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Contents

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other Acts are printed in bold type and preceded by an asterisk.

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE

of 22 January 1980

amending Directive 72/461/EEC on animal health problems affecting intra-Community trade in fresh meat

(80/213/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Articles 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 Directive 72/461/EEC (3), as last amended by Directive 78/54/EEC (4), lays down the health requirements which must be fulfilled by animals from which meat is obtained;

Whereas although the meat obtained from animals not satisfying the health conditions must be excluded from intra-Community trade in fresh meat because of the risk of transmission of contagious or infectious animal diseases, it may be used for other purposes when it has undergone treatment for the destruction of the germs of those diseases;

Whereas such meat should therefore be given a special mark indicating that it is excluded from intra-Community trade as fresh meat and guaranteeing its health qualities for other uses, for example for the preparation of certain categories of meat products,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 72/461/EEC is hereby amended as follows:

1. The following Article shall be inserted:

'*Article 5a*

Notwithstanding Article 5 (1), and in so far as it is not intended for intra-Community trade in fresh meat, the meat referred to in that Article may carry the mark defined in Annex I, Chapter IX of Directive 64/433/EEC, provided that the special mark referred to in the Annex to this Directive is immediately superimposed thereon.

The provisions of Annex I, Chapter IX, point 39 of Directive 64/433/EEC shall apply *mutatis mutandis* to the keeping and use of marking instruments.

Such meat must be obtained, cut, transported and stored separately from, or not at the same time as, meat intended for intra-Community trade in fresh meat.'

(1) OJ No C 289, 19. 11. 1979, p. 42.

(2) Opinion delivered on 24 and 25 October 1979 (not yet published in the Official Journal).

(3) OJ No L 302, 31. 12. 1972, p. 24.

(4) OJ No L 16, 20. 1. 1978, p. 22.

2. The following Annex shall be added:

'ANNEX

Mark for meat intended for a use other than intra-Community trade in fresh meat

1. The overstamping must be done in such a way that the oval stamp defined in Annex I, Chapter IX No 40 of Directive 64/433/EEC is covered by a diagonal cross consisting of two straight lines crossing at right angles, with the point of intersection in the centre of the stamp and the information thereon remaining legible.

2. The marks mentioned in paragraph 1 may also be made with a single stamp which will be an oval stamp 6·5 cm long and 4·5 cm broad; the following information must appear on the mark in perfectly legible characters:

   — on the upper part, the name of the exporting country in capitals,

   — in the centre, the veterinary approval number of the slaughterhouse,

   — on the lower part, one of the following sets of initials: EEC — CEE — EWG — EEG — EØF,

   — two straight lines crossing the stamp diagonally, intersecting at right angles at the centre of the stamp in such a way that the information is not obscured.

   The letters must be 0·8 cm high and the figures 1 cm high.

   The stamp may also carry information whereby the veterinarian who inspected the meat may be identified.'

Article 2

The Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 December 1980.

Article 3

This Directive is addressed to the Member States.

Done at Brussels, 22 January 1980.

For the Council

The President

G. MARCORA

COUNCIL DIRECTIVE

of 22 January 1980

amending Directive 77/99/EEC on health problems affecting intra-Community trade in meat products

(80/214/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission,

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

Whereas Directive 77/99/EEC (2) lays down that only fresh meat suitable for intra-Community trade may be used for the preparation of meat products;

Whereas the application of certain treatments, notably heat treatment which destroys the germs of animal diseases potentially present in certain categories of meat which otherwise comply with the rules of hygiene for human consumption, permits that meat, although excluded from intra-Community trade in fresh meat for animal health reasons, to be used for the preparation of meat products; whereas Directive 77/99/EEC should therefore be amended accordingly,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 77/99/EEC is hereby amended as follows:

1. In Article 2 (1) (b), the following indent shall be added:

   '— Article 1 of Directive 72/461/EEC.'

2. Article 2 (1) (c) shall be replaced by the following:

   '(c) fresh meat: fresh meat as defined in Article 1 of Directives 64/433/EEC, 71/118/EEC and 72/461/EEC and in Article 2 of Directive 72/462/EEC.'

3. The following point shall be inserted in Article 3 (1) (3) (a):

   '(i) a in accordance with Article 5a of Directive 72/461/EEC in the Member State in which the preparation is carried out.'

Article 2

The Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 December 1980.

Article 3

This Directive is addressed to the Member States.

Done at Brussels, 22 January 1980.

For the Council

The President

G. MARCORA

(1) OJ No C 289, 19. 11. 1979, p. 42.
(2) OJ No L 26, 31. 1. 1977, p. 85.

