaccine production. Laboratory facilities must avoid manipulation or storage of infective virus outside protected areas. Pass-through autoclaves must be available in each FMD compound.
2. The Ministry's responsibility in supervising FMD security at individual laboratories should be clarified.
3. Every laboratory handling FMD-virus must have a structured security organization.

4. The role of the National Reference Centre in the supervision and coordination of diagnostic laboratories should be strengthened. Ingredients, especially sera used in FMD diagnosis, should be standardized. The possibility to develop a universally applicable ELISA test for FMD diagnosis should be investigated.
5. Manufacturers must control inactivation of every single lot of virus. Preferably, an inactivation curve should be used, in order to be sure that vaccines are fully inactivated at the end of the inactivation period. After about 50% of the inactivation time has elapsed, virus should have become undetectable in order to guarantee the absence of infective virus from large volumes of vaccine.
6. The use of fully validated elution/concentration and detection procedures is necessary.
7. Aziridin should be substituted for formaldehyde as inactivant (although neither aziridin nor formaldehyde guarantee an innocuous product unless properly handled).
8. Validity of vaccine should be increased to 18 months if sufficient data are available for a given vaccine to warrant this extension. The Istituto Superiore di Sanità, in consultation with the National Reference Centre, should determine the strains of virus to be used in challenge tests. This Institute should maintain its own stocks of challenge virus.

Vaccination campaigns in southeastern Europe buffer zone
1985-1986

The annual vaccination campaigns in southeastern Europe were continued in the buffer zone in Thrace in 1985 and 1986 as recommended by the Twenty-sixth Session of the Commission held in Rome in April 1985. The campaigns were implemented in conformity with the recommendations of the FAO/EEC/OIE FMD Group as agreed at the meetings held in Vienna, September 1984, on the occasion of the Eleventh Conference of the OIE Regional Commission for Europe and at EEC HQ in Brussels on 6 December 1985, and due account was taken of the requirements of the countries concerned with the buffer zone and the epizootiological situation in Turkey (Anatolia) and in the Near East region.

For the provision of the vaccine the OIE policy (Resolution, Vienna 1962/Conclusions, Paris 1965) concerning manipulation of exotic FMD virus in Europe was taken into account.

The cost of the vaccine supplied for the campaigns in the buffer zone was met from the relevant FAO Trust Funds 9111 (EEC) and 9097 (non-EEC) deposited for this purpose. The breakdown of income/expenditure for TFs 9111 and 9097 for the period January 1985 to December 1986 is attached hereto.

1985 Campaigns

Arrangements were made for the supply of 810,000 doses of A₂₂/O₁/ASIA-1 trivalent vaccine for the spring vaccination campaigns through Rhône Mérieux (Teheran production) at a cost of US\$ 486 000. Cost met through TFs 9097 and 9111.

The vaccine was supplied to the three countries concerned in February 1985 and vaccination was carried out simultaneously in the whole buffer zone area (Bulgaria - 250,000 doses, Greece - 60,000 doses, and Turkey - 500,000 doses). In addition, Turkey provided 600,000 doses of locally produced A₂₂/O₁/ASIA-1 vaccine to complement the vaccination coverage in the whole Turkish Thrace area.

1986 Campaigns

As a follow-up to the Commission's recommendation made at its Twenty-sixth Session held in Rome in April 1985, a meeting was convened on 27 November 1985, in Alexandroupolis, Greece, with the participation of representatives from the Greek and Bulgarian Veterinary Services, the FAO European Commission for FMD, and the EEC.

The objective of this meeting was to review and discuss the FMD position and control policy in southeastern Europe and to agree on the programme for the implementation of the vaccination campaigns in the buffer zone in 1986.

The conclusions of the meeting were communicated to the Turkish Veterinary Services who had been unable to attend; they expressed agreement on all the points raised and on the recommendations made. In addition,

they supplied details on their vaccination programme for 1986 in Thrace area and in Anatolia. They requested FAO to supply 500,000 doses of O/A₂₂/ASIA-1 vaccine for the 1986 campaigns since production of vaccine at the FMD Institute in Ankara would not have been sufficient to meet the national needs for maintenance of the buffer zone and the vaccination programmes in Anatolia.

The conclusions of the meeting held in Alexandroupolis were also presented to and discussed at the FAO/EEC/OIE Tripartite group meeting held on 6 December 1985, at EEC Headquarters in Brussels, under the Chairmanship of Prof. Dr. A. Rojahn, Chairman of the EUFMD. The Tripartite Group endorsed the conclusions reached at the meeting in Alexandroupolis, Greece, and agreed that:-

1. The vaccination campaigns in the buffer zone in southeastern Europe should continue.
2. For 1986, vaccination campaigns should be carried out in the buffer zone area of Greece, Bulgaria and Turkey with A₂₂/O₁/ASIA-1 trivalent vaccine.
3. At the request of the countries concerned with the maintenance of the buffer zone, it was agreed that the vaccine should be provided in the second half of March 1986. FAO should coordinate all arrangements in respect of supply and delivery.
4. The vaccination campaigns should be carried out simultaneously by the three countries (Greece, Bulgaria, Turkey) in the respective areas in the buffer zone.
5. The vaccine should be supplied as follows: Greece - 60,000 doses, Bulgaria - 250,000 doses and Turkey - 500,000 doses. The vaccine supplied to Turkey will be used in the border buffer zone areas of Edirne and Kirklareli; the remainder of Thrace should be covered by vaccine provided by the Ankara Institute.

The cost of the 810,000 doses of vaccine required for the campaigns should be covered from the relevant FAO Trust Fund in accordance with the OIE/EEC/FAO rules.

6. FAO would monitor the safety and potency of all vaccines used in the buffer zone and in the Turkish Thrace region. Technical protocols should be requested from all suppliers.

Following the recommendations of the FAO/EEC/OIE Tripartite Group (Brussels, 6 December 1985) and taking into account the request of the countries concerned, arrangements were made for the supply of 810,000 doses of A₂₂/O₁/ASIA-1 trivalent vaccine for the vaccination campaigns in 1986 through Rhône Mérieux, France (Teheran production) at a cost of US\$ 525,801. The cost was met from TF 9111 (EEC). The vaccine was delivered before 15 March to the three countries concerned and vaccination campaigns were implemented and completed by the end of April in the whole buffer zone area.

In addition, Turkey provided 1,159,000 of locally produced A₂₂/O₁/ASIA-1 vaccine to complement the vaccination coverage in the whole Turkish Thrace and Marmara areas (Table 1).

Arrangements for 1987 Campaigns

In conformity with the recommendation agreed at the meeting of the FAO/EEC/OIE FMD group held at EEC Headquarters, Brussels, on 4 December 1986 (see minutes attached) and the requirements of the countries concerned with the buffer zone arrangements were made for the supply of 300,000 doses of A₂₂/O₁/ASIA-1 trivalent vaccine for the implementation of the vaccination campaigns in the buffer zone, Bulgaria 250,000 doses, and to Greece 50,000 doses. The vaccine should be delivered by 15 March to Bulgaria and Greece. Funds for the supply of the required amount of vaccine are available in the relevant FAO TFs 9111 and 9097.

The vaccine required for the implementation of the campaign in the buffer zone in Thrace area (Turkish side) will be provided through vaccine produced at the Ankara FMD Institute and no vaccine will be required from FAO for the buffer zone in Turkey for 1987.

The OIE policy (Resolution/Conclusion 1962 and 1965) and the recommendation agreed in this respect at the Conference of the OIE Regional Commission for Europe held in Berlin, GDR from 15 to 17 September 1986 was taken into account for the provision of the vaccine for the 1987 vaccination campaigns in the buffer zone.

The Turkish position for the implementation of the campaign is reported in the attached minutes of the discussion with the Secretary of the Commission had with the Turkish Veterinary Authorities during his visit to Ankara from 23 to 26 November 1986.

Provision for the maintenance of the buffer zone

Thanks to the generous response of the EEC and non-EEC countries in Europe to the appeal for funds for the continuation of the campaigns made by the Director-General of FAO in 1984, the funds available under TFs 9111 (EEC) and 9097 (non-EEC) will be sufficient to cover the cost of the campaigns until 1989. Since, as expected, Turkey will continue to be in a position to cover its buffer zone area in Thrace with vaccine for local production, there will be sufficient savings to face any emergency FMD outbreak which could arise in southeastern Europe.

FMD vaccine supplied for the maintenance of the buffer zone
in southeastern Europe during the period 1985-1987

Year	Turkey	Bulgaria	Greece	Trivalent virus types	Cost US\$
	No. of cattle doses				
1985	500,000	250,000	60,000	A ₂₂ /O ₁ /ASIA-1	486,000
1986	500,000	250,000	60,000	A ₂₂ /O ₁ /ASIA-1	525,801
1987	no vaccine	250,000	50,000	A ₂₂ /O ₁ /ASIA-1	180,000(Prov.)
Total:	1,000,000	750,000	170,000		1,191,801 (Prov.)

Minutes of meeting held in Dr. Atala's office, 24 November
and at the Sap Institute, 25 November 1986

A) Meeting at the Ministry of Agriculture

At a meeting held in the office of Dr. Atala, Director-General, Protection and Control, Ministry of Agriculture Forestry and Rural Affairs, with the participation of Mr. Rosenegger, FAO Representative, Dr. Stouraitis, Secretary, EUFMD, FAO, and Dr. G. Okay, Director of Animal Health Service, the FMD situation in the Near East region of Turkey was reviewed and discussed in relation with the programme for the implementation of the vaccination campaigns in the buffer zone in Thrace area for 1987.

Dr. Atala stated that vaccine production at the National FMD Institute has now been increased and therefore for the implementation of the vaccination campaign in the buffer zone (Turkish side) the vaccine will be provided by local production and no vaccine supply will be required from FAO. In addition, Dr. Atala stated that similar campaigns will continue to be carried out in the east and southeast border areas of the country.

Dr. Atala's opinion was that since information on the epizootiological situation in the neighbouring countries in the Near East is not available, the vaccination programme in 1987 in the buffer zone in Thrace should be carried out with O₁, A₂₂ and ASIA-1 trivalent vaccine.

B) Meeting at the FMD Institute, 25 November 1986

1. Discussions were held with Dr. Boz, Dr. Okay, and the staff of the Institute. Problems related to the vaccine production plant were reviewed and discussed. Vaccine production for 1986 was estimated at approximately 15-16 million doses of monovalent vaccine. This will be used for the implementation of the vaccination programme in Thrace and Marmara areas in 1987, for the buffer zone in the east and southeast areas, and in the remaining parts of the country for the general vaccination programme.

It was noted that in 1986 the number of FMD outbreaks reported in the country had steadily decreased due to the application of a regular vaccination programme and adequate sanitary measures.

2. During 1986 only type O₁ and A₂₂ FMD virus were reported in Anatolia Thrace area continues to remain free from FMD since 1978.
3. The vaccination programme in Thrace area was carried out in Spring 1986 with vaccine provided through FAO and complemented with vaccine produced at the FMD Institute in Ankara. In addition to this campaign, a second vaccination programme was carried out with the same trivalent vaccine in Thrace area in October-November 1986.
4. As regards the vaccination campaign in 1987 it was agreed that the vaccination programme in the buffer zone area would be implemented with vaccine produced locally and this vaccination campaign would be extended to the whole Thrace area and to the provinces of

Canakkale, Balikesir, Bursa, Bilecik Sakarya and Izmit. It was agreed that the vaccination campaign would start in the middle of March 1987 and would be completed by the end of April. Technical protocols in vaccine innocuity and potency test for the batches of vaccine which will be used in the buffer zone area will be provided to FAO before starting this campaign.

C) Composition of Vaccine for 1987 campaign

It was agreed that the epizootiological situation in the Near East region should be taken into account for the types of virus being included in the vaccine. In addition to O Manisa/69 and A₂₂ Marmatli/65, ASIA-1 Turkey/73 type should be considered since outbreaks of such type had been reported in neighbouring countries of Turkey (Syria, Iran, Iraq) during the 1986 campaigns.

It is recommended that in order to harmonize the vaccination coverage in the buffer zone areas in Bulgaria and in Greece the vaccine to be used should contain the same virus strains as included in the Turkish vaccine.

FAO/EEC/OIE FMD Group
Minutes of meeting held at EEC HQ Brussels, on
4 December 1986

Foot-and-mouth disease vaccination policy in
southeastern Europe buffer zone in 1987

Participants

<u>EEC</u>	<u>FAO</u>	<u>OIE</u>
Dr. M. Contardo	Prof. Dr. A. Rojahn	Dr. L. Blajan
Mr. D. Dexter	Dr. P. Stouraitis	Dr. J. Leunen
Dr. J. Watson		

The meeting was held at the EEC premises under the Chairmanship of Prof. Dr. A. Rojahn, Chairman of the FAO European Commission for the Control of Foot-and-Mouth Disease.

Dr. Stouraitis, Secretary of the EUFMD, provided information on the implementation of the campaigns in the buffer zone in 1986, and on the FMD situation in southeastern Europe and the Near East regions. The vaccination programme carried out in Turkey and vaccine production at the FMD Institute in Ankara which had now reached a production capacity sufficient to permit implementation of the 1987 campaigns in the Turkish area of the buffer zone with vaccine of local production was discussed.

The following points were agreed:

- 1) The vaccination campaign in the buffer zone in southeastern Europe (Greece, Bulgaria and Turkey) should continue.
- 2) For 1987 a trivalent vaccine containing types O₁, A₂₂ and ASIA-1 will be made available through FAO for Greece and Bulgaria. Turkey will implement the campaign with vaccine of local production.

Vaccine

- 1) The vaccine should contain strains similar to and give good protection against those used in the Turkish vaccine, i.e. O₁Manisa/69, A₂₂Mahmatli/65, ASIA-1 Turkey/73.
- 2) The quality controls related to potency, innocuity and sterility should be carried out in accordance with the European Pharmacopoeia, with a PB 50% conforming to minimum 3 or average 6.8. The potency should be assessed by challenge of once-vaccinated cattle.
- 3) The vaccine should be inactivated by primary inactivants.
- 4) Technical protocols containing all data relating to vaccine composition and testing should be provided by the supplier before confirmation of the order.

This information should also be provided by the Turkish authorities in respect of the vaccine to be used in the buffer zone.

Administration

As Turkey would provide its own vaccine, FAO would be required to supply that for Bulgaria (250,000 doses) and Greece (50,000 doses) only, giving a total of 300,000 doses of O, A₂₂ and ASIA-1 trivalent vaccine to be provided by FAO, and financed from the relevant FAO Trust Fund (9111) in accordance with the recommendations adopted during the FAO/EEC/OIE meeting held in Brussels on 4 December 1986.

