COUNCIL DIRECTIVE

of 22 January 1980

introducing Community measures for the control of classical swine fever

(80/217/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 and 100 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament (1),

Having regard to the opinion of the Economic and Social Committee (2),

Whereas one of the Community's tasks in the veterinary field is to improve the state of health of livestock, thereby increasing the profitability of stock farming;

Whereas, moreover, such action should help to remove those remaining barriers to trade between Member States in live animals and fresh meat which are caused by differences in their respective animal health situations;

Whereas an outbreak of classical swine fever can take on epizootic proportions, causing mortality and disturbances on a scale which threatens the profitability of pig farming as a whole;

Whereas provisions must be adopted as soon as the presence of the disease is suspected so that immediate and effective action can be taken as soon as its presence is confirmed;

Whereas it is necessary to prevent any spread of the disease if an outbreak occurs, by carefully monitoring movements of animals and the use of products liable to be contaminated, and by vaccination;

Whereas the methods of diagnosing the disease in all its forms under the auspices of the laboratories responsible and the preparation of vaccine must be harmonized;

Whereas common measures for the control of classical swine fever form a basis for maintaining a uniform standard of animal health; whereas to that end a procedure should be laid down to establish close cooperation between the Member States and the Commission,

*HAS ADOPTED THIS DIRECTIVE:

Article 1

This Directive introduces Community measures for the control of classical swine fever.

Article 2

For the purposes of this Directive the following definitions shall apply:

- (a) 'holding' means any establishment (agricultural or other), situated in the territory of a Member State, in which animals of the porcine species are kept or bred;
- (b) 'breeding pig' means a porcine animal intended or used for reproduction with a view to multiplication of the species;
- (c) 'fattening pig' means a porcine animal fattened and intended for slaughter at the end of the fattening period with a view to meat production;
- (d) 'slaughter pig' means a porcine animal which is intended for slaughter without undue delay in a slaughterhouse;
- (e) 'pig suspected of being infected with swine fever' means any pig exhibiting clinical symptoms or showing post-mortem lesions or reactions to laboratory tests carried out according to Article 11, indicating the possible presence of swine fever;
- (f) 'pig infected with swine fever' means any pig:
 - in which clinical symptoms or post-mortem lesions of swine fever have been officially confirmed, or

⁽¹⁾ OJ No C 127, 21. 5. 1979, p. 90.

⁽²⁾ OI No C 227, 10. 9. 1979, p. 19.

- in which the presence of this disease has been officially confirmed as the result of a laboratory examination carried out in accordance with Article 11;
- (g) 'official veterinarian' means the veterinarian designated by the competent central authority of the Member State;
- (h) 'swill' means waste from kitchens, restaurants or, as the case may be, from industries using meat.

Member States shall ensure that the presence and suspected presence of swine fever are compulsorily and immediately notifiable to the competent authority.

Article 4

1. Where a holding contains one or more pigs suspected of being infected with swine fever, Member States shall ensure that the official veterinarian immediately sets in motion official means of investigation to confirm or rule out the presence of the said disease.

From the moment when the suspected presence is notified, the competent authority shall have the holding placed under official surveillance and shall in particular order that:

- all the pigs in the various categories on the holding must be counted and a list compiled of the number of pigs already dead or likely to be infected in each category; the list must be updated to take account of pig births and deaths during the period of suspicion; the information on the list must be produced upon request and may be checked at each visit,
- all the pigs on the holding must be restricted to their living quarters or be confined in some other place where they can be isolated,
- no pigs may enter or leave the holding.

