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REPORT OF THE MEETING OF THE OIE FOOT AND MOUTH DISEASE AND OTHER EPIZOOTICS COMMISSION

Paris, 12 – 14 February 2003

A meeting of the OIE Foot and Mouth Disease (FMD) and Other Epizootics Commission was held at the OIE Headquarters in Paris, France from 12 to 14 February 2003. The Agenda and List of Participants are given at Appendices I and II, respectively.

The Director General of the OIE, Dr Bernard Vallat, welcomed the participants. In his address, Dr Vallat indicated the importance of integrating and harmonising the submissions of the three Specialist Commissions to the International Committee at the General Session to be held in May 2003. In particular, he emphasised the importance of finalising the guidelines for FMD surveillance, the problem of determining confidence levels for FMD virus circulation and supporting the distinction between risks of trade involving live animals as opposed to products such as meat. He indicated the necessity for making progress towards refining criteria for assessing country applications for compliance with BSE standards. The Commission was also informed on the Global Early Warning & Response System being developed jointly by FAO[1] and the OIE.

The President of the Commission, Dr Gavin Thomson, who chaired the meeting, welcomed the Members and Observers and opened discussions on the agenda.

1. Development of Generic Surveillance Guidelines

Prof. Vincenzo Caporale summarised progress towards developing a set of generic guidelines for disease surveillance and informed the meeting that a draft document is being prepared and will be finalised by March 2003.

The commission also considered a document prepared by the Fish Diseases Commission dealing with the same issue and considered its general applicability to surveillance for diseases of terrestrial animals. It was concluded that although there were some minor details that may present problems for application to diseases of non-aquatic animals, there was no fundamental incompatibility between the approaches of the Fish Diseases Commission and that of the FMD Commission.

[1] FAO: Food and Agriculture Organisation of the United Nations

2. Guidelines for FMD surveillance

A draft of the document was sent to the countries for comment late in 2002 but, so far, no comment has been received. Member Countries are reminded that if comments are not received by mid-April 2003, the present guideline (Appendix III) will be forwarded as it is to the Code Commission for incorporation into the OIE *International Animal Health Code* (the *Code*). Proposals for modification of the Guidelines received up to mid-April will be discussed electronically by the members of the FMD Commission in order to finalise the document.

3. Report on the Evaluation of Non-structural Protein Tests for FMD Diagnosis

The report of the Ad hoc group was evaluated for consistency with the FMD surveillance guidelines (see above). It was concluded that there was no inconsistency between the two documents.

4. Country applications for freedom from rinderpest

Ten applications for countries to be recognised as free from rinderpest disease were evaluated and found to satisfy the requirements of the *Code*, *viz.* those of Benin, Burkina Faso, Egypt, Ghana, Guinea, Mali, Mauritania, Niger, Senegal and Togo. The dossier supplied by one country for zonal freedom was found to be incomplete and the country concerned was requested to supply additional evidence of compliance. If this information is received before the deadline given, the additional information will be considered by members of the Commission and, if found to be satisfactory, that country's submission will be recommended together with the other 10 for ratification by the International Committee at the General Session of May 2003.

5. Country applications for freedom from contagious bovine pleuropneumonia (CBPP)

The application of Portugal for freedom from CBPP was evaluated and found to be satisfactory. This application will be recommended to the International Committee in May 2003.

6. Country applications for freedom from foot and mouth disease (FMD)

Colombia applied for the extension of the zone free with vaccination on the Atlantic Coast. The dossier submitted together with a presentation made by official representatives of the country were judged to be satisfactory subject to additional information on vaccine control being provided. This was done by the country delegation that made the supporting presentation to the Commission. The application of Colombia will be recommended to the International Committee in May 2003.

One country requested the recognition of a zone free from FMD with vaccination. The Commission requested additional information on vaccine compliance with the OIE *Manual of Standards for Diagnostic Tests and Vaccines* and the movement of live animals from the buffer zone into the free zone. If this information is received before the deadline given, it will be considered by members of the Commission and, if found to be satisfactory, that country's submission will be recommended for ratification by the International Committee in May 2003.

The submission of Nicaragua to be considered as free of FMD without vaccination was found to comply with the requirements of the *Code* and will be recommended to the International Committee for ratification in May 2003.

The Commission took cognizance of an application from one Member Country to be considered free from FMD with vaccination, in line with the amendment to be proposed to the International Committee in May 2003 to enable countries where no outbreak of FMD has occurred for the past 18 months (as opposed to 2 years), to qualify for freedom from FMD with vaccination. It was decided that the application would be considered at a special meeting in May 2003 in the light of the decision of the International Committee on the proposed amendment.

7. Evaluation of country applications for recognition of freedom from diseases for which a mechanism within the OIE exists

Due to the increasing volume and complexity of submissions for recognition of freedom from rinderpest, CBPP and FMD, the Commission suggests that henceforth such applications should be evaluated initially by specialist ad hoc groups. The Ad hoc Groups for FMD, CBPP and rinderpest should also develop more comprehensive guidelines for each disease considered, such as already exists for BSE.