At the request of the countries concerned, the vaccine would be supplied by mid-March. FAO would coordinate the supply and delivery.

The campaign should be carried out simultaneously in the buffer zones of all three countries concerned, and the dates of commencement and completion of the programme should be notified immediately to FAO who would notify OIE and EEC.

Following the recommendation made at the OIE Regional Conference for Europe in Berlin in September 1986, regarding the OIE policy on production of vaccines as adopted in 1965, tenders would be invited from vaccine producers outside mainland Europe.

The OIE delegate expressed reservations, as the Berlin recommendation had not been adopted by the OIE Committee, but would be proposed at the next General Session of the OIE in May 1987. In view of the time factor involved, it was decided to proceed with the purchase of the vaccine and the campaign itself in anticipation that the recommendation would be adopted.

It was agreed that there should be closer cooperation with the Turkish authorities with respect to the FMD control programme, especially with respect to vaccine production and vaccination strategy. This would be discussed during the Twenty-seventh Session of the European Commission for the Control of Foot-and-Mouth Disease in April 1987, after which the FAO/EEC/OIE FMD group would send a mission to Turkey to pursue these matters.

The statement of accounts of the relevant Trust Funds were presented and accepted.

Table 1

Cattle and sheep vaccinated in buffer zone in Thrace and Marmara
in Turkey in 1986 campaigns
Spring campaign (March-April) 1986 cattle and sheep

THRACE	Cattle	Sheep
Edirne	76 884	355 674
Kirklareli	63 186	296 831
Tekirdag	59 663	246 924
Istanbul	102 562	100 192
TOTAL:	302 295	999 621
MARMARA	Cattle	Sheep
Canakkale	68 244	93 566
Balikesir	96 684	32 920
Bursa	95 430	22 918
Kocaeli	50 667	1 003
Sakarya	85 711	1 393
TOTAL:	396 736	151 800

Autumn Campaign (October-November) 1986 cattle only

	O ₁ /A ₂₂	Thrace area O ₁ /A ₂₂ /ASIA-1 vaccine
Istanbul	34 200	7 002
Tekirdag	—	63 000
Kirklareli	—	49 950
Edirne	—	90 000
TOTAL:	34 200	272 970
MARMARA	O ₁ /A ₂₂	Thrace area A ₂₂ /ASIA-1
Belikesir	90 000	
Bursa	72 000	
Canakkale	—	7 200
Sakarya	54 000	
Kocaeli (ismit)	45 000	
TOTAL:	261 000	7 200

Note: Number of vaccinated animals in autumn (October-November) 1986 did not yet arrive.

Vaccine: 1 cattle dose = 2.5 sheep dose

Breakdown of Income/Expenditure (Provisional) for Trust Funds 9111 (EEC) and 9097 (non-EEC) for the period 1 January 1985 - 1 December 1986

	<u>TF 9111 (EEC)</u>				
	<u>Income</u>	US\$		<u>Expenditure</u>	US\$
Balance <u>1/1/85</u>		27,465	Travel of Chairman and Secretary to Alexandroupolis and Brussels to discuss 1986 campaigns		2,195
<u>1/</u> Reimbursement from EEC:					
(a) 50,000 doses O/A ₂₂ vaccine for 1984 campaigns-Greece		25,000	<u>Vaccine</u>		
			(a) <u>Outstanding commitment</u>		
			on supply of ASIA-1 vaccine in <u>June 1984</u>		
			(doses: Greece 50,000 Bulgaria 150,000)		
			Total cost US\$ 47,619		
			of which US\$ 11,364 paid in 1984)		31,088
(b) 125,000 doses ASIA-1 vaccine for emergency vaccination in Greece during 1984 outbreak		25,957	(b) <u>Vaccination campaigns</u>		
			1985 (810,000 doses triv. A ₂₂ /O ₁ /ASIA-1 vaccine Turkey 500,000, Bulgaria 250,000, Greece 60,000)		
			Total charge US\$ 486,000		
			difference paid from TF 9097		29,989
EEC contribution (received October 1985)		635,944 <u>2/</u>			
Interest 1985		845	Project Servicing Costs on all items except vaccine		147
			<u>Vaccination campaigns</u>		
			1986 (810 doses triv. A ₂₂ /O ₁ /ASIA-1 vaccine: Turkey 500,000, Bulgaria 250,000, Greece 60,000)		525,801
					<u>589,220</u>
EEC contribution (received May 1986)		1,133,154			
Reimbursement from EEC - triv. FMD vaccine 60,000 doses for 1985 campaigns		36,000	Travel of Chairman and Secretary to Brussels to discuss 1987 campaigns		1,400
		<u>1,884,365</u>			<u>590,620</u>

BALANCE 1 December 1986 = US\$ 1,293,745

1/ Provisional charges

2/ Total amount requested from EEC US\$ 1,596,883 (DG's Appeal 1984)

Received: US\$ 635,944; due: US\$ 960,939

TF 9097

	<u>Income</u>		<u>Expenditure</u>	
		US\$		US\$
Balance 1/1/85		492,460	Vaccination campaigns	
<u>Received in 1985</u> ^{1/}			1985 (810,000 doses triv.	
Austria 30,555			A ₂₂ /O ₁ /ASIA-1 vaccine)	456,047
Hungary 22,518				
Finland 7,200				
		60,273		
Interest 1985		9,024		
		<u>561,757</u>		<u>456,047</u>
Balance		US\$ <u>105,710</u>		
1.12.86				

^{1/} Total amount requested from non-EEC countries (Director-General's Appeal 1984) US\$ 239,448 (Austria*, Finland*, Hungary*, Norway, Portugal, Sweden*, Yugoslavia*, Bulgaria, Switzerland, Spain)

* Contribution received.

Report on recent work at the FAO World Reference Laboratory

Investigation of samples submitted to the WRL for FMD virus identification has continued with results sent as monthly reports to the OIE/FAO. During 1985 240 samples were received from 24 countries and it was possible to identify the virus serotypes in 148 of them. As in previous reports virus of serotype O dominated in these samples (61%). Only 21 samples were suitable for direct typing (14.2%) and the remaining 127 samples required amplification in tissue culture. In 1986, 194 samples were received from 19 countries and positive typing results were obtained from 98 of these samples. Again virus of serotype O was most frequently recovered (63%). In the first three months of 1987 39 samples have been received from eight countries. Type O virus was recovered in 48% and type A in 38%. See Cumulative Reports for 1985/1986.

Virus of type O is circulating widely in the Middle East and this year, including recently received samples in April, the WRL has been sent samples from Bahrain, Saudi Arabia, Syria, Israel and Egypt. Work carried out indicates that the Bahrain, Israel and Saudi Arabian isolates are within the O₁/BFS spectrum of antigenicity, although there are differences between the isolates. The 1987 Israel isolates appear to be identical to the 1985 strain, but it is not yet clear how this virus is being maintained in the livestock population. The Syrian O strain has diverged from the O₁/BFS strain and shows some similarity to the India strain 53/79. Further investigations on this point are underway. Type O virus is also present in Kuwait and is probably surviving in the sheep population, appearing in cattle whenever the vaccination cover of the latter is not fully maintained. There is also some serological evidence to suggest that cattle are frequently in contact with field strains of type O.

Recently in Saudi Arabia there have been a small number of outbreaks of disease due to a variant of subtype A₂₂ virus and a WRL information sheet (No. 46: attached) has been distributed. The salient feature of these outbreaks has been the occurrence of disease in cattle vaccinated six to seven months previously with a quadrivalent vaccine containing antigen of serotypes of O, A₂₂, C and ASIA-1. The strain isolated undoubtedly belongs with the A₂₂ subgroup, but shows some antigenic variations from the A₂₂ Iraq reference strain. So far there is no evidence that the strain has occurred outside of Saudi Arabia. Virus of type A has also been isolated recently in samples from Bangladesh. This strain is antigenically similar to previous type A isolates and the A₂₂ Iraq vaccine strain should provide adequate protection.

The WRL is now using ELISA techniques, in addition to the micro-neutralization test, for the investigation of relationships between virus strains for epidemiological purposes, and also for the identification of the most appropriate vaccine strain for particular field situations. The ELISA methods have significantly reduced the time required to characterize the antigenicity of strains, as well as improving the reproducibility, sensitivity and economy of this work. Further comparisons with the previously established test systems are underway to fully validate the ELISA methodology for this purpose, and it is anticipated that the WRL will be able to offer a much improved service for strain characterization in the near future. The WRL would hope to have the full cooperation of those wishing to use this service in the provision of recent field isolates, and particularly from vaccine producers in making available to the WRL samples of their vaccinal strains and corresponding antisera.

ANIMAL VIRUS RESEARCH INSTITUTE

Pirbright, Woking, Surrey, GU24 0NF, U.K.

WORLD REFERENCE LABORATORY FOR FOOT-AND-MOUTH DISEASE

CUMULATIVE REPORT FOR 1985

During 1985, samples from 24 countries have been examined for types of virus. Virus was demonstrated in 148 of these samples and the types of virus recovered are tabulated below.

COUNTRY	NO. OF SAMPLES	O	A	C	SAT1	SAT2	SAT3	ASIA-1	SVD	NO VIRUS DETECTED
BAHRAIN	3	-	-	-	-	-	-	3	-	-
BHUTAN	1	1	-	-	-	-	-	-	-	-
BURUNDI	3	-	-	-	-	-	-	-	-	3
CAMEROON	10	-	7	-	-	-	-	-	-	3
HONG KONG	23	14	-	-	-	-	-	-	5	4
INDIA	2	-	2	-	-	-	-	-	-	-
IRAQ	7	4	2	-	-	-	-	1	-	-
ISRAEL	5	3	-	-	-	-	-	-	-	2
JORDAN	6	4	-	-	-	-	-	-	-	2
MALAWI	10	3	-	-	-	-	-	-	-	7
MALAYSIA	8	-	-	-	-	-	-	8	-	-
NEPAL	42	26	-	-	-	-	-	9	-	7
NIGERIA	4	-	-	-	-	-	-	-	-	4
OMAN	29	19	-	-	-	-	-	-	-	10
PAKISTAN	8	-	7	-	-	-	-	3	-	5
PHILIPPINES	4	-	-	1	-	-	-	-	-	3
SAUDI ARABIA	16	1	-	-	-	-	-	-	-	15
SUDAN	1	-	1	-	-	-	-	-	-	-
SYRIA	1	-	-	-	-	-	-	-	-	1
TANZANIA	1	1	-	-	-	-	-	-	-	-
TURKEY	10	5	4	-	-	-	-	-	-	1
UNITED KINGDOM	20	-	-	-	-	-	-	-	-	20
YEMEN	24	9	12	-	-	-	-	-	-	3
ZIMBABWE	2	-	-	-	-	-	-	-	-	2
TOTALS	240	90	28	1	-	-	-	24	5	92

21 OUT OF THE 148 POSITIVE SAMPLES (14.19%) WERE TYPED AS ORIGINAL SUSPENSION AND 127 (85.81%) AFTER TISSUE CULTURE.

ANIMAL VIRUS RESEARCH INSTITUTE
Pirbright, Woking, Surrey, GU24 ONF, U.K.

WORLD REFERENCE LABORATORY FOR FOOT-AND-MOUTH DISEASE
CUMULATIVE REPORT FOR 1986

During 1986, 194 samples from 19 countries have been examined for types of virus. Virus was demonstrated in 98 of these samples and the types of virus recovered are tabulated below.

COUNTRY	NO. OF SAMPLES	O	A	C	SAT1	SAT2	SAT3	ASIA 1	SVD	NO VIRUS DETECTED
BANGLADESH	1	-	-	-	-	-	-	-	-	1
BHUTAN	4	-	-	-	-	-	-	2	-	2
BURUNDI	10	1	-	-	-	4	-	-	-	5
CAMEROON	8	-	7	-	-	-	-	-	-	1
HONG KONG	4	4	-	-	-	-	-	-	-	-
KUWAIT	11	9	-	-	-	-	-	-	-	2
LIBERIA	1	-	-	-	-	-	-	-	-	1
MALAYSIA	5	-	-	-	-	-	-	3	-	2
NEPAL	54	18	3	-	-	-	-	1	-	32
NORTH YEMEN	25	17	-	-	-	-	-	-	-	8
PAKISTAN	3	-	-	-	-	-	-	-	-	3
QATAR	4	-	-	-	-	-	-	-	-	4
SAUDI ARABIA	32	7	15	-	-	-	-	-	-	10
SOUTH YEMEN	8	5	-	-	-	-	-	-	-	3
SUDAN	2	1	-	-	-	-	-	-	-	1
SYRIA	4	-	-	-	-	-	-	-	-	4
TANZANIA	1	-	-	-	-	1	-	-	-	-
UNITED KINGDOM	16	-	-	-	-	-	-	-	-	16
ZIMBABWE	1	-	-	-	-	-	-	-	-	1
TOTALS	194	62	25	-	-	5	-	6	-	96

36 OUT OF THE 98 POSITIVE SAMPLES (37%) WERE TYPED AS ORIGINAL SUSPENSION AND 62 (63%) AFTER TISSUE CULTURE.

WRL Information Sheet No. 46
Type A foot-and-mouth disease in Saudi Arabia in 1986

Samples from cattle with clinical signs of foot-and-mouth disease were received in September 1986 by the World Reference Laboratory from three farms in Saudi Arabia.

On the first farm, in Durma, approximately 65% of the herd were affected, 25 animals were reported to have shown severe symptoms.

On the second farm at Al Kharj, 80 miles south east of Druma, thirty 4-6 month old calves were affected and eight calves showed severe symptoms.

Cattle at both farms had been vaccinated approximately one month previously with a quadrivalent vaccine containing types O, A₂₂, C and ASIA-1.

In December 1986 FMD virus type "A" was isolated from samples received by the World Reference Laboratory, from cattle belonging to the College of Agriculture, King Saud University, Saudi Arabia. These animals had also been vaccinated 6-7 months previously with a quadrivalent vaccine containing types O, A₂₂, C and ASIA-1.

This information sheet reports results of unilateral serum neutralisation tests and polyacrylamide gel electrophoresis analysis.

Reference strains used:-

A ₅ France 1/68	received from IFFA Mérieux, France in 1968
A ₅ Parma	received from Istituto Zooprofilattico, Brescia, Italy
A ₂₂ Iraq	received from Dr. Barzanji in November 1964 as original material from an infected herd in Mosul, Iraq.
A ₂₄ Cruzeiro	received from Wellcome Laboratories, Pirbright, in 1975. The outbreak originally occurred in the state of Sao Paulo, Brasil in 1955.
A ₂₂ Marmatli	received from Wellcome, Pirbright in 1976. The outbreak occurred originally in March 1965 in Turkey.
Argentina 1981	received May 1984 from the Pan American Foot-and-Mouth Disease Centre.
Brasil 1979	received from the Pan American Foot-and-Mouth Disease Centre in 1982. The strain was isolated from an outbreak in Rio Grande do Sol, Brasil.