The competent authority may, if necessary:

- (i) extend the ban on leaving the holding to cover other species of animals,
- (ii) if the disease has not been confirmed within 15 days, authorize the departure of animals intended for slaughter without delay under official supervision, provided that the meat from such animals is not permitted to enter intra-Community trade as fresh meat,

- no pigmeat may leave the holding without an authorization issued by the competent authority,
- no pig carcases may leave the holding without an authorization issued by the competent authority,
- no animal feed, utensils, materials or waste likely to transmit the epizootic disease may leave the holding without an authorization issued by the competent authority,
- the movement of persons to or from the holding must be subject to authorization by the competent authority,
- the movement of vehicles to or from the holding must be subject to authorization by the competent authority,
- appropriate means of disinfection must be used at the entrances and exits of buildings housing pigs and of the holding itself,
- an epizootiological enquiry must be carried out in accordance with Articles 7 and 8.
- 2. The measures provided for in paragraph 1 shall not be lifted until the suspicion of swine fever has been officially ruled out.

Article 5

- 1. In cases where the presence of swine fever is officially confirmed, Member States shall ensure that, in addition to the measures listed in Article 4 (1), the competent authority prescribes that:
- all pigs on the holding must be slaughtered without delay under official supervision and in such a way as to avoid the risk of the swine fever virus spreading during transport or slaughter,
- after slaughter of the pigs mentioned above, all carcases must be destroyed under official supervision in such a way that there is no risk of the swine fever virus spreading,
- meat of pigs slaughtered during the period between the probable introduction of disease to the holding and the taking of official measures must wherever possible be traced and destroyed under official supervision in such a way as to avoid the risk of the swine fever virus spreading,
- the carcases of pigs which have died on the holding must be destroyed under official supervision in such a way as to avoid the risk of the swine fever virus spreading,

- all substances and waste likely to be contaminated, such as feedingstuffs, must be subjected to a treatment ensuring the destruction of any swine fever virus present; this treatment must be carried out in accordance with the instructions of the official veterinarian,
- after the pigs have been eliminated, the buildings used for housing the pigs, the vehicles used for transporting them and all equipment likely to be contaminated must be cleaned and disinfected in accordance with Article 10,
- the reintroduction of pigs to the holding may not take place until at least 15 days after completion of the cleaning and disinfection operations carried out in accordance with Article 10,
- an epizootiological enquiry shall be carried out in accordance with Articles 7 and 8.
- 2. In the case of pigs which are not infected or suspected of being infected, and notwithstanding the first and second indents of paragraph 1, Member States may authorize transport of such pigs under permanent veterinary supervision from the holding in question directly to specialized establishments on condition that:
- the pigs are slaughtered without delay,
- the meat from such animals undergoes heattreatment to ensure that the swine fever virus is destroyed, and that every precaution is taken to prevent recontamination of the products thus obtained, always provided that these products are not permitted to enter intra-Community trade.

- 1. In the case of holdings which consist of two or more separate production units and in order that fattening of pigs may be completed, the competent authority may derogate from the first and second indents of Article 5 as regards healthy pig production units on a holding which is infected provided that the official veterinarian has confirmed that the structure and size of these production units and the operations carried out there are such that the production units provide completely separate facilities for housing, keeping and feeding, so that the virus cannot spread from one production unit to another.
- 2. If use is made of the derogation in paragraph 1, the Member States shall draw up detailed rules for applying it in the light of the animal health guarantees which can be given.

Member States which make use of paragraph 1 shall notify the Commission thereof.

3. A decision may be taken, in accordance with the procedure laid down in Article 16, that these measures are to be modified in order to ensure that they coordinate with those adopted by the Member States.

Article 7

The epizootiological enquiry shall deal with:

- the length of time during which swine fever may have existed on the holding before the disease was notified,
- the possible origin of the swine fever on the holding and the identification of other holdings on which there are pigs which may have become infected from the same source,
- the movement of persons, vehicles, pigs, carcases, meat or material likely to have transported the virus to and from the holdings.