COUNCIL DIRECTIVE

of 22 January 1980

on animal health problems affecting intra-Community trade in meat products

(80/215/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission,

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

Whereas Council Directive 77/99/EEC of 21 December 1976 on health problems affecting intra-Community trade in meat products (2) has been applicable since 1 July 1979;

Whereas the implementation of the above Directive will not have the desired effect so long as intra-Community trade is hindered by differences between the health requirements of Member States concerning meat products; whereas, in particular with a view to eliminating these differences, common provisions should be laid down in this field;

Whereas, in order to avoid the spread of epizootic diseases by means of meat products it should be laid down that the meat from which some of the said meat products are manufactured should comply with the health provisions applicable to fresh meat;

Whereas care should be taken that meat products which do not comply with Community rules are not given the health mark provided for in those rules;

Whereas when meat products have been treated in such a way as to destroy all germs of diseases which may be passed on to animals, such treatment should be mentioned on the health certificate which accompanies the products concerned;

Whereas the Member States must have the right to refuse the entry into free circulation in their territory of meat products which have been found to contain germs of a contagious or infectious disease or which do not comply with Community health provisions;

Whereas the consignor should at his own request or at that of a representative be allowed to have the meat products returned to him unless there are health grounds for not doing so;

Whereas, in order to enable those concerned to appreciate the basis for any prohibition or restriction imposed, the reasons for such prohibition or restriction should be brought to the notice of the consignor or his representative and, in certain cases, the competent authorities of the consigning country;

Whereas the consignor should be afforded the opportunity of requesting the opinion of a veterinary expert in the event of a dispute between the consignor and the authorities of the country of destination as to whether a prohibition or restriction is justified;

Whereas the Member States must have the right to prohibit the introduction into their territory of certain meat products from a Member State where an epizootic disease has broken out; whereas, depending on the nature and character of this epizootic disease, such a prohibition may either be limited to meat products coming from a part of the territory of the exporting country, or extended to the whole of that territory; whereas, in the event of an outbreak of a contagious or infectious disease in the territory of a Member State appropriate measures must be taken rapidly to control it; whereas the dangers inherent in such diseases and the requisite protective measures should be viewed in the same light throughout the Community;

Whereas, to facilitate the implementation of the provisions envisaged, a procedure should be laid down establishing close cooperation between the Member States and the Commission within the Standing Veterinary Committee set up by the Council Decision of 15 October 1968 (3),

(1) OJ No C 114, 11. 11. 1971, p. 40.
(2) OJ No L 26, 31. 1. 1977, p. 85.
(3) OJ No L 255, 28. 10. 1968, p. 23.

HAS ADOPTED THIS DIRECTIVE:

Article 1

This Directive lays down animal health requirements for intra-Community trade in meat products.

Article 2

For the purposes of this Directive, the definitions contained in Article 2 of Council Directive 72/461/EEC of 12 December 1972 on health problems affecting intra-Community trade in fresh meat (1), as amended by Directive 78/54/EEC (2), and in Article 2 of Directive 77/99/EEC shall apply where relevant.

Products which have been subjected to natural fermentation and maturation for a long period shall be regarded as having undergone complete treatment until the Council, acting unanimously on a proposal by the Commission, amends the limits given in Annex A, Chapter V (27) (b) to Directive 77/99/EEC.

Article 3

Each Member State shall ensure that meat products intended for intra-Community trade are prepared from or with:

— fresh meat as defined in Article 1 of Council Directive 64/433/EEC of 26 June 1964 on health problems affecting intra-Community trade in fresh meat (3), as last amended by Directive 75/379/EEC (4), and fulfilling the animal health requirements of Articles 3 and 4 of Directive 72/461/EEC,

— fresh meat as defined in Article 2 (a) of Council Directive 72/462/EEC of 12 December 1972 on health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat from third countries (5), as last amended by Directive 77/98/EEC (6), and complying with the animal health requirements of Directive 72/462/EEC.

Article 4

1. By way of derogation from the first indent of Article 3, and subject to the application of paragraph 2, meat products may be intended for intra-Community trade, which are prepared in whole or in part from or with fresh meat as defined in Article 1 of Directive 64/433/EEC which fulfils the requirements laid down by Article 5a of Directive 72/461/EEC, may enter intra-Community trade if they have also undergone one of the following forms of treatment:

(a) heat treatment in a hermetically sealed container, with an Fc value of 3·00 or more;

(b) where the fresh meat has been obtained from animals which do not come from an infected holding subject to prohibition measures pursuant to Article 3 (2) (b) of Directive 64/432/EEC:

(i) heat treatment different from that referred to in (a) in which the internal temperature is raised to at least 70 °C, or

(ii) treatment consisting in natural fermentation and maturation of not less than nine months for boned or boneless hams weighing not less than 5·5 kg and having the following characteristics:

— a_w value of not more than 0·93,

— pH value of not more than 6.