Field strains used:-

Saudi Arabia 12/86	received 4 September 1986 from an infected farm in Durma, Saudi Arabia.
Saudi Arabia 16/86	received 4 September 1986 from an infected farm in Al Kharj, Saudi Arabia.

Saudi Arabia 23/86 & 29/86 received 19 December 1986 from Dr Saleh El Mezaini, Department of Animal Resources, Riyadh, from infected cattle belonging to the college of Agriculture, King Saud University, Saudi Arabia.

Results:-

" r_1 " obtained between Saudi Arabia isolates SAU 12/86 and 16/86 and the reference strains listed below. (" r_1 " is the mean of 2-4 virus neutralisation tests).

	<u>SAU 12/86</u>	<u>SAU 16/86</u>
A ₅ France 1/68	< 0.1	< 0.1
A ₅ Parma	< 0.1	< 0.1
A ₂₂ Iraq 22/64	0.5	0.3
A ₂₄ Cruzeiro	0.1	< 0.1

From the one way neutralisation tests performed:-

- 1) SAU 12/86 and SAU 16/86 both belong to the A₂₂ subgroup, although they both show some antigenic variation from the A₂₂ Iraq reference strain.
- 2) The Saudi isolates show wide antigenic variation from the A₅ and A₂₄ reference strains.

Results:-

" r_1 " obtained between Saudi Arabia isolates 23/86 and 29/86 and the listed reference strains. Results are obtained from the mean of 2-5 unilateral neutralisation tests.

	<u>SAU 23/86</u>	<u>SAU 29/86</u>
A ₅ France	< 0.1	< 0.1
A ₂₂ Iraq	0.1	0.2
A ₂₂ Mahmatli	< 0.1	< 0.1
A ₂₄ Cruzeiro	< 0.1	< 0.1
Argentine 1981	< 0.1	< 0.1
Brazil 1979	< 0.1	< 0.1
A ₂₂ Iraq *	0.1	0.2

From the results:-

1) the Saudi Arabia isolates SAU 23/86 and SAU 29/86 are significantly different to the reference strains.

* Bovine convalescent sera.

Results of gel electrophoresis

The Saudi Arabia isolates SAU 12/86, 23/86 and 29/86 show differences in the structural polypeptide migration patterns when compared with the listed reference strains. However, the Saudi isolates show similar migration patterns to each other.

Activities of the Research Group during 1985 and 1986

The Research Group held two regular sessions during the biennium, one at the Pan-American Foot-and-Mouth Disease Center, Rio de Janeiro, Brasil, from 15 to 18 October 1985, and one in Madrid, Spain, from 14 to 17 October 1986. The reports of these Sessions have been distributed. The conclusions and recommendations are given hereunder:

A. Rio de Janeiro Session, 1985

The invitation to hold this session at the Pan-American Foot-and-Mouth Disease Center (PAFMDC) was extended to the Group on behalf of the Pan-American Health Organization (PAHO) by the Director of the PAFMDC and confirmed by the Director of PAHO. This was the first Session of the Group to be held outside of Europe since 1967, when a Session was held at the Plum Island Animal Disease Center, USA.

Item 1 - Evaluation of Vaccine Potency

The current importance of vaccine potency testing was emphasized with reference to the special interest of the producer, the controller, and the user, respectively.

As a generally accepted viewpoint, it was stated that as far as possible, vaccines should be evaluated in the species for which they are destined. Thus, for vaccines to be used for cattle, testing in cattle is the ultimate aim. The classical cattle tests were reviewed and evaluated.

Since, however, routine use of cattle is not always possible various alternative test methods, e.g. tests in guinea pigs and serological testing, were also evaluated with regard to advantages and limitations.

Although using different techniques and different methods, all papers confirmed the usefulness of such tests. Some of the results indicated that for certain virus strains further studies are needed for establishment of a significant correlation between antigen concentration of the vaccines and antibody response and percentage protection.

The presentation confirmed the valuable progress which has taken place over the years in the field of FMD vaccine potency testing. Nevertheless, the existing great variations in test systems from one laboratory to another makes the necessary comparisons between laboratories very difficult.

The discussion on vaccine potency testing also reflected the need for a standard vaccination strategy for calves with an unknown immunological status especially as regards residual maternal antibodies.

The number of vaccine producing plants has increased considerably in the cattle breeding countries of South America during the last years. More efficient vaccine control systems have been introduced by the National Control Authorities. Antigen is produced using either BHK cells or by the Frenkel method. Formaline and ethyleneimine are both used as inactivants. Most vaccines are formulated with an aluminium, gel - saponin adjuvant, but

the use of vaccine with oil adjuvants is gradually increasing. They are favoured for application in areas where FMD is presumably endemic. Different methods are applied for vaccine control. A comparison of results of mouse protection assays, serum, neutralization tests and challenge of cattle PD50 was presented which included about 10,000 cattle.

It was shown that a vaccine with oil adjuvant that had been stored at -70o for four years maintained its potency. This may provide a method for developing reference FMD vaccines, stable for long periods of time.

Mention was made of the use of oil adjuvanted vaccines in cattle. Because this vaccine has proven to elicit longer lasting immunity and good protection in young animals, its systematic use in cattle in primary endemic areas of South America where the livestock management is very extensive is becoming an important tool for FMD control and eradication.

It was recommended that future efforts in this field should be directed towards inter-laboratory harmonization of standard methods especially as regards the alternative and more economical serological methods for testing the potency of vaccines.

Item 2 - Characterization of strains of different subtypes

Modern immunological, biophysical and biochemical techniques presently available for FMDV characterization were reviewed by the U.K. representative. The ELISA methods have proved very adequate for rapid diagnosis of FMD. This test allows examination of large numbers of samples in 1-2 days. Among other advantages, the ELISA will successfully type samples containing much less antigen than that required in CF tests.

The use of monoclonal antibodies (MABs) may provide a detailed antigenic profile of each strain of FMDV thereby making it possible to assess the antigenic relationships between vaccine strains and field isolates. Exchange of MABs among laboratories is recommended.

Application of molecular biology techniques such as polyacrylamide gel electrophoresis, T1 oligonucleotide fingerprinting, isoelectrofocusing of viral proteins, and rapid sequencing methods, provide means of FMDV strain characterization. The potential value of such analyses in epidemiological studies was illustrated. However, the significance of the correlation between the results of biochemical tests and the biological properties of virus strains remains to be determined.

Item 3 - Items referred to the Research Group by the European Commission for the Control of Foot-and-Mouth Disease

- (a) Necessity to keep cattle vaccinated with AOC European vaccines for challenge with field virus to assess the effectiveness of vaccines used.

The Research Group was in favour of a scheme whereby in each country groups of cattle should be identified which had received either a single dose of vaccine or had been revaccinated, in both cases with the currently produced vaccine. These animals would be available for transfer to the National Control Laboratory for the assessment by challenge infection of the level of protection likely to be given by the vaccine against any new important strain of FMDV occurring in the field.

The Group also emphasized the value of the scheme initiated by the International Association for Biological Standardization in which various FMD Institutes have undertaken to produce and when necessary distribute samples of antisera from cattle and guinea pigs immunized with commercially produced monovalent vaccines currently available. Sera from animals which received either a single dose of vaccine or were revaccinated are available.

The Group strongly recommended national authorities to make use of these reagents in addition to the protection test mentioned above, in assessing the usefulness of existing vaccines against important new field strains.

(b) Harmonization of vaccine strains in Europe

The Group thought it premature at present to recommend an attempt to harmonize the vaccine strains currently in use in Europe. However, in view of the frequency and importance of outbreaks in recent years due to viruses of serotype A, the Group recommended that much more effort should be put into studies to define the antigenic relationships between currently used vaccine strains and as a second phase of these studies, the relationship between vaccine strains and recent European field strains of serotype A.

(c) Necessity to maintain seed virus stocks

The Group discussed the usefulness of the stock of exotic virus strains held at AVRI, Pirbright, as potential vaccine strains. It was agreed that it was very unlikely that these BHK adapted strains could be used by many vaccine manufacturers, since it was uncertain whether they would grow readily in the various lines of cells in industrial use and this factor applied particularly to the Frenkel culture system.

In addition since these strains had been selected and stored in 1970 it was probable that their relevance antigenically to strains presently in the field was small.

In view of the increased interest in Europe in the setting up of inactivated antigen banks for the rapid preparation of vaccine in case of emergency situations and the likelihood that a bank in Europe devoted to exotic strains of antigen would supersede the usefulness of the material stored at Pirbright, the Group thought it likely that the stored material could be discarded in the not too remote future. However, as a precaution against unforeseen events, it recommended that the stored material should be retained for one more year during which time it may become clearer that a European exotic antigen bank would eventually be set up.

FAO Collaborative Study

Following an invitation to participate in another phase of the Study (Phase VIII), favourable responses had been received from all the participants to the earlier phases. Sera from cattle given either a single dose of trivalent vaccine (01 Lausanne, C1 Vosges and A5 Allier) or from revaccinated animals was to be made available by Rhône-Mérieux, France. Samples of sera together with freeze-dried viruses of serotype A, both homologous and heterologous to the A5 Allier in the vaccine, would be distributed. The intention is for each laboratory to include these sera in their own routine tests and subsequently to provide data on their assessment of the neutralizing activity of the sera for comparison between laboratories.

Item 4 - Epidemiology of FMD in South America

A paper was presented on Vesicular Diseases, Epidemiological Surveillance and Information Systems established in the countries of South America to support FMD control programmes. In a first phase, from 1972 to 1978, the field implementation and training of personnel was accomplished. Starting in 1978, the analysis of the information was made to have a better understanding of the epidemiology of FMD. Data was presented of the several indicators which have been developed to monitor the temporal and geographical behaviour of the disease and to evaluate the effectiveness of the control programmes.

Item 5 - Any other business

It was stated that the PAFMDC has worked on oil adjuvanted FMD vaccine for cattle since 1968 in laboratory studies and field trials. The favourable results led to application of this vaccine in government field projects in several countries in South America. The experience of application in larger groups of animals in FMD control programs was also very positive.

Dr. Stouraitis, Secretary of the Commission, underlined the usefulness of this Session which had served as a forum for the exchange of scientific information on matters of common interest in the field of foot-and-mouth disease. He expressed the wish that this would further strengthen the valuable collaboration already existing between the FAO European Commission for the Control of Foot-and-Mouth Disease and the Pan American Foot-and-Mouth Disease Center.

B. Madrid Session, 1986

Item 2 - Immunity to FMD in young animals

From the discussions it was apparent that in countries where vaccination is carried out it is recognised that young cattle are among the most vulnerable to FMD infection around the time when maternal antibody is at a low level. Such animals constitute a special problem in international trade. Attempts to immunize young cattle may be unsuccessful since maternal antibody may suppress the response to vaccination. The degree of suppression appears to be directly correlated to the level of circulating antibody. Also there is a small number of animals which appear to be refractory and do not respond, even to repeated vaccinations. The most effective time for immunization follows the elimination of maternally derived antibodies. Recent evidence indicates that even at an age of up to six months some calves may still have sufficient antibody to reduce the effects of vaccination. At the same time it has to be recognized that there is a large proportion of the young animal population - especially around four months of age - which are without the protection given by maternally derived antibody and are, therefore, highly vulnerable to infection.

It is recommended that:

- 1) In animals with maternal antibody a minimum of two vaccinations with current vaccines will be required to produce an acceptable level of immunity.

- 2) The first vaccination should be delayed to allow elimination of as much of the maternally derived antibody as possible, but probably not much after calves have reached four months of age, since at that age a high proportion can be expected to be capable of an effective response to vaccination.
- 3) If the importing country requires vaccination, animals to be exported should be vaccinated in the country of origin at least once, preferably three weeks before departure. A second vaccination should be given after arrival in the importing country approximately 4 to 6 weeks after the previous vaccination.
- 4) There should be agreement between importing and exporting country as to the most appropriate vaccines, in terms of antigenic strains, types of adjuvant, level of vaccine potency and vaccination régime which should be used in animals to be exported. In addition, the results of sample tests to establish the immune status of young animals vaccinated as described above should be available for the benefit of the importing country.
- 5) It is clear there are significant gaps in the knowledge of this subject and further studies should be made to establish the most effective method of protecting young animals against FMD.
- 6) There is a need for a further exchange of information and ideas on this subject and it should therefore be included in an agenda for the next meeting of the Research Group.

Item 3 - Application of monoclonal antibodies to the characterization of FMD virus strains

Results on studies that were presented on this item justify the following conclusions:

1. If large enough panels of well characterized MABs are available they can be used for detailed analysis of antigenic characteristics of FMD viruses.
2. Panels used for characterization should include MABs that recognise different subtypes and are directed against different antigenic sites.
3. Characterization of MABs should involve the following:
 - a) determination of isotype
 - b) estimation of biological activity such as neutralization, affinity, and properties in different assay systems, including reactivity for viral subunits.
4. MABs have made a valuable contribution towards the identification of epitope sites on the FMD virion.

As stated in previous Sessions of the Research Group, it is recommended that scientists working in this field should continue to exchange reagents and experiences obtained with different MABs and further meetings should be held on a regular basis in order to facilitate this exchange of information.

Item 4 - Methodology for investigating the origin of infection in FMD outbreaks

a) Guideline for the investigation of the origin of infection in FMD outbreaks

The European Commission for the Control of FMD had requested the Group to prepare a guideline document for the use of Veterinary Services involved in the investigation of the origin of infection in FMD outbreaks. Towards this end a paper provided by Dr. M. Eskildsen, Denmark, (see Appendix 11).

b) Investigation of FMDV isolates from Spain, Argentina, and Colombia

Three papers were presented demonstrating the use of different laboratory techniques to characterize FMDV strains isolated during FMD outbreaks in Spain and South America.

The techniques employed were sequencing of the RNA encoding the antigenic region of VP₁ by primer extension and RNA analysis by T₁ oligonucleotide fingerprinting. The main findings were that variation in FMDV isolates was not restricted to the major antigenic site of VP₁ and that isolates with multiple non-identical sequences co-circulated during outbreaks. It was suggested that this heterogeneity of FMDV may pose a limitation to the efficiency of existing and future (synthetic) vaccines.

Two papers were presented on the serological and immunological characterization of strains of FMDV isolated in Argentina in 1983-85 and in Colombia in 1985. Both papers were presented by Dr. A. Fernandez. The isolates from Argentina in 1983-85 were also analysed biochemically by T₁ oligonucleotide mapping. Based on the range of tests used the most appropriate vaccine strains were selected for use in vaccines to control the outbreaks.