8. Bovine spongiform encephalopathy

Based on the fact that many countries are unable at present to comply fully with the requirements of the *Code* as free from BSE, and the difficulty of according a scientifically-based weighting to the presence of other TSEs within a country, the Commission recommends that until such time that countries are able to fulfill all the criteria stipulated in chapter 2.3.13 of the *Code* and that a method for evaluating the risk posed to human health by the presence of other TSEs becomes available, the status of provisional freedom should be considered by the OIE recognition procedure in accordance with Article 2.3.13.4 of the Code. This will be proposed to the International Committee at the General Session in May 2003.

9. Disease notification

The Commission noted two documents, one provided by Australia and the other by the Fish Diseases Commission, proposing alternative approaches to disease notification. Since the documents were provided to the Commission for information only, no formal position on either was taken.

The background to a request from the European Union (EU) for information on the future evaluation of swine vesicular disease (SVD) as a List A disease was presented by Dr David Paton. He pointed out that the EU is in the process of reconsidering its approach to SVD and, if possible, would like to harmonise its approach with that of the OIE. The Commission, however, was unable to provide a definite answer because the matter of disease notification is currently under consideration by the Code Commission. Nevertheless, the question of the inclusion of diseases such as SVD in the current List A highlights the importance of resolving the matter of disease notification within the OIE.

10. Status of provisional freedom from rinderpest disease

Self-declarations of provisional freedom from rinderpest disease by Member Countries have created a problem for the OIE on a number of occasions because they contain statements that may be inaccurate or incomplete. Furthermore, the fact that such information is published on the OIE Web-site has been used by Member Countries as proof of the veracity of statements contained in the self-declaration.

The Commission therefore believes that when reporting on the status of provisional freedom from rinderpest, the OIE should include a disclaimer indicating that the OIE is not responsible for inaccurate information on country or zone disease status based on information that has not been verified by the OIE Central Bureau or by an OIE Specialist Commission.

11. Swill

A draft document on swill prepared at the request of the Code Commission was evaluated and modified (Appendix IV). It was discussed with a representative of the Code Commission who felt that more detail on treatment alternatives should be provided. The present document relies on boiling of swill for 1 hour or that the competent authority proves the equivalence of any other method used to inactivate pathogenic infectious agents. Further discussion on the matter will take place at the next meeting of the FMD Commission.

12. Definition of vaccines, vaccination and emergency vaccination against FMD

The FMD Commission was requested by the Code Commission to develop the above definitions for possible inclusion in the FMD *Code* chapter. The main concern is that at present "vaccination" as used in the current *Code* chapter on FMD implies 100% protection of the animals within the vaccinated population. In practice, vaccination achieves levels of herd immunity considerably less than 100%. Therefore, criteria need to be developed to establish minimum levels of herd immunity that are required in vaccinated populations. Furthermore, reference to "compulsory systematic vaccination" in the present chapter needs to be either defined or replaced. The definitions so far developed are shown in Appendix V.

13. Development of guidelines for interpretation of biomolecular characterization of FMD viruses

Progress on this initiative that stemmed from the previous Commission meeting in Rio de Janeiro was reported. The proposed frame-work for further progress was modified and the Secretary of the European FMD Commission requested to co-ordinate a workshop and related activities in that regard.

…/Appendices

Appendix I

MEETING OF THE OIE FOOT AND MOUTH DISEASE
AND OTHER EPIZOOTICS COMMISSION
Paris, 12 – 14 February 2003

Agenda

1. Development of Generic Surveillance Guidelines
2. Guidelines for FMD surveillance
3. Report on the Evaluation of Non-structural Protein Tests for FMD Diagnosis
4. Country applications for freedom from rinderpest
5. Country applications for freedom from contagious bovine pleuropneumonia (CBPP)
6. Country applications for freedom from foot and mouth disease (FMD)
7. Evaluation of country applications for recognition of freedom from diseases for which a mechanism within the OIE exists
8. Bovine spongiform encephalopathy
9. Disease notification
10. Status of provisional freedom from rinderpest
11. Swill
12. Definition of vaccines, vaccination and emergency vaccination against FMD
13. Development of guidelines for interpretation of biomolecular characterization of FMD viruses

MEETING OF THE OIE FOOT AND MOUTH DISEASE AND OTHER EPIZOOTICS COMMISSION

Paris, 12 – 14 February 2003

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List of participants

MEMBERS

Dr Gavin R. Thomson *(President)*
AU-IBAR
P.O. Box 30786
Nairobi
KENYA
Tel: (254-2) 31 80 85
Fax: (254-2) 22 65 65
E-mail: gavin.thomson@oau-ibar.org

Prof. Vincenzo Caporale *(Vice-President)*
Director
Istituto Zooprofilattico Sperimentale
dell'Abruzzo e del Molise 'G. Caporale'
Via Campo Boario
64100 Teramo
ITALY
Tel: (39.0861) 33 22 33
Fax: (39.0861) 33 22 51
E-mail: caporale@izs.it

Dr Eduardo Correa Melo *(Secretary General)*
Director, Foot and Mouth Disease Coordinator
Centro Panamericano de Fiebre Aftosa
Caixa Postal 589
20001-970 Rio de Janeiro
BRAZIL
Tel: (55-21) 36 61 90 00
Fax: (55-21) 36 61 90 01
E-mail: ecorrea@panaftosa.ops-oms.org