Article 8

- 1. (a) Where the official veterinarian finds, or considers on the basis or confirmed data, that swine fever could have been introduced from other holdings on to the holding referred to in Article 4, or from the latter holding on to other holdings, as a result of the movement of persons, pigs or vehicles or in any other way, those other holdings shall be placed under official surveillance in accordance with paragraph (c), and this surveillance shall not be lifted until the suspected presence of swine fever on the holding referred to in Article 4 has been officially ruled out.
 - (b) Where the official veterinarian finds, or considers on the basis of confirmed data, that swine fever could have been introduced on to the holding referred to in Article 5 from other holdings as a result of the movement of persons, pigs or vehicles or in any other way, those other holdings shall be placed under official surveillance in accordance with paragraph (c).

Where the official veterinarian finds, or considers on the basis of confirmed data, that

swine fever could have been introduced from the holding referred to in Article 5 on to other holdings as a result of the movement of persons, pigs or vehicles or in any other way, those other holdings shall become subject to the provisions of Article 4.

- (c) The purpose of the official surveillance shall be to detect immediately any suspicion of swine fever, count the pigs and monitor their movements and, where appropriate, implement some or all of the measures provided for in Article 4 (1).
- 2. When a holding has been subject to the provisions of paragraph 1 (a) and the first subparagraph of paragraph 1 (b), the competent authority may authorize removal from the holding of pigs other than those on account of which the said measures were imposed, for transport directly to a slaughter-house under official supervision for the purpose of immediate slaughter.

Prior to granting such authorization, the official veterinarian must have carried out an examination of the pig herd and confirmed that none of the pigs is suspected of being infected with swine fever.

3. The competent authority may, where it considers that conditions permit, limit the measures provided for in paragraph 1 (a) and the first subparagraph of paragraph 1 (b) to a part of the holding and the pigs contained therein, provided that the pig units there have been housed, kept and fed-completely separately.

Article 9

- 1. Once the diagnosis of swine fever has been officially confirmed, the competent authority shall establish a protection zone with a minimum radius of 2 km around the infected holding.
- 2. (a) The following measures shall be applied in the protection zone:
 - the movement of pigs on public or private roads shall be prohibited other than for transport in transit,
 - the pigs may not be removed from the holding on which they are kept except to be transported directly to a slaughterhouse under official supervision for the purpose of immediate slaughter. Such transport may be authorized by the competent authority

only after the official veterinarian has carried out an examination of all pigs on the holding and confirmed that none of the pigs is suspected of being infected with swine fever,

- itinerant boar service shall be prohibited,
- fairs, markets, shows or other gatherings of pigs, including collection and distribution of pigs by dealers, shall be prohibited.
- (b) The measures applied in the protection zone shall be maintained until at least 15 days after all pigs on the holdings or in the production units to which Article 6 (1) applies and where there were pigs infected with swine fever have been destroyed, and the cleaning and disinfection operations carried out on such holdings or in such units in accordance with Article 10 have been completed.
- 3. Where the prohibitions provided for in paragraph 2 (a) are maintained beyond the 15 days prescribed because of the occurrence of further cases of the disease and as a result problems arise in housing the pigs, for the purposes of animal welfare the competent authority may, following an application by the owner explaining the grounds for such application, authorize the removal of fattening pigs from a holding within the protection zone, provided that:
- (a) the official veterinarian has verified the facts;
- (b) the pigs have been examined and declared sound and are transported directly to the holding of destination without coming into contact with other animals, the means of transport used being cleaned and disinfected before and after use;
- (c) the holding of destination is located either in the protection zone or within 20 km of that zone and has adequate housing facilities;
- (d) the holding of destination is placed under official surveillance upon the pigs' arrival, so that any suspicion of swine fever can be detected immediately, animals can be counted and their movements monitored.

The competent authority may also, under the conditions laid down in (a) and (b), authorize the transport of breeding pigs between two holdings situated within the protection zone.

The official surveillance measures provided for in (d) shall be maintained for as long as are the measures provided for in accordance with paragraph 2 (b) in the protection zone surrounding the holding from which the pigs have been sent.