Item 5 - FAO Collaborative Study - Phase VIII

The Group agreed that future collaborative activity should be carried out in three stages, as follows:

- Stage 1. Completion of the A₅ testing, submission of results and analysis;
- Stage 2. Repetition of the 0 and A procedures using C virus and post-vaccinal C antisera;
- Stage 3. Production of a sufficient pool of trivalent post-vaccinal antiserum for distribution to collaborating laboratories for inclusion in their routine tests. Drs. Mowat and Lombard were requested by the Group to make an estimate of the short and long-term costs which this activity would involve and to submit this to the Secretary.

Item 6 - Requirements for innocuity testing - draft proposal for the European Pharmacopoeia

A draft document prepared by Drs. Barteling, Kilm and Donaldson was discussed by the Group. Certain modifications were proposed and a redrafting and circulation to members of the Group and other interested

parties before the next meeting was requested. The finalized text would then be submitted to the European Pharmacopoeia.

Item 7 - Prospects for new vaccines

Dr. Mowat reviewed the major developments seen in the production of FMD vaccines during the last 60 years and then outlined progress in which new and novel approaches have been made. In connection with the latter he illustrated the impact which new biochemical techniques have had on the understanding of the structure and function of FMD virus and how these have led to the development of a range of novel experimental products. Some success has been obtained under experimental conditions. There is, therefore, cause for guarded optimism. To date results suggest that while fusion proteins and synthetic peptides can stimulate a specific response, these agents are only weakly immunogenic and at present require to be potentiated in cattle by commercially unacceptable adjuvants. A better understanding of the tertiary structure of FMDV immunogenic sites and the production of structural copies in fusion proteins and synthetic peptides may improve their potency. The greater safety and stability of the new FMD vaccines based on these developments could be of considerable benefit but ultimately their success will be dependent on their ability to compete with traditional vaccines on a commercial basis.

Item 8 - Topics referred to the Research Group by the European Commission for the Control of Foot-and-Mouth Disease at previous sessions

Topic (1) - Identification of vaccine strains used in Europe; their serological relationship

The Group considered that the most appropriate way to obtain this information would be by means of a questionnaire sent by the Secretary through the National Authorities in Europe to laboratories handling FMD virus for vaccine production and testing. The information received would be discussed at the Session of the Research Group to be held in September 1987.

Topic (2) - Feasibility of evaluating the level of immunity in vaccinated animals in the buffer zone using serological tests

The Group was of the opinion that before any statistically valid serological analysis could be carried out on animals in the buffer zone it would be necessary to have data on the distribution of herds, herd composition and stocking density. The Secretary agreed to seek this information through the National Veterinary Authorities of the countries concerned (Bulgaria, Greece, Turkey).

Topic (3) - Seed virus stocks held at AVRI, Pirbright

The Group expressed the view that these strains are now no longer relevant, that their storage is an unnecessary expense and recommended that they should be disposed of.

Item 10 - Any other business

Date and place of next Session

Pending formal clearance from his Government, Dr. G. Dannacher extended an informal invitation to the Group to hold its next meeting in Lyons, France, during the second half of September 1987.

Items suggested for inclusion in the Provisional Agenda were:

- immunity to FMD in young animals, including pigs and small ruminants
- identification of vaccine strains, especially type A
- collaborative laboratory study
- further developments in the application of monoclonal antibodies
- the use of FMD vaccines in combination with other vaccines.

Closing remarks

In closing the Session, Dr. van Bekkum, on behalf of the Research Group, extended special thanks to Dr. Domingo and to the staff of the Subdirección General de Sanidad Animal for the excellent arrangements which had been made for the meeting, and for their active and valuable contribution to the discussions. He thanked all those who had contributed to the success of the meeting, including all the speakers, those who had presented papers, the drafting committees, the rapporteur and the secretariat.

Dr. van Bekkum informed the meeting that since he had officially retired it would be his last time chairing a Session of the Research Group. He took the opportunity to recall briefly his long association - since 1959 - with work in the field of FMD, and the outstanding progress made over the years especially through the sixties and seventies particularly at laboratory level where an amazing amount of development had been made in and knowledge acquired of vaccine production and vaccination. He referred to the composition of the Group with which he had had a long-standing association. Development had also been reflected in the composition of the Group which initially had been a small group of technical people which over the years had expanded to cover a broader spectrum, including biotechnology. He emphasized the fact that despite progress, a gap still existed between what the man in the field required and what science could offer and that this would continue to be the case for some time to come.

Referring to his term of office as Chairman and member of the Research Group, he stated that it had been a great pleasure for him to collaborate with other scientists in the field of FMD, and that he had very much appreciated the cooperation and assistance he had always received both from the Group and from the Secretariat.

On behalf of the Group, Dr. N. Mowat, Vice Chairman, thanked Dr. van Bekkum for his outstanding contribution to research in the field of FMD, and for his sterling qualities as Chairman during his period of office with the Research Group. The Secretariat of the Commission and the members of the Group wished him a long and happy retirement.

Methodology for investigating the origin of infection
in foot-and-mouth disease (FMD) outbreaks

Guidelines

Introduction

Tracing the origin of infection in FMD outbreaks requires both detailed knowledge of the identity of the field virus and comprehensive epidemiological information.

Antigenic variation among foot-and-mouth disease (FMD) viruses which encompasses seven different serotypes and more than 60 subtypes, is the current basis for the identification of FMDV isolates. The distinction between subtypes, which was clear in early studies, has become progressively more difficult as the number of strains investigated has increased and techniques have become more sensitive.

The molecular basis for diversity in classical subtyping stems from change in the viral genome during the replication of the virus. During replication the proteins in the viral capsid are subjected to change, the consequence of this being the occurrence of antigenic variation within subtypes (antigenic "drift").

It therefore follows that the identification of a field isolate and its possible origin should include a detailed characterization of the isolate using different parameters and its comparison with other relevant strains.

Serological techniques (e.g. complement fixation, neutralization test and ELISA) using polyclonal antibodies are of great use for the classification of virus isolates. However, for tracing the origin of an outbreak more precise methods are available. These include ELISA and neutralization tests, in which monoclonal antibodies are incorporated, as well as recently developed biochemical methods. This combination of tests provides the possibility of the characterization of the outbreak virus at the molecular level.

Since FMDV is genetically highly variable, complete identity between field strains which are epidemiologically related may not be found. Identification of the origin of an isolate may often therefore, have to be expressed in terms of probable evolutionary link(s) deduced from comparative serological and biochemical results as well as from epidemiological investigation.

Four annexes:

1. Epidemiological investigation
2. Characterization of FMDV isolates
3. An example of the outcome of comprehensive epidemiological investigation in each case of an outbreak.
4. Selected references.

Guidelines

In view of the potential of FMD for rapid spread, speed is essential to minimize the risk of complications arising from possible secondary spreading. A successful outcome of control operations is dependant on the full cooperation of herd owners and field veterinarians, the Veterinary Service and the diagnostic laboratory. Additional support may be needed from meteorologists, aerobiologists and statisticians.

The action to be taken includes:

A. Collection of epidemiological data:

(for details: see Annex 1)

1. Systematic examination and registration of data about the infected premises.
2. Collection of data about the surrounding farms.
3. Collection and analysis of meteorological data for the local area as well as for relevant neighbouring and more remote locations, i.e. surrounding countries.
4. Evaluation of conditions for airborne spread both in the period prior to the outbreak and afterwards.
5. Review of all importations of cloven-hoofed animals, meat and meat products.
6. It may be necessary to supplement these investigations with serological surveys and/or virological investigations such as probang-testing of selected domesticated animals and wildlife.

B. Characterization of the field isolate:

(For details: see Annex 2)

Sample collection and submission

At the earliest possible occasion the National Laboratory should send a sample of virus from the primary case to the World Reference Laboratory (WRL) for confirmation and further characterization. Ideally an aliquot of field material should be sent, but if this is not possible animal passage material, obtained from the original host species, or low cell culture passage material is acceptable. The history of animal or cell passage material should be provided.

In anticipation of a possible case of FMD the appropriate equipment for sample collection and transportation to the National Laboratory (and the WRL) should be stored in readiness locally. (Instructions for the procedures for collecting and transporting of FMD specimens to the WRL are provided by Kitching R.P. and Donaldson, A.I. in the OIE Publication Rev. Sci. Tech. In press XX 1987).

In case of an epizootic, selected field isolates can also be sent to the WRL for characterization. The number of isolates sent should be limited to field isolates from selected cases where epidemiological investigations have not revealed a probable link with a previous case.

Laboratory testing:

1. Determination of serological relationships ("r₁" values) of the field isolate(s) with virus strains of epidemiological relevance including current vaccine strains.

Production of antiserum against the field isolate taken from the first case of an outbreak for later complete serological characterization.

2. Comparative serological characterization using panels of monoclonal antibodies (ELISA).
3. Electrofocusing analyses comparing the isolate with the same reference strains as in the serological tests.
4. T₁-mapping for further comparison of the isolate with selected strains of epidemiological importance as indicated in the electrofocusing and serological tests.
5. Sequencing of the bases of the viral nucleic acid.

Epidemiological investigation

The selection of relevant reference virus strains for the comparative serological and biochemical characterization of field virus implies a thorough knowledge of the current epidemiological situation. Likewise, the collection of comprehensive epidemiological data is of utmost importance in order to deduce any probable links between FMD outbreaks/cases.

The necessary epidemiological data includes:

- comprehensive information about the current FMD situation, internationally and nationally: It is of special importance to know the location of any infected herds within the country as well as in neighbouring countries, and details about herd size and animal species involved (cattle/swine), vaccination strategy, immunity level in the animal population, vaccines used (virus strains, inactivant), animal movements etc.
- meteorological conditions during the preceding 3 - 4 weeks in the local area as well as in more remote locations with possible outbreaks, including information about wind speed, wind direction, relative humidity, temperature, topography (land/sea) etc.
- estimation of basic conditions for airborne spread such as high virus output from possible sources (e.g. infected pig herds), low virus dispersion, high virus survival, operation of prediction models.
- importation of cloven-hoofed animals, meat and meat products (origin, port of entry and destination).

Particular information about the infected premises:

- precise location (map references) of the infected premises (name, telephone number and mailing address of the herd owner).
- person (or team) assigned to herd investigation.
- time notified, date and time of investigation.
- a detailed analysis of the current FMD vaccination history of the herd.
- first day of sickness, clinical signs observed by the owner, number of animals with clinical signs.
- result of systematic clinical examinations made by the official investigator (or team) including number of affected animals, estimates of age of lesions and estimated date of infection.
- possible presence of animals with subclinical infection - with special attention to sheep and goats (probang-testing and/or serology).
- diagram of the buildings with location of the animals(s) first seen to be sick, ventilation systems, open windows and doors, pickup points for milk and animals for movement off the premises.

- farm management: herd size and species, feeding of animals, use of skim milk, water supply, purchase and sale of animals, handling of manure, maintenance of buildings.
- use of drugs and biological products including vaccines.
- the status of domesticated non-cloven hoofed animals and pets, rodents, wildlife and arthropods.
- data on all contacts into the herd during a 3-4 weeks period prior to the first signs of illness, including all animal movements, animal products, milk collection, animal hauliers, farm equipment, feed suppliers, visits by veterinarians, agricultural adviser, A.I.-personnel, service and repair personnel, livestock dealers, butcher, and all other visitors.
- data on all contacts, including visits, off the infected premises during 3-4 weeks prior to the first signs of illness.
- investigation of the health status of animals in surrounding farms, especially with regard to FMD - taking all necessary steps to ensure that this operation does not cause the secondary spread of infection.
- vaccination history of surrounding herds.

In addition to the above investigations and collection of data, serological surveys and/or virological investigation (probang-testing) in suspect-infected herds (including selected imported animals) and wildlife may be needed to disclose other undetected foci.

It is important that members of the Veterinary Service field staff are fully aware of the methods of FMD sample collection and transportation and have had the opportunity of observing clinical FMD at regular intervals, even if only under laboratory conditions.

An example of the outcome of a comprehensive epidemiological investigation in each single case of an outbreak is shown in Annex 3.

Characterization of FMDV isolates

Serological examination

1. Complement fixation (CF) and neutralization tests

The use of CF and neutralization tests to establish antigenic relationships between FMDV strains is well documented, and in the course of time these test systems have been modified and improved (e.g. development of quantitative CF and two-dimensional micro-neutralization tests). In general the two test methods show good correlation.

The antigenic relationships obtained in these assay systems are based on differences between homologous and heterologous reactions expressed as ratios (r_1 and r_2 , respectively). A reciprocal relationship can be calculated as a percentage ($R = 100 \frac{r_1}{r_2}$). Arbitrary levels of these values have been used to indicate type and subtype differences.

The " r_1 " values with relevant reference strains can be obtained shortly after receipt of the field material, whereas the " r_2 " and "R" values, (required for a complete serological characterization of the isolate), must await the production of a specific antiserum against the isolate. If available, convalescent field sera may be used for the establishment of " r_2 " values.

It is important to notice that the results obtained should be interpreted with care. Unequal "r" values, i.e. one-way cross-reactions are not infrequently observed, and it may be necessary to include a "dominance" factor in the calculations.

2. ELISA

In recent years various enzyme-linked immunosorbent assays for FMDV have been described. These have been adapted for typing and differentiation of FMDV strains. Similar antigenic relationships between virus strains ("r" and "R" values) can be obtained using ELISA systems as in the classical serological tests. In addition, ELISA offers considerable advantage compared to classical tests: it is much more sensitive; it requires smaller amounts of reagents; it requires less time; and it is easily adapted for large-scale investigations.

There is a wide range of modified ELISA methods, so proper correlation with a standard serological test system should be established before adapting any special ELISA.

3. Monoclonal antibodies

By including relevant monoclonal antibodies in the test system, the ELISA can be used for the characterization of virus strains at the single epitope level, thus greatly increasing the precision of the reactions.

4. Cross immunity test

Cross immunity testing in animals was originally used as the basis of FMDV type differentiation. Although now generally restricted to immunoprophylactic purposes it may still be of value when investigating virus evolution and the origin of outbreaks.

Biochemical characterization

The dramatic increase in knowledge of molecular biology during the last decades has led to the development of biochemical methods for the rapid characterization of the genome and capsid proteins of FMDV respectively:

1. Electrofocusing test

This test system provides a sensitive and rapid method for comparing closely related strains by electrophoretic separation of the virus-induced polypeptides in polyacrylamide gels according to their isoelectric points. This is achieved by a pH gradient across the gels. It can reveal single charge change in the amino acid composition of the polypeptides.