2. Each Member State shall ensure that:

(a) the fresh meat referred to in paragraph 1 is:

(i) transported and stored separately from, or not at the same time as, the fresh meat referred to in Article 3,

(ii) used in such a way as to avoid it being introduced into meat products intended for intra-Community trade other than those indicated in paragraph 1;

(b) the health certificate specified in Annex A, Chapter VIII of Directive 77/99/EEC contains, without prejudice to footnote (3) of that certificate, the following words under the heading 'Nature of products': 'Treated in accordance with Article 4 (1) of Directive 80/215/EEC'.

Article 5

1. Member States shall ensure that meat products which do not fulfil the requirements of Articles 3 and 4 are not given the health mark provided for in Directive 77/99/EEC, Annex A, Chapter VII.

2. The country of destination may prohibit the entry of meat products into circulation in its territory

(1) OJ No L 302, 31. 12. 1972, p. 24.
(2) OJ No L 16, 20. 1. 1978, p. 22.
(3) OJ No 121, 29. 7. 1964, p. 2012/64.
(4) OJ No L 172, 3. 7. 1975, p. 17.
(5) OJ No L 302, 31. 12. 1972, p. 28.
(6) OJ No L 26, 31. 1. 1977, p. 81.

if it has been established that Articles 3 and 4 have not been complied with.

3. In such case, the country of destination must, at the request of the consignor or his representative, authorize the return of the whole consignment of meat products, provided that this is not contrary to animal health considerations.

4. The competent authority of the country of destination may order the consignment to be destroyed at the expense of the consignor, the consignee or their representative without indemnification by the State, where entry into circulation is prohibited pursuant to paragraph 2 and where the exporting country or country of transit, as the case may be, does not authorize return of the consignment.

5. The decisions taken by the competent authority under paragraphs 2, 3 and 4 must be communicated to the consignor or his representative, together with the reasons for such decisions. Where the consignor or his representative so requests, these decisions and the grounds on which they have been taken must be communicated to him forthwith in writing with an indication of the remedies for which current legislation makes provision, their forms and the time limits within which they are open. The decisions must also be communicated to the competent central authority of the exporting country.

Article 6

1. This Directive shall not affect the remedies for which legislation current in Member States makes provision against the decisions of the competent authorities referred to in this Directive.

2. In the case of meat products which may not enter circulation pursuant to Articles 3 and 4, each Member State shall grant consignors the right to obtain the opinion of a veterinary expert.

Each Member State shall ensure that, before the competent authorities take any other measures such as destroying the meat products, the veterinary expert has an opportunity of determining whether the conditions of Articles 3 and 4 have been fulfilled.

The veterinary expert must be a national of a Member State other than the exporting country or the country of destination.

Acting on a proposal from the Member States, the Commission shall draw up a list of the veterinary experts who may be instructed to formulate such opinions. After consulting the Member States, it shall lay down the general rules which are to be applied, in particular as regards the procedure for formulating these opinions.

Article 7

1. A Member State may take the following measures if there is a danger that animal diseases may be spread by the introduction of meat products from another Member State into its territory:

(a) in the event of an outbreak of classical foot and mouth disease, classical swine fever or Teschen disease in the other Member State, the introduction of products prepared from the meat of animals which are susceptible to these diseases, other than products which have undergone one of the treatments referred to in Article 4 (1), may be temporarily prohibited or restricted from those parts of the territory of the Member State in which the disease has appeared;

(b) if an epizootic disease becomes widespread or if there is an outbreak of another serious and contagious or infectious animal disease, the introduction, from the entire territory of that State, of products prepared from the meat of animals which are susceptible to these diseases may be temporarily prohibited or restricted.

2. Each Member State must notify the other Member States and the Commission without delay of the outbreak in its territory of any disease referred to in paragraph 1 and of the measures it has taken to combat it. It must also notify them without delay of the disappearance of the disease.

3. Measures taken by a Member State under paragraph 1, and repeal thereof, must be communicated without delay to the other Member States and to the Commission, together with the reasons for such action.

It may be decided, according to the procedure laid down in Article 8, that these measures should be amended, in particular to ensure coordination with those adopted by the other Member States, or abolished.

4. If the situation provided for in paragraph 1 arises and if it seems necessary that other Member States should also apply the measures taken pursuant to the said paragraph, together with any amendments made in accordance with paragraph 3, the appropriate provisions shall be adopted according to the procedure defined in Article 8.

5. In drawing up the amendments referred to in the second subparagraph of paragraph 3, or the provisions referred to in paragraph 4, a decision may be taken in accordance with the same procedure to adapt them in the light of the disease in question, the treatments that the products concerned have undergone, the date on which the meat used was obtained and the processing period.