OTHER PARTICIPANTS

Dr David Paton
Department of Exotic Disease Control
Pirbright Laboratory, Institute for Animal Health
Ash Road, Pirbright, Surrey GU24 0NF
UNITED KINGDOM
Tel: (44-1483) 23 10 12
Fax: (44-1483) 23 26 21
E-mail: david.paton@bbsrc.ac.uk

Dr Keith Sumption
Secretary of the European Commission
for the Control of Foot and Mouth Disease
FAO
Via delle Terme di Caracalla
00100 Rome
ITALY
Tel: (39) 06 570 55528
Fax: (39) 06 570 55749
E-mail: keith.sumption@fao.org

Dr Juan Lubroth
Senior Officer - Infectious Disease Group
FAO Animal Health Service
Animal Production and Health Division
Via delle Terme di Caracalla
00100 Rome
ITALY
Tel: (39-06) 570 54184
Fax: (39 06) 570 53023
E-mail: juan.lubroth@fao.org

Dr Victor E. Saraiva-Vieira
Centro Panamericano de Fiebre/OPS-OMS
Foot and Mouth Disease Center/PAHO-WHO
Av. Presidente Kennedy
7778 Sao Bento, Duque de Caxias
25040-000 Rio de Janeiro
BRAZIL
Tel: (55 21) 22 46 07 17
Fax: (55-21) 36 61 90 01
E-mail: vsaraiva@panaftosa.ops-oms.org

OIE CENTRAL BUREAU

Dr Bernard Vallat
Director General
12 rue de Prony
75017 Paris
FRANCE
Tel: 33 - (0)1 44 15 18 88
Fax: 33 - (0)1 42 67 09 87
E-mail: oie@oie.int

Dr Alejandro Schudel
Head, Scientific and Technical Department
E-mail: a.schudel@oie.int

Dr Dewan Sibartie
Deputy Head, Scientific and Technical Department
E-mail: d.sibartie@oie.int

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GUIDE TO THE ESTABLISHMENT OR THE REGAINING OF RECOGNITION FOR A FOOT AND MOUTH DISEASE-FREE COUNTRY OR ZONE

The following are foot and mouth (FMD) surveillance guidelines for countries or zones applying to the OIE for FMD freedom without vaccination, or for countries or zones applying to the OIE for FMD freedom with vaccination. They also provide guidance for countries or zones seeking re-recognition of freedom from FMD, with or without vaccination, following an outbreak. It is not the intention here to exclude other verification strategies, but if an alternative strategy is used it is essential that it is scientifically defensible. The Guidelines are intended to expand on and explain the requirements of chapter 2.1.1. of the *OIE International Animal Health Code*.

Surveillance for FMD may be part of a continuing disease surveillance programme involving regular checks on livestock at all stages of the production chain up to slaughter or export, or it may be a specific programme designed to establish that FMD infection is absent from the national herd in the whole territory or part of it (free zone).

General Conditions

A surveillance system for FMD must be supported by an efficient and adequately funded state veterinary service (chapter 1.3.3 of the *Code*) with expertise in the epidemiology of FMD, and access to a diagnostic laboratory capable of undertaking FMD diagnosis and serology and a farming community committed to the recognition and reporting of FMD. Training of veterinarians, whether state or private practitioner, and animal health auxiliaries in the clinical recognition of FMD and the collection and dispatch of samples is essential, together with an information programme directed at farmers and other animal workers on the importance of early notification of disease outbreaks. A procedure must be in place for the rapid transport of samples to the laboratory, and access through the laboratory for onward dispatch of samples to the national, regional or world reference laboratories.

Passive surveillance is an ongoing programme that should be used by all veterinary services to monitor for the appearance of disease in the national livestock populations. Active surveillance is specific in respect of confirmation of the suspect presence of a particular disease and quantification of its prevalence or to demonstrate freedom from a disease/infection for a geographically defined area.

An FMD surveillance programme must:

1) Respond to observations and reports made by the public, and from state and private veterinarians, and in particular the farmer and animal health workers who have day-to-day contact with the national herds and flocks (passive surveillance). Farmers must be encouraged to report promptly any clinical disease resembling FMD. They must be supported by government information programmes and the state veterinary service directly or through private veterinarians. All reported suspect cases of FMD should be investigated within 24 hours, and, if still considered suspect, samples must be taken and submitted to the national laboratory by rapid transport. This requires that sampling kits, drugs to sedate animals from which samples are being taken, transport and communications and the wherewithal for the decontamination of equipment and clothing of those involved in disease investigation are made available at all times. Both state and private veterinarians who may be involved with investigating suspect outbreaks of FMD must be familiar with the clinical signs and epidemiology of FMD, and have been trained in sample collection. They should also have access to relevant information on the current FMD status of their own and neighbouring countries, and any particular risk factors, and be able to call for additional advice and help from a specialised government FMD epidemiological team. Laboratory results must be sent as soon as possible to the relevant person in the state veterinary service, and to the veterinarian submitting the sample, to encourage future co-operation.