2. T₁-mapping

This technique relies on the extreme specificity of the enzyme RNase T₁, which cleaves RNA at guanine residues. The resulting mixture of oligonucleotides can then be separated by electrophoresis in a polyacrylamide gel - in the first dimension on the basis of charge of the individual oligonucleotides, and in the second dimension on the basis of their size. Each RNA gives its own distinct pattern or "fingerprint".

It should be recognized, however, that T₁-maps and the serological/immunological relationship of FMD strains can vary independently.

The more rapid one-dimensional mapping of ribonuclease T₁ hydrolysates may also be useful.

3. Sequencing of the bases of the viral nucleic acid is a promising recent development providing useful information on the genetic map of a virus.

Annex 3

Probable epidemiological links between FMD cases during the 1982 epizootic in Denmark established by comprehensive epidemiological investigation in each single case:

Epidemiological links	Case numbers	Number of cases
Vehicles	10, 16, 17	
	19, 20, 21	6
Persons	2, 3, 4, 6,	6
	8, 13	
Local area spread	7, 9, 12	5
	14, 15	
Airborne spread	1, 18	2
No link established	5, 11, 22	3
Total		22

Transmission of virus by vehicles was connected with milk collection and the transportation to slaughter of pigs which were in the disease incubation period.

The term "local area spread" refers to a situation where a known source is located within a distance of 2 km from an infected herd, and where the spread of virus from this known source might have occurred in different ways, e.g. via the air, arthropods or rodents.

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Guide to the economic evaluation of FMD vaccination programmes

This guide has been formulated by a group of veterinarians, economists and statisticians from several European countries. It compares the likely costs of two policies for controlling foot-and-mouth disease:

- a) prophylactic vaccination of the national cattle herd and
- b) stamping out of all susceptible animals in infected herds.

Two versions of the guide have been produced - a shorter version for veterinary administrators and the full version, which includes various mathematical formulae, which should be used by economists and others engaged on a cost-effectiveness evaluation.

A draft of the guide was presented to the Twenty-sixth Session of the FAO European Commission for the Control of Foot-and-Mouth Disease in April 1985, and after it was accepted seven countries volunteered to explore the feasibility of using the guide to review their FMD control programmes. These countries were:

Countries using vaccination
Federal Republic of Germany
Netherlands
Spain
Switzerland

Countries using "stamping-out"
Finland
Ireland
United Kingdom

Copies of the studies produced can be obtained from FAO, Rome if required.

The results of this exercise were discussed by the Working Group at a meeting held at Pirbright, UK in September 1986. All the participants found that the guide provided a practical basis for evaluating control programmes but they commented on three areas of the evaluation and these have been included as **ADDENDA 1 - 3** in the guide.

The first comment was that certain of the costs are insignificant and if they cannot be easily calculated then they should be ignored (**ADDENDUM 1**).

The second comment was that effects on the export trade are difficult if not impossible to evaluate. Suggested approaches to export costs are given in **ADDENDUM 2**.

The third comment was that the large number of economic and epidemiological variables involved in such a study are more easily and quickly handled using computer modelling techniques. These are briefly described in **ADDENDUM 3**.

Introduction

1. This document sets out a model cost-effectiveness study for European countries wishing to carry out economic analyses before taking decisions on their vaccination strategies for controlling FMD.

The analytical framework

2. It is assumed that FMD is an external threat to the national herd which manifests itself as a random outbreak and that no European country would contemplate allowing FMD to become endemic. It is further assumed that each national government is faced with two alternatives:

- a) routine prophylactic vaccination of a large proportion of the national herd.
- b) stamping out the disease by slaughtering all susceptible stock on infected holdings with or without ring vaccination.

Finally it assumes that, in the European situation, neither of these alternative policies would allow FMD epidemics so massive as to result in complete disruption of the domestic markets in meat, milk and other animal products.

3. The purpose of the analysis is to determine which is the better of the two alternatives for the country concerned. For this, the costs of both alternatives are calculated and compared. In order to make the comparison as simple as possible, these costs should be calculated and compared on an annual basis (see NOTE 1). The major cost elements of the two policies are set out in Table 1.

4. The costs that are identical to both alternatives are excluded from the analysis. Thus the national veterinary service will maintain a disease surveillance system, including diagnostic facilities, irrespective of whether there is a national vaccination scheme. Likewise outbreaks of FMD due to strains not normally found in Europe (eg ASIA-1) may occur under either policy and are excluded from this analysis.

The cost of vaccination programmes

Vaccine costs

5. These include:

- (i) The cost of the number of doses of vaccine required to vaccinate the proportion of the national herd covered by the programme. When calculating this the cost per dose is the price paid to the manufacturer plus any subsidy on vaccine sales and less any sales taxes. Such taxes and subsidies are internal transfer payments which do not affect the national resource cost of vaccine. The estimated number of doses required should be adjusted to include an allowance for wastage.
- (ii) The cost of any potency and safety tests undertaken by the veterinary service in addition to those undertaken by the manufacturer.
- (iii) The cost of handling and storing the vaccine before use.
- (iv) The cost of an emergency store of vaccine (see ADDENDUM 1). This is the annual cost of maintaining a strategic store of vaccine for use in case of outbreaks of the disease. Calculation of the cost of vaccine should be made according to the principles laid down in 5(i)-(iii) above.

Table 1. The costs of the alternative policies

Routine vaccination		Stamping out	
<u>Vaccination programme</u>	See paragraph	Maintaining a strategic bank of vaccine	See paragraph
Vaccine (including emergency vaccine bank) and storage	5	Vaccine and storage	8
Vaccination	6		
*Side effects	7		
<u>FMD outbreaks</u>	9	<u>FMD outbreaks</u>	9
*Controlling outbreaks including ring vaccination (if carried out)	10	*Controlling outbreaks including ring vaccination (if carried out)	10
*Slaughtered animals	11-12	*Slaughtered animals	11-12
*Loss of production	13	*Loss of production	13
*Interruption of domestic trade	14-17	*Interruption of domestic trade	14-17
<u>Loss of export trade</u>	18-19	<u>Loss of export trade</u>	18-19
Effect of national vaccination status		*Effect of change in national vaccination status if ring vaccination used	
*Effect of outbreaks		*Effect of outbreaks	

* Denotes costs which are uncertain.

Vaccination costs

6. This is the cost of visiting the farm and vaccinating the animals. Where this work is delegated to veterinary surgeons or lay vaccinators that are not in government employment this cost is the payments to these people plus relevant administration costs. Where the vaccination is undertaken by government staff the cost consists of the total hourly cost of employing the staff concerned plus the cost of administrative overheads together with that of travel to and from the farm.

Side-effects

7. These include:

- (i) The cost of temporary loss of milk yield, allergic reactions, abortions and other reactions that occur as a direct result of vaccination.
- (ii) The costs of FMD outbreaks which are side effects from the manufacture or use of vaccines. The best way of allowing for this cost is to include it under the cost of FMD outbreaks which occur despite routine vaccination. This can be done by adjusting the number of outbreaks which occur despite routine vaccination (eg amongst young animals and other unvaccinated stock) to include those which occur because of it.

The cost of maintaining a strategic store of vaccine

8. The principles underlying the calculation of this cost are identical to those laid down in para 5(iv). These costs include the purchase price of the vaccine and the maintenance of the storage facilities.

The cost of FMD outbreaks

9. In this paper an outbreak is an occurrence of disease in an agricultural establishment, breeding establishment or premises, including all buildings and adjoining premises - (OIE definition).

The cost of controlling outbreaks or series of outbreaks (epidemics)

10. This consists of the cost of carrying out control procedures on all holdings where FMD is diagnosed and the cost of all control procedures elsewhere.

- (i) The cost of control procedures on the holdings where FMD is diagnosed include:
 - Slaughter and disposal of carcasses;
 - Disinfection;
 - Destruction or handling of possible fomites;
 - Valuing stock for compensation purposes;
 - Other tasks.

Where these tasks require government staff time, administration or transportation these costs must be included.

- (ii) The cost of any ring vaccination carried out. (see the costs of vaccination outlined in para 5).

(iii) The cost of general control procedures which include:

- Diagnosing disease and carrying out epidemiological investigations,
- Tracing infection
- Administering quarantine and other controls
- Administrative support.

The cost of slaughtered animals

11. The analysis assumes that if FMD is diagnosed on a holding all susceptible stock are slaughtered. The cost therefore consists of the total value of the susceptible livestock on all holdings where FMD has been diagnosed (the cost of carrying out the slaughter and disposal of carcasses is included under 10(i) above. The value of the animals will depend on their age, class and condition and will be the total value of all susceptible animals which are slaughtered or die of FMD (see NOTE 2 on methods of valuation).

12. If any value-added is lost by the processing industries and distribution trades this must also be included in the cost of slaughtered animals (if imports are drawn in as a substitute then the loss of value added is reduced).

13. The cost of lost production

(i) On the holding:

This is the cost of the delay before restocking can take place on holdings where livestock have been slaughtered due to FMD. This delay means that all future receipts from sales of livestock and all future variable costs are delayed. Fixed costs are not affected. The delay is effectively a delay of all future gross margins. NOTE 3 attached describes how the cost of this delay can be calculated.

(ii) To the processing industries and distribution trades:

This is the cost of the delay in the receipt of the value added from processing and distributing products from livestock whose production has been delayed. (A formula for calculating this cost is given in NOTE 4).

The cost of interruption of domestic trade (see ADDENDUM 1)

14. Following an outbreak of FMD, domestic trade in livestock and livestock products is likely to be reduced or to cease altogether for a short period. If sales of milk from any holdings are temporarily prohibited then the cost of this is the total value of the sales concerned. (NOTE 2 sets out a method for valuing livestock. A similar method should be applied to milk). Sales of livestock and meat however are delayed rather than permanently lost.

15. For farmers, this delay means that all future receipts from sales of livestock are delayed whilst fixed and variable costs are unaffected. NOTE 5 describes how the cost of the delay in farmer's receipts is calculated.

16. For the processing and distribution industries, the delay in sales of both livestock and meat will cause a delay in the receipt of the value-added from the sales concerned. NOTE 6 describes how this cost is calculated.

17. Estimating the quantity of meat and the number of animals whose sale is delayed may be extremely difficult. If so it will be important to examine the effect of alternative assumptions as part of a scenario or critical point analysis (see later).

Loss of export trade (see ADDENDUM 2)

18. A country's (or region's) exports of susceptible animals and of meat from such animals are temporarily banned following an outbreak of FMD. Some importing countries also ban imports of susceptible animals from places in which any livestock has been vaccinated in recent years; in such cases routine vaccination results in a ban on imports of livestock which is permanent unless the policy is changed. Ring vaccination under a stamping-out policy may also hinder exports of animals and agricultural products. Limited bans of short duration may have little effect on the trade in animals or in meat but bans lasting more than a year might well result in a sustained reduction in a country's share of export markets or the complete loss of some markets.

19. The consequences of the bans will be felt (to a greater or lesser degree depending on the importance of the export trade) in the disruption of the domestic markets and of the industry in the exporting country concerned; its potential for developing its export trade will also receive a setback. These costs against which must be set any related benefits such as lower domestic consumer prices for meat because of the forced temporary over-supply of the domestic market, cannot be quantified. They may be of marginal importance for minor exporting countries but will be serious for major exporting countries and must always be taken into account in reaching the final policy decision.

The comparison of the alternative policies

20. The cost-effectiveness study of national FMD policies compares two alternatives: routine vaccination and stamping out. Provided that both their total costs are known with certainty, then the cheaper policy is the best (allowing for non-measurables such as loss of export trade). Unfortunately it is impossible to be certain about the costs because of the random nature of outbreaks of the disease, uncertainty over the size of herds where the outbreaks will occur or which might have to be vaccinated and uncertainty over the extent to which the disease will spread. A further problem is error in the measurement of values for slaughtered livestock and other variables.

21. The conventional way of handling such problems is sensitivity analysis. This is the use of alternative assumptions about the values of the uncertain variables to see how these affect the results. This requires knowledge of the set of values which the uncertain variables can take and the probabilities with which these values are likely to occur. To avoid the many difficulties associated with attempts to specify these probabilities, two approaches are recommended:

- a. scenario analysis
- b. critical point analysis

See ADDENDUM 3 concerning the use of computer modelling as an end to these analyses.

Scenario analysis

22. This involves the construction of two sets of alternative scenarios, one for each policy. Each scenario consists of a set of values for all the variables which enter into the calculation of the costs of the two policies. For a given policy the values of the uncertain variables will vary between scenarios whilst those of the certain variables do not change. Usually at least three alternative values will be used for each uncertain variable under each policy: the most likely value and two extreme values (high and low). Every possible combination of values for the uncertain variables is then used to generate the two sets of scenarios for the two policies.

23. The next step is to calculate the total costs of each policy under each of its own scenarios. In order to simplify the analysis, it is necessary to restrict the number of scenarios at this stage. However, care must be taken to leave out intermediate rather than the worst and best cases. The cost of the worst cases must always be evaluated, however slight the risk may be. Despite this precaution the accuracy of scenario analysis can be seriously affected by restricting the number of scenarios in the analysis.

24. The final step is to compare the sets of total costs that have been calculated for the two policies under the alternative scenarios. Normally this will show that routine vaccination is cheaper under some scenarios whilst stamping out is cheaper under others. There may be scenarios where the costs of the two policies are broadly equivalent. A decision is taken on the basis of the above information together with some consideration of the probability of the various scenarios occurring and the acceptability of the risks involved. It is possible, for example, that stamping out might be the cheapest under all scenarios except those assuming a very large number of outbreaks, but the risk of such major epidemics occurring might be judged to be unacceptable. One would then decide in favour of routine vaccination.

Critical point analysis

25. This method estimates the critical point at which the costs of one policy equal those of the other.

26. The first step is similar to scenario analysis in that scenarios are constructed but differs in that scenarios are only needed for one of the two policies, subsequently referred to as policy A. This policy should be the one whose possible effects are the most uncertain (because the risks involved are most difficult to establish) and usually this will be the policy which is not in current use, since there is no experience on which to draw.

27. Having constructed the alternative scenarios for policy A, the total cost of policy A is calculated under each one. Thereafter for each scenario of Policy A, the critical number of outbreaks under policy B is calculated from the following formula:

$$N = \frac{TCA - TFCB}{VCB}$$

where N is the critical number of outbreaks under policy B

TCA is the total cost of policy A for a given scenario

TFCB is the total fixed costs of policy B which do not vary with the number of outbreaks.

VCB is the variable cost (ie excluding the fixed cost) under policy B when only one outbreak is assumed.