Member States shall ensure that:

- the disinfectants to be used and their concentrations are officially approved by the competent authority,
- the cleaning and disinfection operations are carried out under official supervision, in accordance with the instructions given by the official veterinarian.

Article 11

- 1. Member States shall ensure that:
- sampling and laboratory testing to detect the presence of classical swine fever are carried out in accordance with Annex I. The provisions of Annex I may be supplemented or amended in accordance with the procedure laid down in Article 16,
- a national laboratory is responsible for coordinating standards and methods of diagnosis in each Member State in accordance with the provisions of Annex II.
- a laboratory designated by the Community liaises between the national laboratories referred to in the second indent.
- 2. The Council, acting on a proposal from the Commission, shall designate the laboratory referred to in the third indent of paragraph 1 and shall determine its powers and the conditions of its operation before the date on which this Directive is implemented.

Article 12

- 1. Without prejudice to existing Community provisions in this field, Member States shall inform the Commission and the other Member States about the epizootiology and development of the disease in accordance with Annex III.
- 2. The provisions of Annex III may be supplemented or amended in accordance with the procedure laid down in Article 16.

Article 13

Member States shall ensure that:

 when pigs are moved out of the holding on which they are kept, they are marked such that the holding from which they come or their holding

- of origin, and the animals' movements, may be readily identified; the competent authority may, however, in the case of certain categories of pig and in certain circumstances, having regard to the health situation, authorize other ways of rapidly indentifying the holding from which they come, or their holding of origin, and the animals' movements. The arrangements for marking the animals or for identifying the holdings referred to above shall be determined by the competent authorities,
- all persons engaged in the transport or marketing of pigs are able to supply the competent authority with information concerning the movements of pigs which they have transported or marketed, and to furnish proof of such movements; the same obligation shall be incumbent on all persons keeping pigs in respect of the pigs entering or leaving their holding.

Article 14

Member States shall ensure that:

- (a) in general:
 - the use of specific immune-serum or sero vaccination is prohibited,
 - requirements relating to swine fever vaccine established in accordance with the procedure laid down in Article 16 are observed,
 - swine fever vaccines imported into a Member State from third countries fulfil the same conditions as those produced in the Member States and are authorized and checked by the competent central authority in the importing Member State;
- (b) where swine fever is detected on a holding or in a production unit:
 - (i) the measures to control the disease may be supplemented by the vaccination of pigs in the other production units or on holdings threatened with contamination in a territorial area demarcated by the competent authority.
 - Without prejudice to national provisions where they provide for preventive vaccination of pigs against swine fever, whether in all or part of the national territory, where all categories of pigs are vaccinated pursuant to the preceding subparagraph, sows of breeding age vaccinated may leave the vaccinated area only to be taken to a slaughterhouse for slaughter,
 - (ii) the pigs vaccinated are permanently marked in accordance with the instructions of the competent authority.

Member States shall ensure that:

- 1. the use of swill originating from means of international transport, such as ships, land vehicles or aircraft, is prohibited for the feeding of pigs and that such swill is collected and destroyed under official supervision;
- 2. swill for the feeding of pigs must be heat-treated so as to ensure the destruction of swine fever virus. Swill so treated may be used for feeding to fattening pigs only and pigs fattened on a holding using such swill may leave the holding only to go for slaughter.

However, the competent authority may allow the feeding of other categories of pigs with swill provided that the pigs kept on the holding cannot leave except to go for slaughter;

3. the collection, transport and treatment of swill intended for feeding to pigs are subject to official authorization.

Swill must be transported in vehicles or containers so designed that it cannot leak or fall out of the vehicle during transport.

Each time after use, the vehicles or containers used for the transport of swill must be cleaned and disinfected according to the instructions of the competent authority;

- 4. the authorization referred to in paragraph 3 for the treatment of swill is granted subject to the following conditions:
 - the holding must have completely separate facilities for treated and untreated swill,
 - the premises for storage of untreated swill and the premises where treatment takes place must be easy to clean and disinfect;
- 5. swill collected in accordance with paragraph 3 may be used only on the holding where it has been heat-treated.