The level of this surveillance can be assessed by the number of farmer, private veterinarians and other reports received by the state veterinary service and the number of investigations carried out, together with the results of the investigations, and the time-table of events in the investigation process following initial reports.

2) When relevant, regular and frequent clinical inspection and serological testing of high-risk groups of animals, such as those adjacent to an FMD infected country or zone (for example, bordering a game park in which infected wildlife are present) should be implemented.

These general conditions are required for all Member Countries submitting their annual request for re-confirmation of FMD-free status. Evidence of an enhanced surveillance programme is required from Member Countries and zones applying for the first time for recognition of freedom from FMD with or without vaccination.

Countries or zones applying for freedom from FMD where vaccination is not practised

Apart from the general conditions, a Member Country applying for recognition of freedom from FMD where vaccination is not practised must show evidence of an effective surveillance programme in which the FMD-susceptible population either undergoes regular clinical examination or a statistically significant sample of this population is examined to show that disease has not been present in the population for the last 12 months. In addition a statistically significant proportion of the population must be subjected to serological surveillance to demonstrate absence of FMD virus (FMDV) infection for the preceding 12 months. This requires the support of a national or other reference laboratory able to undertake serology for FMDV antibody using tests approved by the OIE, as described in the most recent edition of the OIE *Manual of Standards for Diagnostic Tests and Vaccines*, or as updated by a resolution from the International Committee of the OIE between editions of the *Manual*.

In general, the target population for random surveys for disease and infection will cover the susceptible species within the country or zone to be declared free from disease. Countries wishing to show freedom from FMD in which a pig-specific strain of virus had been prevalent should concentrate on sampling the national pig population. In countries in which an African buffalo population is present, this should also be sampled if included in the proposed FMDV infection-free zone.

The objective of the random sample design is to keep the volume of surveillance work to the minimum consistent with demonstrating the absence of disease/infection at the required level of statistical confidence. The sample must be selected on a random basis during each of the consecutive sampling campaigns, the frequency of sampling being dependent on the epidemiological situation, but should be at least once during the year preceding the application. It must be ensured that every sampling unit has an equal probability of being selected. The selection of individual sampling units should not affect the probability of selecting any other sampling unit. It must be emphasised that random selection of the sampling units is absolutely essential; otherwise the required level of statistical confidence cannot be achieved.

In order to provide representative information on the infection status of the target population, the random sample survey ought to be completed within the shortest possible period of time.

The population may be divided into sections (strata) with similar epidemiological conditions within each stratum. Stratification implies that a suitable system of separating the target population into a series of sections or strata from which random samples can be drawn has been developed. A stratum should be a subpopulation of the total population that is raised using a similar production and husbandry system under similar ecological conditions within geographical or administrative areas (provinces, states, etc.) with a similar risk of infection. Which stratification criteria will be most appropriate will depend on the conditions prevailing in the individual country.

During the process of stratification the following two conditions have to be met:

- All sampling units (village, flock or herd depending on farming system) within a particular stratum can be accessed during the survey and have an equal chance of being selected.

- An individual sampling unit is included in only one stratum.

The total number of strata required will depend on the country or zone concerned and additional strata or an increased level of sampling may be applied to areas within a country or zone considered to be at higher risk of FMDV infection. Care should be taken that the number of strata does not exceed the capacity of the field and laboratory service as the required number of random samples will have to be collected from each of the strata. The number of samples is determined, to a considerable extent, by the number of strata. Hence the number of strata should be kept to a minimum but also reflect major epidemiological differences. Further detail may be obtained from suitable epidemiological texts (see references).

If a Member Country wishes to declare a specific zone within the country free from FMDV infection this must be taken into consideration in the stratification process. The basis for the sampling process would then be the population within each zone.

The objective of the random sample survey is the detection of clinical or serological evidence of FMD within the population if it is present at a predetermined prevalence. The probability of detecting evidence of FMD or FMD infection in a given sample of animals depends on the prevalence of FMDV infection in the population and the size of the sample. Hence, the sample size and expected disease prevalence determine the level of confidence in the result of the survey. The lower the prevalence the larger the sample size has to be in order to achieve a given confidence in the outcome of the survey. It is recommended that a sampling strategy be used to give a 95% probability of detecting evidence of FMD or FMD infection if it is present in 1% of the primary sampling units. In other words, if at least 1% of herds/flocks are infected with FMD virus, the sample size has to be large enough to give a 95% chance that at least one infected herd/flock will be detected through examination of the random sample of herds/flocks.

Clinical surveillance aims at the detection of clinical signs of FMD by close inspection of the mouth, feet and udder of a randomly selected sample. It is essential that all animals within the selected primary sampling unit are examined for signs of FMD. Any herd/flock where suspicious animals are detected should be classified as infected until contrary evidence is produced.