28. In order to calculate VCB it will be necessary to make some assumptions about the values of other uncertain variables such as the size of the outbreak (ie the number of animals in the infected herd). Initially the most likely values could be used for these variables. Thus one might assume that the infected herd is of average size for the country concerned. The effect of alternative assumptions for these variables on the critical number of outbreaks (N) should also be considered.

29. The basic rule for making the final decision is to choose Policy A if the number of outbreaks which one would expect to take place under policy B is greater than all values of N. If it is less than all values of the N the rule is to choose Policy B. If the results are mixed then one must consider the probability of each scenario occurring.

30. The above rule should only be followed if one is willing to take the risk that the actual number of outbreaks may not be as expected. For example, if the number of outbreaks is expected to be less than the critical level N one can only choose policy B if one is willing to take the risk that the actual number of outbreaks may turn out to exceed the critical level.

31. Examples of scenario analysis and critical point analysis are given in annexes 1 and 2. In principle both techniques should produce identical results. In practice however this will not always be the case because critical point analysis is likely to be more accurate. Moreover, decisions are easier to take when this technique is used. Whenever scenario analysis is used, it is desirable to carry out a critical point analysis as well in order to check the results.

NOTES

1. It is assumed that neither policy requires investment in capital assets which could not potentially be used for the alternative policy. Thus one could switch from either policy to the other after a single year without having to dispose of any capital equipment which would no longer be needed.

2. In European Community (EC) countries livestock would be valued at the national farmgate price less the cost per animal of the national share of EC support measures under the Common Agricultural Policy. In other European countries, livestock should be valued at national farmgate prices less the effect of any national support measures (eg tariffs, import quotas, production quotas, production subsidies, headage payments etc.) which raise national prices above notional world prices.

3. Gross margins vary with the type of livestock. For each type of livestock slaughtered the cost of the delay before re-stocking is calculated as the discounted present value of all future gross margins from these animals less the same figure further discounted for the delay before re-stocking. The formula for this is:-

$$\frac{1}{d} \left[1 - \left(\frac{1}{(1+d)^n} \right) \right] \times \begin{array}{l} \text{gross margin} \\ \text{per animal} \end{array} \times \begin{array}{l} \text{number of animals} \\ \text{slaughtered (due to FMD)} \\ \text{or which die of FMD} \end{array}$$

where d is the discount rate and n is the delay before restocking can take place. A discount rate (d) of 5% would be represented in the formula by 0.05. The delay (n) is expressed as a proportion of a year so that three months would be represented by 0.25.

4. The amount of value added by the processing industry varies with the type of livestock. For each type of livestock slaughtered the cost of the delay in the receipt of the value added is:

$$\frac{1}{d} \left[1 - \left(\frac{1}{(1+d)^n} \right) \right] \times \begin{array}{l} \text{value added} \\ \text{per animal by} \\ \text{the processing} \\ \text{and distribution} \\ \text{industries} \end{array} \times \begin{array}{l} \text{number of animals} \\ \text{slaughtered (due to FMD)} \\ \text{or which die of FMD} \end{array}$$

where d and n are the same as in NOTE 2.

5. The value of animals whose sale is delayed will depend on their age, class and condition. For each type of animal, the cost of the delayed receipts is their discounted value less the same figure discounted further for the delay. The formula for this is:-

$$\frac{1}{d} \left[1 - \left(\frac{1}{(1+d)^n} \right) \right] \times \begin{array}{l} \text{value of one} \\ \text{animal} \end{array} \times \begin{array}{l} \text{number of animals} \\ \text{whose sale is delayed} \end{array}$$

6. The value added by the processing and distribution industries will vary with the type of meat and livestock sales. For a given type, the cost is calculated as:-

$$\frac{1}{d} \left[1 - \left(\frac{1}{(1+d)^n} \right) \right] \times \begin{array}{l} \text{value added} \\ \text{per animal} \\ \text{(or per tonne} \\ \text{of meat)} \end{array} \times \begin{array}{l} \text{number of animals} \\ \text{whose sale is delayed} \\ \text{(or quantity of meat} \\ \text{in tonnes)} \end{array}$$

ADDENDA

ADDENDUM 1 INSIGNIFICANT COSTS

The seven country group experts which used the guide to evaluate their national FMD control programmes considered that the following costs were usually insignificant and could be omitted from the calculations:

- a) THE COST OF INTERRUPTION OF DOMESTIC TRADE following an outbreak of FMD. The cost to farmers near an outbreak but not directly involved and the costs to the processing and distribution trades are difficult to calculate but are probably fairly small. The exception to this is a domestic economy heavily reliant on agriculture where an outbreak of FMD can have major "knock-on" effects in the national economy.
- b) THE COST OF A VACCINE BANK

This is a minor cost and can be omitted from the calculations.

ADDENDUM 2 COSTS WHICH ARE DIFFICULT TO CALCULATE: EXPORT COSTS

The experience of the 7-nation group of experts is that effects on export trade are extremely difficult to calculate:

1. One approach to this problem is to calculate the value of national exports of animals and animal products and then assume that a proportion of that trade is lost or gained in the event of a change of status. This can be no more than an assumption as the reaction of trading partners to a change in disease (or vaccination) status is often unknown and the range of agricultural products embargoed may vary widely even including such products as flower bulbs.
2. It is often assumed that a change of status will lead to a small and predictable increase in an export trade which is relatively static. However, a change in status may allow a country to realise major export opportunities in a rapidly fluctuating world market and these opportunities should not be forgotten in the overall analyses.
3. Export losses that are assumed to arise as a result of widespread disease or vaccination may not in fact occur. This is because:
 - a) trade may shift so that exports lost to one market may be diverted to another
 - b) a loss of exports may result in a fall in domestic prices and therefore a gain for the consumer. In EEC member states the Commission might overcome this by intervention measures.

The 7-nation group agreed that certain broad statements can be made about the effect of disease or vaccination status on export trade:

1. For countries where the export trade in animals and animal products is a significant part of the economy a change in status may have major effects on trade. In general continuous prophylactic

vaccination of the national herd has a greater negative effect on exports than does the occasional outbreak of FMD. If however, a country experiences a more or less continuous series of minor outbreaks of FMD or a major epidemic it may be regarded as an "endemic area" by its trading partners and this would have a greater effect than vaccination.

2. For countries where the export trade in animals and animal products is relatively unimportant compared with the domestic trade in these items, the export effects of "vaccination" status may not differ greatly from that of "disease" status. Several countries found that this difference was so small as to have no overall effect on the economic analyses and thus export effects could safely be ignored.

ADDENDUM 3 COMPUTER MODELLING AS AID TO ASSESSMENT OF POLICIES

The experts in several of the seven countries that have used the guide have employed computer modelling techniques and have found them of value in several ways:

- a) To assess the number of outbreaks that may occur under a given strategy. Whilst the number of primary outbreaks which may occur in a country is dependent on the risk of importing disease and the chance of vaccine - related infection, the subsequent number of secondary outbreaks depends on such factors as population density, speed of detection, and the proportion of susceptible herds or animals. These factors can be incorporated in a model and a model using data from the 1967/68 epidemic in the UK has been constructed by MILLAR (1979). The Dutch and Swiss experts used this model employing the British data and empirical data from outbreaks in the Netherlands. Details are available from Dr. Dijkhuizen, Department of Farm Management, Agricultural University Wageningen, Netherlands or from Dr. Meyer, Institute for Agricultural Economics, ETH Zurich.
- b) To calculate the economic effects of a range of strategies. A large number of cost variables are involved in each calculation eg vaccine cost, value of slaughtered animals, herd sizes, cost of administrative procedures and these variables can be included in an economic spreadsheet calculator or model, which once constructed, considerably reduces the time taken to make calculations.

Spreadsheet models were used by and are available from Dr. Meyer, Zurich, or Dr. Dijkhuizen, Wageningen.

A SHORT GUIDE TO THE ECONOMIC EVALUATION OF FMD VACCINATION PROGRAMMES

This shortened version of the guide is intended for veterinary administrators; it avoids the mathematical analyses contained in the full version.

Background

1. This document sets out a model cost effectiveness study for European countries wishing to carry out economic analyses before taking decisions on their vaccination strategies for controlling FMD.

The analytical framework

2. It assumes that FMD is an external threat to national herds and that no European country would contemplate allowing the disease becoming endemic. It further assumes that each national government is faced with two alternatives:

- a) routine prophylactic vaccination of a large proportion of the national herd.
- b) stamping out the disease by slaughtering all susceptible stock on infected holdings with or without ring vaccination.

Finally it assumes that, in the European situation, neither of these alternative policies would allow FMD epidemics so massive as to result in complete disruption of the domestic markets in meat, milk and other animal products.

3. The purpose of the analysis is to determine which is the better of the two alternatives for the country concerned. For, this, the costs of both alternatives are calculated and compared on an annual basis. the major cost elements of the two policies are set out in Table 1.

Table 1. The costs of the alternative policies

<u>ROUTINE VACCINATION</u>	<u>STAMPING OUT</u>
<u>Vaccination Programme</u>	<u>Maintaining a strategic bank of vaccine</u>
Vaccine (including emergency vaccine bank)	Vaccine and storage
Vaccination	
*Side-effects	
<u>FMD outbreaks</u>	<u>FMD outbreaks</u>
*Controlling outbreaks including ring-vaccination (if carried out)	*Controlling outbreaks including ring vaccination (if carried out)
*Slaughtered herds	*Slaughtered herds
*Loss of production	*Loss of production

*Interruption of domestic trade

*Interruption of domestic trade

Loss of export trade

Loss of export trade

Effect of national vaccination status

*Effect of outbreaks

*Effect of outbreaks

*Effect of change of national vaccination status if ring vaccination used.

* Denotes costs which are uncertain.

4. Where a country employs routine prophylactic vaccination the costs are:

- a) the cost of the vaccination programme.
- b) the costs of FMD outbreaks that occur despite the policy
- c) the costs to the export trade of the national vaccination status.

5. Where a country operates a stamping out policy the costs are:

- a) the cost of maintaining a strategic store of vaccine
- b) the costs of FMD outbreaks
- c) the cost to the export trade of sanctions following outbreaks.

6. Certain costs are identical to both alternatives and are therefore excluded from the analysis. Thus the national veterinary service will maintain a disease surveillance system, including diagnostic facilities, irrespective of whether there is a national vaccination scheme. Likewise outbreaks of FMD due to strains not normally found in Europe (e.g. ASIA-1) may occur under either policy and are excluded from this analysis.

7. The comparison of the two alternatives is dealt with by setting out the cost of each item i.e.

- | | |
|--------------------------------|-------------------|
| a vaccination programme | - para 8 et seq. |
| maintaining a store of vaccine | - para 11 |
| FMD outbreaks | - para 12 et seq. |
| loss of export trade | - para 17-18 |

The final step is to make a series of alternative assumptions about the uncertain variables (indicated by* in Table 1) and to incorporate these in a final analysis (para. 19 et seq.).

The cost of vaccination programmes

Vaccine costs

8. These include:

- i) The cost of the number of doses of vaccine required to vaccinate the proportion of the national herd covered by the programme. The estimated number of doses required should be adjusted to include an allowance for wastage.

- ii) The cost of any potency and safety tests undertaken by the veterinary service in addition to those undertaken by the manufacturer.
- iii) The cost of handling and storing the vaccine before use.
- iv) The cost of an emergency store of vaccine. This is the annual cost of maintaining a strategic store of vaccine for use in case of outbreaks of the disease.

Vaccination costs

9. This is the cost of visiting the farm and vaccinating the animals. Where this work is delegated to veterinary surgeons or lay vaccinators that are not in government employment this cost is the payments to these people plus relevant administration costs. Where the vaccination is undertaken by government staff the cost consists of the total hourly cost employing the staff concerned plus the cost of administrative overheads together with that of travel to and from the farm.

Side-effects

10. These include:-

- i) The cost of temporary loss of milk yield, allergic reactions, abortions and other reactions that occur as a direct result of vaccination.
- ii) The costs of FMD outbreaks which are side effects from the manufacture or use of vaccines. The best way of allowing for this cost is to include it under the cost of FMD outbreaks which occur despite routine vaccination.

The cost of maintaining a strategic store of vaccine

11. These costs include the purchase price of the vaccine and the maintenance of the storage facilities.

The cost of FMD outbreaks

12. In this paper an outbreak is an occurrence of disease in an agricultural establishment, breeding establishment or premises, including all buildings and adjoining premises - (OIE definition).

The cost of controlling outbreaks or series of outbreaks (epidemics):-

13. This consists of the cost of carrying out control procedures on all holdings where FMD is diagnosed and the cost of all control procedures elsewhere.
- i) The cost of control procedures on the holdings where FMD is diagnosed include:
 - Slaughter and disposal of carcasses;
 - Disinfection;
 - Destruction or handling of possible fomites;
 - Valuing stock for compensation purposes
 - Other tasks
 - Staff, administration and transportation costs

- ii) The cost of any ring vaccination carried out:
(see the costs of vaccination outlined in para.9)
- iii) The cost of general control procedures which include:
 - Diagnosing disease and carrying out epidemiological investigations,
 - Tracing infection
 - Administering quarantine and other controls
 - Administrative support.

The cost of slaughtered herds

14. The analysis assumes that if FMD is diagnosed on a holding all susceptible stock are slaughtered. The cost therefore consists of the total value of the susceptible livestock on all holdings where FMD has been diagnosed (the cost of carrying out the slaughter and disposal of carcasses is included under 13(i) above). The value of the animals will depend on their age, class and condition, and will be the total value of all susceptible animals which are slaughtered or die of FMD.

The cost of lost production:

15. On the Holding:
- i) This is the cost of the delay before restocking can take place on the holdings where livestock have been slaughtered due to FMD.
 - ii) To the processing industries and distribution trades:
This is the cost of the delay in livestock production as it affects these industries.

The cost of interruption of domestic trade

16. Following an outbreak of FMD, domestic trade in livestock and livestock products is likely to be reduced or to cease altogether for a short period. If sales of milk from any holdings are temporarily prohibited then the cost of this is the total value of the sales concerned. Sales of livestock and meat however are delayed rather than permanently lost.

Loss of export trade

17. A country's (or region's) exports of susceptible animals and of meat from such animals are temporarily banned following an outbreak of FMD. Some importing countries also ban imports of susceptible animals from places in which any livestock has been vaccinated in recent years; in such cases routine vaccination results in a ban on imports of livestock which is permanent unless the policy is changed. Ring vaccination under a stamping-out policy may also hinder exports of animals and agricultural products. Limited bans of short duration may have little effect on the trade in animals or in meat but bans lasting more than a year might well result in a sustained reduction in a country's share of export markets or the complete loss of some markets.
18. The consequences of the bans will be felt (to a greater or lesser degree depending on the importance of the export trade) in the disruption of the domestic markets and of the industry in the

exporting country concerned; its potential for developing its export trade will also receive a setback. These costs are difficult to quantify. They may be of marginal importance for minor exporting countries but will be serious for major exporting countries and must always be taken into account in reaching the final policy decision.