Member States may authorize the treatment of swill in specialized establishments equipped for the purpose, on which there are no animals and which are under official control. In this case, by way of derogation from paragraph 2, the swill may, after heat-treatment, also be used for the feeding of pigs

- other than fattening pigs, provided that its distribution and use are controlled so as to avoid any risk of the swine fever virus spreading;
- 6. the authorization referred to in paragraph 3 is not required in the case of small holdings using their own swill for feeding to their own pigs, provided that such swill is heat-treated in a manner such as to ensure the destruction of swine fever virus.

Article 16

- 1. Where the procedure laid down in this Article is to be followed, the matter shall without delay be referred by the chairman, either on his own initiative or at the request of a Member State, to the Standing Veterinary Committee (hereinafter referred to as 'the Committee') set up by the Council Decision of 15 October 1968.
- 2. Within the Committee the votes of the Member States shall be weighted as laid down in Article 148 (2) of the Treaty. The chairman shall not vote.
- 3. The representative of the Commission shall submit a draft of the measures to be adopted. The Committee shall deliver its opinion on these measures within a time limit set by the chairman having regard to the urgency of the questions under examination. Opinions shall be delivered by a majority of 41 votes.
- 4. The Commission shall adopt the measures and shall implement them immediately, where they are in accordance with the opinion of the Committee. Where the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall without delay submit to the Council a proposal on the measures to be taken. The Council shall adopt the measures by a qualified majority.

If the Council has not adopted any measures within three months of the date on which the matter is referred to it, the Commission shall adopt the proposed measures and shall implement them immediately unless the Council has voted against the said measures by a simple majority.

Article 17

Article 16 shall apply until 21 June 1981.

Article 18

On the basis of a report on the experience acquired in controlling swine fever, together with any changes as may be suggested, the Council shall review the requirements herein two years after implementation of this Directive.

Article 19

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive on a date to be decided by the Council, acting unanimously on a proposal from the Commission, before 1 July 1980.

Article 20

This Directive is addressed to the Member States.

Done at Brussels, 22 January 1980.

For the Council

The President

G. MARCORA

ANNEX I

DIAGNOSTIC PROCEDURES FOR THE CONFIRMATION OF SWINE FEVER

The following guidelines, standards and minimum criteria are laid down for the diagnostic procedures. The designated national swine fever laboratories shall define the materials and methods for use in the diagnosis of swine fever.

A. COLLECTION OF MATERIALS FOR DIAGNOSIS

- 1. For virus isolation and antigen detection, tonsil tissue is considered essential. Samples of kidney, spleen and ileum, together with maxillary and mesentric lymph nodes should also be collected. Each sample of the tissue should be placed in a separate plastic bag and labelled. The samples should be transported and stored in leak-proof containers. They should not be frozen but kept cool at refrigerator temperature and tested without delay.
- 2. (a) Blood samples for virus isolation should be collected, preferably from pigs showing signs of fever or other signs of disease. Sterile non-cytotoxic tubes should be used for this purpose, and the samples should be kept cool, preferably at refrigerator temperature and then subjected to laboratory testing without delay.
 - (b) Blood samples may be collected for virus isolation from leucocytes of suspected pigs. Blood is prevented from clotting preferably by the addition of EDTA (1). The samples should be kept cool at refrigerator temperature and submitted to laboratory testing within two days.
- 3. Blood samples for the detection of antibody as an aid to diagnosis of clinical outbreaks and for the purposes of surveillance, should be taken from animals which have recovered from suspect infection and from sows known to have been in contact with infected or suspect cases. In such suspect holdings all of the first 20 suspect or in-contact animals, and 25 % of any additional animals, should be sampled. In order to ensure a high probability of detection of antibody induced by swine fever virus, samples should be collected from each unit of the holding at this level. Sero diagnosis should not be attempted where vaccination has been officially carried out.