Serological surveillance aims at the detection of antibodies against FMDV. A positive reaction to an FMDV antibody detection test can have four possible causes:

- natural infection with FMDV
- vaccination
- maternal antibodies from an immune dam (antibody reaction is usually only up to six months of age in cattle, however, in some individuals and in buffalo calves, maternal antibody can be detected for longer);
- non-specific reactions, for example to some other unrelated antigen (heterophile reactions)

Thus antibodies detected in animals (other than African buffalo) over six months of age and born after a country or region has ceased vaccination should be in response to natural infection and be indicative of circulating virus. This group of animals will be considered eligible as secondary sample units for the purpose of serological surveillance. It may be possible to use serum collected for other survey purposes, but the objective of a statistically valid random survey for the specific presence of FMDV should not be compromised.

If vaccination cannot be excluded as the cause of positive serology, additional testing for the presence of antibodies to the nonstructural proteins (NSPs) of FMDV could indicate the previous presence of live FMDV.

It is unusual to find only one or two sero-positive animals in an infected herd/flock. For this reason and for practical as well as economic reasons it is considered acceptable to include only a random sample of animals from each primary sampling unit in the serological surveillance. The sample size has to be sufficient to achieve a 95% probability of detecting sero-positive animals. If a herd is infected a significant time after the cessation of vaccination, it would be expected that the serological prevalence will exceed 20%.

FMDV persists in the pharyngeal region of recovered ruminants for up to 3 years in cattle and nine months in sheep, and therefore oesophageal–pharyngeal (OP) fluid sampling is an additional valuable tool in surveillance for FMDV. OP samples should be collected from herds and flocks selected by positive serology. The collection of OP samples will depend on the availability of collection equipment (e.g. probang), facilities for storing the OP material until testing, and access to a laboratory able to work with live FMDV. Sheep can also be sampled by collecting OP fluid, and a similar sampling strategy can be applied, bearing in mind that the carrier state is shorter in this species.

Staff collecting OP samples should be given specific training on the techniques for the collection, transport and storage of OP fluid. It is essential that the OP fluid is placed in a neutral buffer and immediately frozen in or over liquid nitrogen or solid CO_2 after collection, and kept in this state until thawed in the diagnostic laboratory and placed on susceptible tissue culture (see OIE *Manual of Standards for Diagnostic Tests and Vaccines*).

It is preferable to stratify the sampling frame to reflect the possibility of FMD having been present up to three years previously. OP samples should be collected from each group of yearlings, two-year-old and three-year-old cattle/sheep in the selected herds and flocks.

The results of the random sample survey will provide evidence both to the national authorities and to the OIE that no FMDV infection is present in the country or zone. It is therefore essential that the random sample survey can be audited through clear documentation and the presence of complete records.

Countries or zones applying for freedom from FMD where vaccination is practised

In addition to the general conditions, a Member Country or zone applying for recognition of freedom from FMD with vaccination must show evidence of an effective surveillance programme for clinical disease and demonstrate that FMD has not occurred in the country or zone for at least 2 years. Furthermore, surveillance for FMDV-infection must show that FMDV has not been circulating in the vaccinated population within the last 12 months. This will require serological surveillance incorporating tests able to detect antibodies to NSPs as described in this Guide.

Evidence to show the effectiveness of the vaccination programme is recommended.

Countries or zones re-applying for freedom from FMD where vaccination is either practiced or not practised, following an outbreak

In addition to the general conditions, a Member Country re-applying for freedom from FMD where vaccination is practised must show evidence of an active surveillance programme for FMD as well as FMDV infection.

Four strategies are recognised by OIE in a programme to eradicate FMD infection following an outbreak:

1) slaughter of all clinically affected and in-contact susceptible animals,

2) slaughter of all clinically affected and in-contact susceptible animals and vaccination of at-risk animals, and subsequent slaughter of vaccinated animals,

3) slaughter of all clinically affected and in-contact susceptible animals and vaccination of at-risk animals, without subsequent slaughter of all vaccinated animals,

4) vaccination used without slaughter of affected animals or subsequent slaughter of vaccinated animals

The time periods before which an application can be made for re-instatement of freedom from FMD depending on which of these alternatives is followed are indicated in article 2.1.1.7 of the FMD chapter of the *Code*.

In all circumstances, a Member Country or zone re-applying for freedom from FMD with vaccination must report the results of an active surveillance programme in which the FMD susceptible population undergoes regular clinical examination or where active surveillance has targeted a statistically significant sample of the susceptible population. In addition, a statistically significant sample, based on the susceptible population at risk during the outbreak, would need to be tested for absence of FMDV infection. The procedures to follow are described above, but when a Member Country or zone has used vaccination to help control the outbreak, and not subsequently slaughtered the vaccinated animals, it will be necessary to demonstrate that the sampling scheme employed takes into account the sensitivity of the diagnostic system used for the detection of vaccinated animals which may have been infected following exposure to live virus.