The comparison of the alternative policies

19. This cost effectiveness study of national FMD policies compares two alternatives: routine vaccination and stamping out. One of these will be the existing policy and data will be available to cost it; the other will be the hypothetical alternative and costing it will involve an estimate of the risk of outbreaks (the number of outbreaks and the size of herds etc.) and other uncertainties under that policy.
20. The purpose of the final analysis is to weigh up these uncertainties and to arrive at a clear decision as to which policy is best. The full version of the guide sets out two alternative techniques, Scenario analysis, and critical point analysis, which should be used to complete the study. The application of either technique in practice is likely to be complex and the advice of professional economists will be needed. The following example however provides some indication of how the best technique (critical point analysis) works.
21. This method estimates the critical point at which the costs of one policy equal those of the other. In essence the analytical method is as follows:-
 - a) cost its existing vaccination policy
 - b) cost an FMD outbreak
 - c) estimate how many outbreaks per year under a stamping out policy would be equivalent in cost to the vaccination policy. This is called the critical number.
22. This puts two clear alternatives before veterinary administrators: either:
 - a) the expected number of outbreaks under stamping out is greater than the critical number in which case the existing policy is best or
 - b) the expected number of outbreaks is less than the critical number in which case the best policy is stamping out.
23. A cost effectiveness analysis provides veterinary administrators with a comparison of the costs of alternative strategies. The final decision on a policy must include a veterinary judgement on the major imponderables such as effects on export trade, the effectiveness of surveillance systems, and the attitude of the agricultural industry.

Minimum conditions for the importation of beef into Europe
from countries where FMD is endemic and is caused by
viruses not considered exotic to Europe*

1. The exporting country must have an effective State Veterinary Service which is the direct responsibility of a Chief Veterinary Officer or Director.
2. Foot-and-mouth disease must be compulsorily notifiable. The type and subtype position and any changes therein must be notified to the appropriate authority in the importing country and all new strains of virus forwarded to the WRL. If vaccine against FMD is used it should be a nationally approved inactivated vaccine.
3. If foot-and-mouth disease is confirmed on a livestock holding the movement of all susceptible species off that premises must be prohibited until a fixed period has elapsed since the last case. An area around the outbreak should also have been free of disease for a period of time.
4. Bovine animals, which should be transported direct from their holding of origin to the approved slaughterhouse concerned without passing through a market, without contact with animals which do not comply with the conditions required for export of their meat to Europe and, if conveyed in a means of transport, the latter has been cleaned and disinfected before loading.
5. The animals must be slaughtered in approved slaughterhouses which conform to international standards and where they will be subjected to ante-mortem inspection by Government veterinarians and post-mortem inspection under the direct responsibility of Government veterinarians. De-boning and processing plants must also be under the direct responsibility of Government veterinarians.
6. Lairage facilities at approved slaughterhouses must be adequate and capable of being cleansed and disinfected effectively.
7. If foot-and-mouth disease is found at ante or post-mortem inspection, the animals or carcasses so affected and all in-contact animals or carcasses must not be exported, and the premises cleansed and disinfected following removal of the affected batch.
8. The beef exported must not contain any bones or major lymphatic glands. The de-boned meat must originate from carcasses which have matured at a room temperature of more than +2°C for at least 24 hours before the bones were removed. The pH value should fall to at least 5.8.
9. The beef so exported must be clearly marked in an approved manner so that its identity of the slaughterhouse of origin can readily be recognised.

It is permissible for an importing country to impose stricter conditions.

* Recommendation of the Nineteenth Session 1972 as revised at the meeting held in Paris in 1985, and adopted by the Twenty-seventh Session, Rome, April 1987.

Financial report and approval of the budget

BUDGET FOR 1987

(Note by the Director-General of FAO)

1987 Administrative Budget

1. In accordance with the Constitution of the Commission and with its Financial Regulation III, the proposed Annual Administrative Budget is presented herewith.
2. The budget estimates have been drawn up in the form established in the Financial Regulations.
3. In the absence of "supplementary details", the estimates for Chapter II are presented in a single total in accordance with Financial Regulation III 3.5.
4. The proposed Annual Administrative Budget for 1987 totals US\$ 174 000, a certain amount of which (US\$ 28 075) is not covered by contributions from Member Governments. In accordance with Financial Regulation VI 6.2.2, it is proposed to meet the deficit in the General Account from the Special Account.
5. Under Code .10 "Personal Services" of Chapter I, the budget estimates for 1987 allow as in 1986 for one P-5 Secretary to the Commission, one G-6 Administrative Assistant and temporary conference staff. Total contributions received in 1986 from Member Governments amount to US\$ 126 222, including accrued interest.

1987 Special Budget

6. In the Special Budget for the Special Account in 1987, it is recommended that the following amounts be provided for (a) US\$ 10 000 to cover any necessary travel and per diem of the members of the Standing Technical Committee; (b) US\$ 15 000 towards the Collaborative Laboratory Study which is being carried out by the Research Group; (c) US\$ 6 000 for publication of a Brochure on the achievements of the Commission since its establishment; (d) US\$ 6 000 for fellowships/study tours.
7. Attached is the Budget for 1987 which covers the Annual Administrative Budget and the Special Budget for the Special Account.

Assistance given by FAO

8. Besides the above expenditure, there are services provided by the Organization which have not been included in the cost estimate. Items not charged to the Commission include part-time services of senior officials of the Organization, budgetary and financial services, office accommodation, equipment, supplies of stationery, document processing and publication as well as postal and cable services.

EUROPEAN COMMISSION FOR THE CONTROL OF FOOT-AND-MOUTH DISEASE - TRUST FUND 9042

	<u>1986</u> Approved budget/ actual expenditure	<u>1987</u> ^{1/} Budget as revised by 49th Session of Exec. Committee
GENERAL ACCOUNT	US\$	US\$
<u>Application of resources</u>		
<u>Ch. I - Administrative expenditure</u> (Articles IV and XII .2 of Constitution)		
.10 <u>Personal services</u>		
1 P5 Animal Health Officer)		
1 G6 Administrative Assistant)		
Temporary assistance and interpretation) 95 500	113 406	119 500
for meetings for years in which General)		
Session is held 1987/1989)		
Home leave - biennial entitlement of)		
secretariat)	--	3 000
.20 <u>Travel secretariat/Chairman, and rapporteur</u> <u>for years in which General Session is held</u>	7 000	26 217
.30 <u>Contractual services World Reference Lab.</u>	8 000	8 000
.40 <u>Gen. Op. Expenses (Hosp./Misc.)</u>	700	465
<u>Ch. II - Special Functions - Art.V of Constitution</u>		
.50 <u>Emergency expenditure</u>	20 000	(see 2/)
	<u>141 200</u>	<u>147 623</u>
		<u>174 000</u>

Annual income from contributions pledged by member countries: US\$ 145 925

<u>SPECIAL ACCOUNT</u>		
.20 <u>Travel Research Group</u>	15 000	12 000
.30 <u>Contractual services</u>		
(a) <u>Collaborative Laboratory Study</u>	2 000	--
(b) <u>Immunological trials of new FMD virus</u> <u>strains which may present differences</u> <u>from FMD vaccines used at present in</u> <u>Europe</u>	10 000	--
.32 <u>Author's contract for Brochure</u>	2 000	2 000
.34 <u>Publication of Brochure</u>	6 000	--
.80 <u>Fellowships/study tours</u>	5 000	4 360 ^{3/}
	<u>40 000</u>	<u>18 360</u>
		<u>37 000</u>

1/ See detailed budget for 1987 as revised by Forty-ninth Session of the Executive Committee

2/ .50 Emergency expenditure - in 1986 this allocation was transferred to .20 Travel in order to meet cost of missions in Italy (US\$ 8 000 in 1986/US\$ 6 000 to date in 1987)

3/ Bill for bench fee not received in 1986 - total cost approx. US\$ 5 600

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

Trust Fund 9042 - Administrative Budget for 1987

(Ch. I - Administrative expenditure under Articles IV and XIII.3)

	<u>US\$</u>	<u>US\$</u>
.10 <u>Personal Services</u>		
01. P5 Animal Health Officer (12 months)	75 000	
G6 Admin. Assistant (12 months)	39 000	
03. Temp. assistance G2 (2 months)	4 000	
05. Overtime - for staff in connection with Twenty-seventh Session	1 500	
	<hr/>	119 500
.14 <u>Home leave</u> Secretariat biennial entitlement		3 000
.20 <u>Travel</u> - Secretariat, Chairman, and Members of Exec. Comm. when required		22 000
.30 <u>Contractual Services</u> - services by World Reference Laboratory, Pirbright, for 1987		10 000
.40 <u>General operating expenses</u>		
.45 Hospitality	1 000	
.49 Miscellaneous	500	
	<hr/>	1 500

(Ch. II - Emergency expenditure under Art.V of the Constitution)

.50 <u>Supplies and Materials</u> (Special Functions/Art.V of the Constitution)		18 000
Pledged 1987	US\$ 146 637**	
Transfer from Special Account to meet deficit (Fin.Reg.VI 6.2.2)	US\$ 27 363	
	<hr/>	
	174 000	<hr/>
	<hr/>	174 000

SPECIAL ACCOUNT

.20 <u>Travel</u> - Research Group		10 000
.30 <u>Contractual Services</u> - Collaborative Laboratory Study		15 000
.34 Publication of Brochure		6 000
.80 Fellowships/study tours		6 000
	<u>Uncommitted balance</u>	2 610
Balance 31.12.86	US\$ 66 973	
Transfer to Gen. Acct. to meet deficit	US\$ 27 363	
	<hr/>	
	US\$ 39 610	<hr/>
	<hr/>	39 610

** This figure includes the contribution for Albania which joined the Commission in November 1986. The Commission at its 27th Session agreed with the recommendation of the Forty-ninth Session of the Executive Committee i.e. that Albania's annual contribution should be set at US\$ 712.

Trust Fund No. 9042.00 MTF/INT/001/MUL - International
European Commission for the Control of Foot-and-Mouth Disease

Pledge Position at 31 December 1986
(including year-end closure adjustments)

<u>Government of</u>	<u>Outstanding 31/12/85</u>	<u>Contributions 1986</u>	<u>Received at 31/12/86</u>	<u>Outstanding 31/12/86</u>
(expressed in US Dollars)				
AUSTRIA	0.00	4 270.96	4 270.96	0.00
BELGIUM	0.00	7 118.28	7 118.28	0.00
BULGARIA	0.00	2 135.48	2 135.48 ***	0.00
CYPRUS	0.54	711.82	711.82	0.00
CZECHOSLOVAKIA*	0.00	4 270.96	4 270.96	0.00
DENMARK	0.00	7 118.28	7 118.28	0.00
FINLAND	0.00	4 270.96	4 270.96	0.00
FRANCE	-5 694.62	14 236.56	8 541.94	0.00
GERMANY	0.00	14 236.56	14 236.56 ***	0.00
GREECE	0.00	2 135.48	2 174.11	-38.63
HUNGARY	0.00	4 270.96	4 270.96	0.00
ICELAND	0.00	711.82	711.82	0.00
IRELAND	0.00	2 135.48	2 135.48	0.00
ITALY	4 289.70	14 236.56	19 063.75	-537.49
LUXEMBOURG	0.00	711.82	711.82	0.00
MALTA	0.00	711.82	711.82	0.00
NETHERLANDS	0.00	7 118.28	7 118.28	0.00
NORWAY	2 135.48	2 135.48	4 270.96	0.00
POLAND	14 236.56	7 118.28	0.00	21 354.84
PORTUGAL	0.00	2 135.48	2 135.48	0.00
SPAIN	8 827.08	7 118.28	12 253.58	3 691.78
SWEDEN	0.00	7 118.28	7 118.28	0.00
SWITZERLAND	0.00	7 118.28	7 118.28	0.00
TURKEY	3 358.86	4 270.96	0.00	7 629.82 **
UNITED KINGDOM	-5 694.62	14 236.56	8 541.94	0.00
YUGOSLAVIA	0.00	4 270.96	4 270.96	0.00
	<u>21 389.24</u>	<u>145 924.64</u>	<u>135 282.76</u>	<u>32 101.84</u>

* Czechoslovakia member as of 1 January 1986

** Turkey made following deposits without specifying Number of Trust Fund to which contributions should be credited:

	US\$
18.6.79	2 933.84
28.7.81	7 736.44
2.10.81	620.54
	<u>11 290.82</u>

This amount held in suspense account pending verification.