B. THE LABORATORY DIAGNOSIS OF SWINE FEVER

The principal basis for the laboratory diagnosis of swine fever shall be the demonstration of viral antigen in organ tissues as described in paragraph 1.

In the case of negative or inconclusive results, the tests shall be repeated on the same samples. Additional samples should be collected from the same source.

Virus isolation is required in cases of inconclusive or negative results from material derived from animals giving rise to suspicion of swine fever or with material from holdings which have had contact with cases of swine fever. Where, in such circumstances, the demonstration of viral antigen or virus isolation has not been successful, tests for the detection of neutralizing antibody shall be applied to blood samples of animals which have recovered from the suspect disease and from those known to have been in contact with the disease.

Materials, methods and diagnostic criteria shall be prescribed by the national swine fever laboratory in each Member State.

⁽¹⁾ Ethylene diamine tetraacetic acid: sodium salt.

1. Demonstration of viral antigen

For the demonstration of viral antigen in organ tissues, the direct immunofluorescence technique shall be applied to thin cryostat sections (up to five microns) of tonsils and tissues of other organs as specified in A (1).

For the application of the direct immunofluorescence test the following requirements shall be adopted:

- (a) hyperimmune serum shall be prepared from pigs free from infections or antibody which could affect the specificity or quality of the reaction;
- (b) fluorescein conjugated immunoglobulin prepared from swine fever hyperimmune pig serum as specified under (a) shall have a minimum working titre of ¹/₂₀ as determined in swine fever infected cell cultures and confirmed by check tests on tissue sections. The working dilution of the conjugate shall combine a maximum of brilliance with a minimum of background staining;
- (c) any sample showing specific cytoplasmic fluorescence shall be considered positive for swine fever. In case of doubt, the results should be confirmed by virus isolation in cell cultures;
- (d) when fluorescence has been detected which is suspected to be due to vaccinal virus, the holding shall be regarded as a suspect holding until such time as the competent authority may decide.

2. Virus isolation and identification in cell cultures

- (a) Virus isolation from tissue samples is performed on susceptible (PK 15) cell cultures or equally susceptible cell lines. Cell cultures grown on cover-slips are exposed to a suitably prepared 10 % suspension of tissue from the suspect animal; starting with a 10 % suspension, the cultures shall be stained and examined for specific cytoplasmic fluorescence at intervals from 24 to 72 hours from the time of inoculation.
- (b) Virus isolation from blood samples, collected and handled as indicated in paragraph A (2) (b), is performed by the inoculation of cell cultures according to the procedures described in paragraph A (2) (a) or (b) respectively. These cultures should be exposed to buffy coat suspension reconstituted to the original blood volume. In the case of serum samples the cell cultures should be exposed to not more than a 20 % dilution of the serum to be tested.

C. DETECTION OF ANTIBODY INDUCED BY SWINE FEVER VIRUS IN BLOOD SAMPLES

The detection of neutralizing antibody in blood samples is carried out to assist in the diagnosis of swine fever in holdings containing pigs showing clinical signs of the disease or in pigs believed to have had contact with infected pigs. It may also be carried out for the purposes of surveillance or for surveys in herds of unknown status.

For these purposes, blood samples should be subjected to an approved test.

The following tests based on the direct immunofluorescence technique are approved for use and must be carried out with the inclusion of appropriate positive and negative serum controls.

1. Plaque reduction test (PRT)

This test is based on the microplaque counting method. Three-fold dilutions of serum commencing at ¹/₂₀ are tested against an equal volume of virus suspension containing 300 to 1000 plaque forming units (PFU) of a virulent strain of swine fever virus using at least two monolayer cultures per dilution.

The results are expressed as the plaque reduction titre, which is the reciprocal of the serum dilution which reduces the number of fluorescent foci by 90 % as compared with the ¹/₂₀ diluted negative control serum. The titres are determined graphically.