The use and interpretation of serological tests (see Fig 1)

The recommended serological tests for FMD surveillance are described in the *Manual of Standards for Diagnostic Tests and Vaccines* (OIE 2000). In unvaccinated populations, the screening can be carried out using the liquid-phase blocking ELISA (LPBE) or the solid phase competition ELISA (SPCE). The sensitivity of the LPBE approaches 100% but it can have a specificity in cattle as low as 95%, and will therefore give up to 5% false positive results at a titre greater than 40. Because the objective of the survey is to discover evidence of infection if the latter is present, it is acceptable for the purposes of the survey to raise the cut-off value for negative/positive sera. The rationale for raising or lowering the cut-off titre should be given in reports of tests for which this has been used. Raising of the cut-of value may still result in false positive results, and therefore positive sera should be re-tested by the virus neutralisation test (VNT), in which a titre of 45 or greater is classified as positive. Any animals whose sera are positive by the VNT should be re-sampled to confirm this status, and if still positive they should be tested for evidence of infection. The remaining animals in the herd/flock should also be tested for the presence of antibodies to FMDV and, if found positive, sampled by collection of OP material using a probang cup. The SPCE has been shown to have a higher specificity, but similar sensitivity to the LPBE, and should be used in preference to the LPBE where possible.

For serological surveillance in countries or zones in which vaccine is, or has been used, the LPBE or SPCE can still be the test of choice in those FMD susceptible species not included in the vaccination programme. Animals that have been vaccinated will have antibodies to the structural proteins of FMD virus, and some may have antibodies to the NSPs, depending on the number of times they have been vaccinated, and the amount of the NSPs present in the vaccine used. However, animals that have recovered from infection with FMD virus will have high levels of antibody to the NSPs. There are eight NSPs associated with the replication of FMD virus, namely L, 2A, 2B, 2C, 3A, 3B, 3C and 3D, and antibodies can be found to all of these in most recovered animals. Some do not persist for more than a few months, and some animals may fail to produce detectable levels to all of them. ELISA tests have been developed to detect 2C, 3B or 3ABC antibodies, the former being detectable for up to one year after infection, and the latter for up to two years. A western blot technique (EITB) has also been used to detect the NSP antibodies to 2C, 3ABC, 3A, 3B and 3D; it is particularly specific and sensitive in identifying animals previously infected. All these tests have been validated in cattle.

A class of animal exists, however, that has been infected with FMD virus and could remain carrying the virus without developing detectable antibodies to the NSPs. These are animals which have received highly potent vaccine and then had contact with the virus during an outbreak, but because of their level of immunity, suppress viral replication and show no evidence of disease. Because the virus does not replicate significantly in these animals, there is little expression of the NSPs and therefore development of detectable levels of antibodies may not occur. However, on a herd basis there are always less protected animals following vaccination, and if these animals are challenged with the virus, they will produce antibodies to the NSPs, and can develop clinical disease. It is therefore important that NSP antibody tests be interpreted by assessing the level of these antibodies in the sera of a representative sample from the whole herd.

There is the option to use the NSP antibody test together with the LPBE or SPCE, particularly in areas where vaccination has been used and virus activity is suspected. LPBE titres or SPCE inhibition higher than would be expected from vaccination alone may suggest FMD virus infection and this can be confirmed by testing for the presence of antibodies to the NSPs, and by taking OP samples.

The diagnostic sensitivity of tests used influences the numbers of animals that need to be sampled in a survey to provide evidence of absence of infection. The diagnostic specificity of the test influences the proportion and number of positive results to be expected in the absence or presence of infection, and therefore the selection and use of confirmatory tests. Results of surveys which indicate a significantly higher proportion of positive test results in comparison with that expected from the estimate of the false positive rate derived from the diagnostic specificity (ie 100 minus diagnostic specificity) may be interpreted as evidence of infection in the population and therefore a confirmatory test of high specificity, and where appropriate other investigations, should be conducted.

Figure 1 provides a flowchart of the test protocol that could be used to test the samples collected in the random survey. If the population being tested has not been previously vaccinated against FMD, the serum samples can be tested using the LPBE or SPCE. Sera positive on the test used should be retested using the VNT, which is the "gold standard" test for FMDV antibodies. In addition, or in place of the VNT if the laboratory is not able to manipulate live FMDV, the positive sera may be retested using a NSP antibody test, such as the 3B, 3ABC or EITB. If the positive sera are from a ruminant species, OP samples may also be collected and tested for the presence of live FMDV. A positive VNT or NSP test would indicate that live virus had been circulating, and would require further investigation of the herd or flock to show whether it was still present; a positive OP sample would provide definitive evidence. Further investigation should include serum testing of the whole herd or flock from which the positive samples were obtained, in addition to taking further OP samples to show whether live virus is still present.

NSP tests must be used for testing sera from vaccinated herds or flocks, as such sera will be positive by VNT. LPBE and SPCE can be used in addition, as described above. 3ABC or 3B positive samples may be repeat tested using the EITB for confirmation. All animals from herds and flocks from which positive samples are obtained must be re-tested for antibodies to NSP's, and OP samples collected for detection of live FMDV.

Data on the sensitivity and specificity of the NSP tests currently available is not fully documented, in particular for species other than cattle, or for vaccinated animals carrying live FMDV. However, this is under investigation in a number of laboratories worldwide. Member Countries submitting data to the FMD Commission derived using commercial or other NSP tests should provide information on the characteristics of the test being used, and adjust the number of samples collected to accommodate the test parameters. In addition, the testing of OP samples for the presence of FMDV may be less than 50% sensitive, even using very sensitive tissue culture such as primary bovine thyroid cells or lamb kidney cells. Repeat OP samples should be collected from serum-antibody positive animals after a two-week interval, if the initial attempt at virus isolation is negative, or further tests such as PCR carried out on the samples.