***Amount actually taken up in February 1987

Trust Fund No. 9042 MTF/INT/001/MUL - International
European Commission for the Control of Foot-and-Mouth Disease

5% increase in contributions as of 1 January 1988

<u>Government of</u>	<u>Present scale</u> <u>US\$</u>	<u>+ 5%</u> <u>US\$</u>	<u>New Scale</u> <u>US\$</u>
ALBANIA	711.82	35.59	747.41
AUSTRIA	4 270.96	213.55	4 484.51
BELGIUM	7 118.28	355.91	7 474.19
BULGARIA	2 135.48	106.77	2 242.25
CYPRUS	711.82	35.59	747.41
CZECHOSLAVAKIA	4 270.96	213.55	4 484.51
DENMARK	7 118.28	355.91	7 474.19
FINLAND	4 270.96	213.55	4 484.51
FRANCE	14 236.56	711.83	14 948.39
GERMANY, F.R.	14 236.56	711.83	14 948.39
GREECE	2 135.48	106.77	2 242.25
HUNGARY	4 270.96	213.55	4 484.51
ICELAND	711.82	35.59	747.41
IRELAND	2 135.48	106.77	2 242.25
ITALY	14 236.56	711.83	14 948.39
LUXEMBOURG	711.82	35.59	747.41
MALTA	711.82	35.59	747.41
NETHERLANDS	7 118.28	355.91	7 474.19
NORWAY	2 135.48	106.77	2 242.25
POLAND	7 118.28	355.91	7 474.19
PORTUGAL	2 135.48	106.77	2 242.25
SPAIN	7 118.28	355.91	7 474.19
SWEDEN	7 118.28	355.91	7 474.19
SWITZERLAND	7 118.28	355.91	7 474.19
TURKEY	4 270.96	213.55	4 484.51
UNITED KINGDOM	14 236.56	711.83	14 948.39
YUGOSLAVIA	4 270.96	213.55	4 484.51
	<u>146,636.46</u>	<u>7 331.79</u>	<u>153 968.25</u>

List of Participants

DELEGATES

Albania

Dr. P. Gjoni
Director
Veterinary Research Institute
Tirana

Dr. E. Panariti
Veterinary Research Institute
Tirana

Prof. N. Nosi
Permanent Representative of the
People's Socialist Republic
of Albania to FAO
Via Asmara 9/A
00199 Rome

Austria

Dr. F. Walla
Director of Veterinary Services
Federal Ministry of Health and
Environment Protection
Radetzkystrasse 2
A-1030 Vienna

Dr. D. Kinzel
Permanent Representative of Austria
to FAO
Permanent Representation of the
Republic of Austria to FAO
Via di Affogalasio 41, Int. 1
00148 Rome

Belgium

Dr I. Fontaine
Inspecteur Général du Service
de l'Inspection Vétérinaire
Ministère de l'Agriculture
Manhattan Office Tower
21 Avenue du Boulevard
1210 Bruxelles

Dr. R. Strobbe
Chef de Département
Institut national de recherches
vétérinaires
99 Groeselenberg
B 1180 Bruxelles-Uccle

M. A. Saintraint
Ambassadeur de Belgique auprès
de la FAO
Représentation permanente du Royaume
de Belgique auprès de la FAO
Via Omero 8
00197 Rome

Bulgaria

Dr. N. Tanev Belev
Chairman
State Veterinary Services
15^a Pencho Slaveikov Blvd.
1606 Sofia

Dr. K. Ourouchev
Senior Veterinary Officer
State Veterinary Services
15^a Pencho Slaveikov Blvd.
1606 Sofia

Dr. M. Milanov
Director
Institute for the Control of FMD
75 Trakia Blvd.
8800 Sliven

Czechoslovakia

Dr. Miloslav Olach
Deputy Chief Veterinary Officer
Federal Ministry of Agriculture
Praha 1, Tésnov 17

Dr. Rudolf Hubik
Director
BIOVETA n.p.
Terezin

Denmark

Dr. Erik Stougaard
Director of Veterinary Services
Ministry of Agriculture
Frederiksgade 21
1265 Copenhagen K

Dr. M. Eskildsen
Director
State Veterinary Institute for
Virus Research
Lindholm DK-4711
Kalvehave

Finland

Dr. R. Berger
Director-General of Veterinary
Services
Veterinary Department
Ministry of Agriculture and
Forestry
Vourikatu 16
00100 Helsinki

Ms. Riitta Heinonen
Chief Inspector
Veterinary Department
Ministry of Agriculture and
Forestry
Vourikatu 16A
00100 Helsinki

Mr. Carl Arne Hartman
Permanent Representative of
Finland to FAO
Embassy of the Republic of Finland
Viale Gioacchino Rossini 18
00198 Rome

France

Dr L. Perpère
Chef du Service vétérinaires de
la Santé et de la protection animales
Ministère de l'Agriculture
175 Bd. du Chevaleret
75646 Paris Cedex 13

Germany, Fed. Rep. of

Prof. Dr. A. Rojahn
Ministerialdirigent
Bundesministerium für Ernährung,
Landwirtschaft und Forsten
Postfach 140270
D-5300 Bonn 1

Greece

Dr. H. Drizos
Directeur des Services vétérinaires
d'EVROS
Ministère de l'Agriculture
Rue Proussis 59
Alexandroupoli

Hungary

Dr. András Kemény
Deputy Head of the Animal Health
Division
Ministry of Agriculture and Food
Budapest V
Kossuth L. tér 11

Dr. Gábor Bencze
Head of Chemistry Department
FMDV Section of PHYLAXIA
1143 Budapest
Zászlós U. 31

Ireland

Mr. R.G. Cullen
Director of Veterinary Services
Department of Agriculture and Food
Agriculture House
Kildare Street
Dublin 2

Italy

Prof. L. Bellani
Direttore Generale dei Servizi
Veterinari
Ministero della Sanità
Piazza G. Marconi
Grattacielo Italia
00144 Roma, EUR

Dott. An. Mattioli
Vice Direttore dei Servizi
Veterinari
Ministero della Sanità
Piazza G. Marconi
Grattacielo Italia
00144 Roma, EUR

Dott. F. Fabbrovich
Dirigente Superiore Veterinario
Ministero della Sanità
Piazza G. Marconi
Grattacielo Italia
00144 Roma, EUR

Dott. S. Giuliano
Direzione Generale dei Servizi
Veterinari
Capo Divisione V
Ministero della Sanità
Piazza G. Marconi
Grattacielo G. Marconi
00144 Roma, EUR.

Luxembourg

Dr. R. Frisch
Directeur des services
vétérinaires
Ministère de l'Agriculture
89 rue d'Anvers

Malta

Dr. C.L. Vella
Director of Veterinary Services
Ministry of Agriculture and
Fisheries
Veterinary Services Division
Mint Street

Netherlands

Dr. M.J. Dobbelaar
Director of Veterinary Services
Ministry of Agriculture
and Fisheries
Bezuidenhoutseweg 73
The Hague

Dr. P. de Leeuw
Scientific Director
Central Veterinary Institute
Houtribweg 39
Postbus 65
Lelystad

Dr. J.G. van Bekkum
Central Veterinary Institute
Houtribweg 39
Postbus 65
Lelystad

Dr. J. Smak
Veterinary Officer
Ministry of Agriculture and
Fisheries
Bezuidenhoutseweg 73
2500 EK The Hague

Norway

Dr. Olav Sandvik
Director of Veterinary Services
Ministry of Agriculture
Box 8007 Dep
0030 Oslo 1

Poland

Dr. J. Mazurek
Director of Polish Veterinary
Services
Ministry of Agriculture Forestry
and Food Economy
Wspolna 30
Warsaw

Prof. M. Truszczyński
Director General
Veterinary Research Institute
Partyzantów 57
24-100 Pulawy

Portugal

Dr. C.A.M. de Andrade Fontes
Director Geral de Pecuaria
Ministerio da Agricultura
Rua Victor Cordon, 4
Lisboa

Mr. A. de Almeida Ribeiro
Second Secretary
Embassy of the Portuguese Republic
Via Giacinta Pezzana 9
00197 Rome

Spain

Dr. M.A. Diaz Yubero
Director General de
Sanidad Animal
Ministerio de Agricultura,
Pesca y Alimentación
Embajadores 68
28012 Madrid

Dr. Manuel Flores
Jefe Sección Higiene y Profilaxis:
Subdirección General de Sanidad Animal
Ministerio de Agricultura, Pesca
y Alimentación
Embajadores No. 68
Madrid

Sweden

Dr. Bengt Henricson
Chief Veterinary Officer
Veterinary and Animal
Production Department
National Board of Agriculture
S-55183 Jönköping

Switzerland

Prof. Dr. P. Gafner
Directeur de l'Office vétérinaire
fédéral
Schwarzenburgstrasse 161
3097 Liebefeld-Bern

Turkey

Mr. Hasan Öztürkmen
Chief of Vaccine Production Laboratory
Sap Enstidusu P.K. 714
06044 Ankara

United Kingdom

Mr. W.H.G. Rees
Chief Veterinary Officer
Ministry of Agriculture,
Fisheries and Food
Government Buildings Block B
Hook Rise South, Tolworth
Surbiton, Surrey, KT6 7NF

Yugoslavia

Dr. Dusan Jakovljević
President Adjoint
Comité fédéral pour l'agriculture
Secteur vétérinaire
Bul. Avnjo-A 104/I
Belgrade 11070

Dr. M. Tapavicki
Permanent Representative of Yugoslavia
to FAO
Embassy of the Socialist Federal
Republic of Yugoslavia
Via dei Monti Parioli 20
00197 Rome

OBSERVERS

International Organizations

OIE

Dr L. Blajan
Directeur Général
OIE
12 rue de Prony
75017 Paris
France

Dr J. Leunen
Représentant de l'OIE
12 rue de Prony
Paris
France

Dr V.R. Welte
Epidemiologist
Head of Information Service
OIE
12 rue de Prony
Paris
France

EEC

Dr Evans Dexter
Principal Administrator
Division of Veterinary Legislation
Directorate General for Agriculture
Commission of the European Communities
rue de la Loi 86
1040 Bruxelles
Belgique

World Veterinary Association

Dr. M. Boldrini
Via Cesare Baronio 150
00179 Rome

PAHO

Dr. Hans G. Barnemann
Chief of Laboratories
Centro Pan-Americano de Fiebre Aftosa
Caixa Postal 589 - ZC/00
Rio de Janeiro
Brasil

Australia

Mr. W.A. Scanlan
Counsellor, Veterinary Services
Australian Embassy
6-8 Rue Guimard
1040 Brussels
Belgium

Canada

Mr. G.H. Musgrove
Permanent Representative of Canada
to FAO
Canadian Embassy
Via Zara 30
00198 Rome

France

Dr. M. Lombard
Rhône-Mérieux
Direction des opérations
internationales
254 rue Marcel Mérieux
69007 Lyon

Dr J. Terré
Directeur Général Adjoint
Rhône-Mérieux
254 rue marcel Mérieux
69007 Lyon

German Democratic Republic

Dr. G. Zagrodnik
Chief of Veterinary Border Services
Ministry of Food and Agriculture
Chausseestrasse 110
1040 Berlin

Iraq

Dr. Tawfik Al Mesh-Hedani
Alternate Permanent Representative
of Iraq
The Embassy of the Republic of Iraq
Via della Camilluccia 355
Rome

Israel

Mr. Ilan Hartuv
Permanent Representative of Israel
to FAO
Embassy of Israel
Via Michele Mercati 12
00197 Rome

Dr. A. Shims'hony
Director
Veterinary Services and Animal
Health
P.O.B. 12, Beit-Dagan 50250

Italy

Dott. M. Aleandri
Direttore
Istituto Zooprofilattico
Via Appia Nuova, 1411
Roma

Dott. M. Amadori
Assistente
Istituto Zooprofilattico Sperimentale
della Lombardia e dell'Emilia
Via A. Bianchi 7
25100 Brescia

Dr. G. Antiguano
Funzionario Veterinario Regione Lazio
Piazza Cavalieri del Lavoro, 12
00173 Roma

Dott. G. Autorino
Assistente Veterinario
Istituto Zooprofilattico Sperimentale
per Lazio e Toscana
Via Appia Nuova 1411
00174 Roma

Dott. C. Buonavoglia
Istituto Superiore di Sanità
Viale Regina Elena 299
00161 Roma

Mr. L. De Grossi
Assistente Veterinario
Istituto Zooprofilattico
Via Appia Nuova, 1411
00174 Roma

Dott. L. Di Trani
Istituto Superiore di Sanità
Viale Regina Elena 299
00161 Roma

Mr. G. Masotti
Assistente Veterinario
Istituto Zooprofilattico
Via Appia Nuova, 1411
Roma

Miss P.S. Nicolussi
Regione Veneto
Dipartimento Servizi Veterinari
Via Torino
Mestre, Venezia

Mr. G. Paganelli
Veterinario Regionale
Servizio Veterinario Regione
Emilia Romagna
Viale A. Moro 30
Bologna

Prof. E. Palliola
Dirigente Ricerca
Istituto Superiore di Sanità
Viale Regina Elena 299
00161 Roma

Prof. G. Panina
Istituto Zooprofilattico Sperimentale
della Lombardia e dell'Emilia
Via A. Bianchi 7
25100 Brescia

Prof. V. Papparella
Università degli Studi di Napoli
Facoltà di Medicina Veterinaria

Miss L. Peracca
Funzionario Servizio Veterinario
Regione Toscana
Via Di Novoli 26
Firenze

Mr. M. Pieramati
Ministerio della Sanità
Regione Umbria
Via Marioni 6
Perugia

Dott. E. Radicioni
Veterinario Regionale
Servizio Veterinario Regione Umbria
Via Marconi 6
Perugia

Prof. G. Rognoni
Università di Milano
Facoltà di Veterinaria
Via Celaria, 10
20133 Milano

Mr. M. Ramasco
Ministero della Sanità
Piazza G. Marconi
Grattacielo Italia
00144 Roma

Prof. F. Scatozza
Università degli Studi di Parma
Facoltà di Medicina Veterinaria
Zarotto 48
Parma

Dr. M. Valpreda
Responsabile Servizio Veterinario
Regione Piemonte
Via Regina Margherita, 1536
Torino

Dott. P. Vivoli
Capo Laboratorio
Istituto Zooprofilattico Sperimentale
per Umbria e Marche
Via G. Salvemini 1
06100 Perugia

Prof. R. Zoletto
Istituto Zooprofilattico Sperimentale
Tre Venezie
Via Orus 2
Padova

New Zealand

Dr. C. Baddeley
Counsellor
Veterinary Services
New Zealand High Commission
New Zealand House
Haymarket London
SW1Y 4TQ

Sweden

Dr. Bengt Nordblom
Veterinary Counsellor
National Board of Agriculture
S-55183 Jönköping

Dr. Martin Wierup
Professor
National Veterinary Institute
Uppsala

United Kingdom

Dr. G. Davies
Veterinary Head of Intelligence and
Resource Planning
Ministry of Agriculture, Fisheries
and Food
Hook Rise South, Tolworth
Surbiton, Surrey KT6 7NF

Dr. B.W. Mahy
Director
Animal Virus Research Institute
Pirbright, Woking GU24 0NF

Dr. G.N. Mowat
Deputy Head
Pirbright Laboratory
World Reference FMD
c/o L.A.D.R.
Pirbright, Woking
Surrey GU24 0NF

Mr. E.W. Sullivan
Chief Veterinary Officer
Department of Agriculture for Northern
Ireland
Dundonald House
Belfast

Ms. J. Raftery
Administrative Assistant
European Commission for the
Control of FMD
Animal Production and Health
Division

Mr. K.C. Taylor (Rapporteur)
Veterinary Head of Notifiable Diseases
Section
Ministry of Agriculture,
Fisheries and Food
Hook Rise South, Tolworth
Surrey, Surrey KT6 7NF

Mrs. Christine Ellefson-Tavella
Typist, Animal Health Service
Animal Production and Health
Division

USA

Dr. R.E. Reichard
Veterinary Attaché
United States Department of
Agriculture
Animal and Plant Health Inspection
Service
American Embassy
Rome, Italy

USSR

Dr. G. Sucharev.
Virologist
USSR Agroindustrial Committee
Ministry of Agriculture
Kalinin Street, 27
Moscow

Dr. V. Sologoub
USSR Agroindustrial Committee
Ministry of Agriculture
Kalinin Street, 27
Moscow

FAO

Dr. Y. Ozawa
Chief, Animal Health Service
Animal Production and Health
Division

Secretariat

Dr. P. Stouraitis
Secretary, European Commission
for the Control of Foot-and-
Mouth Disease
Animal Production and Health
Division