2. The neutralization index test (NI test)

The test is based on the microplaque counting method. A stock of virus is titrated in cell cultures in the presence of an equal volume of a ¹/₂₀ dilution of serum. At least two monolayer cultures are required for each log₁₀ dilution of virus suspension.

The degree of neutralizing activity is expressed as the difference between the infectious titre in the presence of a ¹/₂₀ dilution of known negative serum and the titre of the same virus suspension in the presence of the suspect serum. This difference is the neutralization index and is expressed logarithmically.

3. The virus neutralization and immunofluorescence test (NIFT)

This test is based on the determination of the 50 % endpoint. Cultures are inoculated with constant amounts of virus after incubation with serum and the results are based on the absence of any specific cytoplasmic fluorescence.

The sera are diluted ½5 for screening purposes. Two-fold dilutions of serum starting at ½5 are prepared when a full titration is necessary. Each dilution is mixed with an equal volume of virus suspension containing 100 to 200 infectious doses (TCID 50). At least two cultures are used at each dilution level. The NIFT results are expressed as the reciprocal of the dilution at which half the inoculated cell cultures fail to show any specific fluorescence. An end-point between two dilution levels is interpolated.

D. EVALUATION OF THE RESULTS OF LABORATORY TESTING

- 1. The demonstration of viral antigen in organ tissues or virus isolation from tissue samples following the techniques defined in B (1) and (2) shall form the basis of confirmation of the presence of the disease except in the case of a reaction demonstrated to be due to vaccinal virus according to B (1) (d).
- 2. Following the detection of antibody reacting with swine fever virus, the herd of origin shall be regarded as suspect.
 - (a) In order to rule out the suspicion of swine fever raised by the detection of antibody, the test described in Section E below shall be used to distinguish between swine fever reacting antibody that may have been induced by BVD virus and such antibody due to swine fever virus itself. All original samples shall be retested by the differential test.
 - (b) If suspicion cannot be ruled out on the first differential test, a further test carried out at least 30 days later to follow up the possible spread of infection. All of the first 20 animals on the suspect holding shall be sampled and 25 % of any additional animals.

3. Interpretation of serological results

(a) Plaque reduction test (PRT)

A titre of \geq 50 in any pig together with clinical or epizootiological evidence giving rise to suspicion of disease shall constitute a positive diagnosis.

A titre of \geq 50 in any pig without clinical or epizootiological evidence gives rise to suspicion of disease and should be followed by differential diagnostic procedures.

(b) Neutralization index (NI test)

A titre of ≥ 1.0 in any pig together with clinical or epizootiological evidence giving rise to suspicion of disease shall constitute a positive diagnosis.

A titre of ≥ 1.0 in any pig without clinical or epizootiological evidence gives rise to suspicion of disease and should be followed by differential diagnostic procedures.

(c) Virus neutralization and immunofluorescence test (NIFT)

A titre of \geq 5 in any pig together with clinical or epizootiological evidence giving rise to suspicion of disease shall constitute a positive diagnosis.

A titre of \geq 5 in any pig without clinical or epizootiological evidence gives rise to suspicion of disease and should be followed by differential diagnostic procedures.

E. DIFFERENTIAL DIAGNOSIS BETWEEN SWINE FEVER (SF) AND BOVINE VIRUS DIARRHOEA (BVD)

1. Tests for the differential diagnosis of swine fever (SF) and bovine virus diarrhoea (BVD) are based on parallel end-point titrations of the sera with both SF and BVD virus strains using fully comparable methods.

The SF and BVD virus strains for use should have been officially approved. To rule out the suspicion of swine fever raised by the detection of antibody blood samples should be examined by comparative end-point titrations for neutralizing antibody against SF virus and BVD virus.