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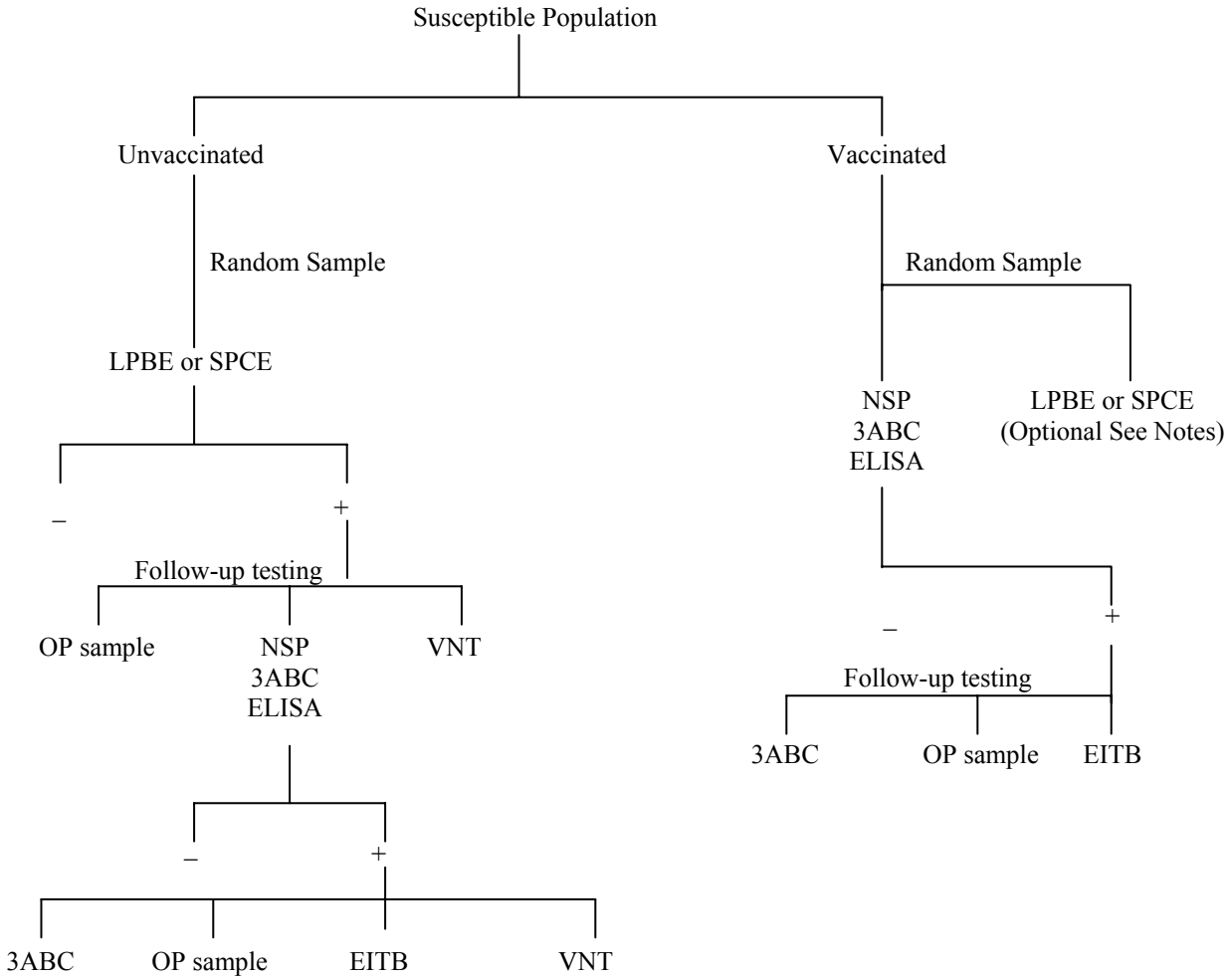
Fig 1: Schematic representation of laboratory tests for determining evidence of FMDV infection through, or following serological surveys



The above diagram indicates the tests which are recommended for use in the investigation of sampling units in which a positive test result has been obtained

Key:

ELISA	:	enzyme-linked immunosorbant assay
LPBE	:	liquid-phase blocking ELISA
SPCE	:	solid-phase competition ELISA
VNT	:	virus neutralisation test
NSP	:	nonstructural protein(s) of FMDV
3ABC	:	NSP antibody test
EITB	:	western blot for NSP antibodies of FMDV
OP	:	oesophageal–pharyngeal sample

SWILL

Definition

Swill is kitchen, catering or fresh market waste derived as a by-product from the preparation of human foodstuffs or unconsumed human food that is intended for feeding livestock. This practice is most often associated with swine rearing.