- 2. The results of the comparative serological tests between swine fever and bovine virus diarrhoea shall be interpreted as follows:
 - (a) if the comparative tests show:
 - that more than one pig has antibody to SF with no antibody to BVD, or
 - that the titres against SF virus are equal to or higher than the titres against BVD in a large proportion of the pigs,

swine fever shall be confirmed;

- (b) if the comparative tests show some of the titres to SF virus to be equal to or higher than the titres to BVD virus in a proportion of the pigs there shall be suspicion of swine fever and differentiation shall proceed as follows:
 - those pigs which show neutralizing titres against SF virus which are higher than or equal to the titres against BVD virus shall be slaughtered and their foetuses, together with any tissues estimated to be of value, shall be subjected to examination for swine fever antigen or virus,
 - if swine fever antigen or virus is detected, swine fever shall be confirmed,
 - if the examination defined in the second indent above fails to reveal the presence of swine fever antigen or virus, the holding shall be considered as suspect until a further set of blood samples collected at least 30 days later has been subjected to further comparative tests,
 - if these subsequent comparative tests show all animals to have significantly (four-fold or greater) higher titres against BVD virus than SF virus, suspicion shall be ruled out,
 - if one or more animals show a titre against SF virus that is equal to or higher than its titre to BVD virus, swine fever shall be confirmed;
- (c) if the BVD titres are such as not to exlude the possibility of swine fever, the holding shall be considered as suspect and be retested after at least 30 days.

ANNEX II

The national swine fever laboratories are as follows:

Denmark:

Statens veterinære Institut for Virusforskning, Lindholm;

Italy:

Istituto zooprofilattico sperimentale dell'Umbria e delle Marche,

Perugia;

Great Britain:

Central Veterinary Laboratory, Weybridge, Surrey, England;

Northern Ireland:

Veterinary Research Laboratory, Stormont, Belfast;

Belgium:

Institut national de recherches vétérinaires, Groeselenberg 99, B-1180

Bruxelles;

France:

Laboratoire central de Recherches vétérinaires d'Alfort, rue Pierre

Curie 22, 94700 Maisons Alfort;

Luxembourg:

Laboratoire bactériologique de médicine vétérinaire de l'État, avenue

Gaston Diderich 54, Luxembourg;

Ireland:

Veterinary Research Laboratory, Abbotstown, Castleknock, Co.

Dublin;

Germany:

Bundesforschungsanstalt für Viruskrankheiten der Tiere, Tübingen;

Netherlands:

Central Veterinary Institute, Lelystad.

The national swine fever laboratory in each Member State shall be responsible for coordinating the standards and diagnostic methods laid down in each swine fever diagnostic laboratory within the Member State. To this end:

- (a) they may provide diagnostic reagents to individual laboratories;
- (b) they shall control the quality of all diagnostic reagents used in that Member State;
- (c) they shall arrange comparative tests periodically;
- (d) they shall hold isolates of swine fever virus from cases confirmed in that Member State.

ANNEX III

Epizootiological information

- 1. Within 24 hours of notification of the first outbreak of swine fever, the Member State concerned must forward the following information to the Commission and the other Member States:
 - the date on which swine fever was suspected,
 - the date on which swine fever was confirmed and the methods used for confirmation,
 - the location of the infected holding and its distance from the nearest pig farms,
 - the number of pigs of each category on the holding,
 - for each category, the number of pigs in which swine fever has been confirmed and the morbidity of the disease.
- 2. The information specified in paragraph 1 shall be followed as soon as possible by a report stating the following:
 - the date on which the pigs on the holding were slaughtered and destroyed,
 - where the derogation provided for in Article 6 has been applied, the number of pigs slaughtered and destroyed and the number of pigs which are to be slaughtered at a later date and the time limit laid down for their slaughter,
 - any information relating to the possible origin of the disease or the origin of the disease if this has been ascertained.
- 3. The Member State concerned shall forward the information specified in paragraph 1 to the Commission and the other Member States within the time limit laid down in that paragraph in respect of each subsequent outbreak of swine fever on other holdings, until the number of infected holdings and the dispersion of the disease show it to be extensive.