As a general principle the feeding of swill to pigs should be avoided because its content is usually not clearly defined and varies from day to day. This means that swill-fed pigs may unknowingly be exposed to substances or infectious agents that are either harmful to humans who subsequently eat the meat derived from swill-fed pigs or that are harmful to the pigs themselves. In the latter respect, swill may contain either processed or unprocessed pig tissues that could be infected with a number of viruses that severely affect the productivity of pigs such as those that cause CSF, FMD, ASF and SVD. For this reason swill is increasingly proscribed as a method for feeding pigs. However, because pigs are highly effective at transforming food waste into high quality protein, it may be that it is permitted by Member Countries under circumstances listed below:

Swill should as far as practically possible not contain the following:

- Products derived from pigs[1];
- Proteins derived from animals that were infected with any significant pathogen;
- Tissues of animals ,that contain biologically active chemical or hormonal residues;
- Food waste from vehicles (aircraft, trains, and buses) used for transport across international borders.

However, in practice and as indicated above, the content of swill is often not clearly identified and its content may vary. A further safety precaution is therefore the treatment of swill so that harmful bacterial and viral agents, in particular those that cause CSF, FMD, ASF and SVD are rendered non-infectious. It is assumed that the causative agent of bovine spongiform encephalopathy (BSE) that may be fed to pigs in swill contaminated by specified bovine offal is not a danger to human health because pigs have not been shown to be susceptible to BSE by the oral route. Nevertheless, bovine tissues should also be excluded from swill if the likelihood of the presence of BSE-affected tissues is a consideration. Feeding of proteins derived from pets and experimental animals, to other animals should also be strictly prohibited.

Procedure

Heat treatment of swill, either on a continuous treatment or batch basis, is the method most often employed to increase its safety. Other methods may be used but are usually more expensive and difficult to apply for logistical reasons. A simple standard for heat treatment is therefore detailed below. If any other method is used it is incumbent upon the Member Country to show that the method employed is at least as effective as the heat-treatment method (i.e., demonstration of equivalence).

Swill must be heated to boiling temperature for a period not less than 60 minutes with constant or at least frequent stirring. The period of the treatment may be shortened by increasing the temperature applied to the swill by subjecting it to increased pressure in an appropriate pressure vessel. It is incumbent upon the exporter to show that the quicker heating using pressure vessels is at least as effective as boiling for 60 minutes.

Written records documenting the process of inactivation of swill must be kept by the producer of the swill for a period of 6 months and its distribution (user name and locality) recorded.

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[1] Scientific and ethical opinion recognizes that the protein derived from an animal species should not be fed to the same species.

DEFINITION/GUIDELINES OF/ON VACCINES, VACCINATION AND EMERGENCY VACCINATION AGAINST FMD

Vaccine (FMD)

FMD vaccines are products that, when administered according to the manufacturer's instructions, induce immune responses able to protect the inoculated animals against the clinical effects of natural infection. Vaccines protect against disease but not necessarily against infection.

Vaccines currently recommended by the OIE for use against FMD are defined in the *Manual of Standards for Diagnostic Tests and Vaccines* (the *Manual)* Chapter 2.1.1 Section B.

Vaccination

In terms of the OIE *International Animal Health Code* (the *Code*), and specifically in respect of Chapter 2.1.1, "vaccination" means the systematic administration of FMD vaccine to an epidemiologically appropriate proportion of the susceptible animal population of the country or zone concerned with the result that circulation of FMD viruses does not occur. The vaccines must be manufactured from strains that are antigenically appropriate to the field situation in the country or zone concerned. The vaccine used must meet the standards set in the *Manual*

It is not possible to define *a priori* the species composition or the proportion of each species within the susceptible population that will need to be vaccinated to ensure that FMD viruses do not circulate in the country or zone because that will vary to some extent between different regions of the world and even between sub-regions. It will also depend on the behavioural characteristics of the FMD virus strains prevalent in the country or zone concerned or which threaten the country or zone. Therefore, a country may decide to vaccinate certain animal species and not others depending on the epidemiological conditions. Regular re-vaccination is necessary to maintain high levels of herd immunity but the vaccination schedule will be determined by the animal species concerned and epidemiological circumstance.

It is recommended that when vaccination is applied, the competent authority of the country or the zone concerned should monitor the effectiveness of the vaccination programme. This requires that it be shown that the vaccine has been administered to a high proportion (>80% is usually accepted as the minimum) of the target population based on accurate census figures. It should furthermore be shown by testing a statistically significant sample of the vaccinated population that average levels of neutralising (or equivalent) antibody are at or above the protective threshold.

Emergency vaccination

In the event of re-incursion of FMD into a country or zone where mass vaccination is practiced, revaccination to increase herd immunity levels (if the outbreak strain is homologous to the vaccine previously applied) should be undertaken. Additional information can be found the *Manual* Chapter 2.1.1 Section B.

Under emergency situations, FMD vaccines may be used in previously FMD-free countries or zones where vaccination was not practiced to assist in the control and elimination of the outbreak. Vaccines used under such circumstances should have a high antigenic payload ($PD_{50} \geq 6$) and contain vaccine strains appropriate to the causative virus. To achieve high levels of herd immunity re-vaccination within 3-6 weeks may be advantageous. The consequences for Member Countries of vaccination in a country or zone recognised by the OIE as being free from FMD without vaccination are detailed in chapter 2.1.1.of the *Code*.