Article 8

1. Where the procedure laid down in this Article is to be followed, the matter shall be referred to the Standing Veterinary Committee (hereinafter called 'the Committee'), set up by the Council Decision of 15 October 1968, by its chairman, either on his own initiative or at the request of a Member State.

2. Within the Committee, the votes of the Member States shall be weighted as provided in Article 148 (2) of the Treaty. The chairman shall not vote.

3. The Commission representative shall submit a draft of the measures to be taken. The Committee shall deliver its opinion on the measures within two days. Opinions shall be delivered by a majority of 41 votes.

4. Where the measures are in accordance with the opinion of the Committee, the Commission shall adopt them and shall apply them immediately. Where they 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 15 days of the date on which the proposal was submitted to it, the Commission shall adopt the measures proposed and shall apply them immediately, save where the Council has decided against them by a simple majority.

Article 9

Article 8 shall apply until 21 June 1981.

Article 10

Acting unanimously on a proposal from the Commission, the Council shall, before 1 July 1980, decide on any provisions concerning swine fever to be inserted into this Directive with respect to certain products in the light of the solutions adopted on intra-Community trade in fresh pigmeat.

Article 11

1. Acting on a proposal from the Commission, the Council shall lay down the animal health requirements applicable to intra-Community trade in fresh poultrymeat and to imports of such poultrymeat from third countries.

2. Pending the entry into force of the Community provisions referred to in paragraph 1, national animal health provisions concerning the import of meat products prepared in part or in whole from or with fresh poultrymeat shall remain applicable while complying with the general provisions of the Treaty.

Article 12

Until the implementation of Community animal health Directives concerning imports of meat products other than those referred to in Article 11 (2) from third countries, national provisions applicable to the import of these products shall not be more favourable than those which result from this Directive.

Article 13

The Member States shall bring into force the measures necessary to comply with:

— the second indent of Article 3, on the date provided for in the second subparagraph of Article 32 (2) of Directive 72/462/EEC,

— the other provisions of this Directive, by 31 December 1980 at the latest,

and shall forthwith inform the Commission thereof.

Article 14

This Directive is addressed to the Member States.

Done at Brussels, 22 January 1980.

For the Council

The President

G. MARCORA

COUNCIL DIRECTIVE

of 22 January 1980

amending Directive 71/118/EEC on health problems affecting trade in fresh poultrymeat

(80/216/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas Directive 71/118/EEC of 15 February 1971 on health problems affecting trade in fresh poultrymeat (4), as last amended by Directive 77/27/EEC (5), lays down the slaughtering and inspection requirements for poultrymeat intended for intra-Community trade and trade within Member States;

Whereas poultry rearing and the marketing of poultrymeat is carried on to a large extent by small-scale producers who sell their produce at local markets and account for a significant part of the agricultural activity in certain Community regions; whereas such activities should be allowed to continue under certain conditions;

Whereas the method of production of 'foie gras' makes evisceration of the recently slaughtered bird impossible without seriously damaging the liver;

Whereas while ensuring that the hygiene and inspection requirements established under Community legislation, and in particular under the relevant provisions of Annex I, Chapters I, III and XIV to the Directive referred to, are strictly maintained, the necessary specific amendments should be made to such legislation,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 71/118/EEC is hereby amended as follows:

1. The following subparagraph shall be added to Article 3 (1) (A) (a):

   'Notwithstanding the requirements of the first subparagraph, birds intended for the production of 'foie gras' may be stunned, bled and plucked on the fattening farm, provided that these operations are carried out in a separate room which complies with the requirements of Annex I, Chapter I, C, and that, in accordance with Annex I, Chapter XIV, the uncondeviscerated carcases are transported immediately to an approved cutting plant which is equipped with a special room as defined in Annex I, Chapter II, (2) (b) a, where the carcases must be eviscerated within 24 hours.'

2. In the second subparagraph of Article 3 (5), the words 'and until 15 August 1981' shall be deleted.

3. In Annex I, Chapter II (2):

   — the following subparagraph shall be added:

   '(b) a If evisceration is carried out there, a room for the evisceration of ducks and geese reared for the production of 'foie gras' which have been stunned, bled and plucked on the fattening farm',

   — the words 'and under (b) a' shall be added to the first line of point (h).

4. In Annex I, Chapter III (3) (c), 'and (b) a' shall be inserted after the words 'and to (2) (b)'.

(1) OJ No C 247, 1. 10. 1979, p. 16.
(2) OJ No C 34, 11. 2. 1980, p. 106.
(3) Opinion delivered on 24 and 25 October 1979 (not yet published in the Official Journal).
(4) OJ No L 55, 8. 3. 1971, p. 23.
(5) OJ No L 6, 8. 1. 1977, p. 19.

5. The following subparagraph shall be added to Annex I, Chapter IV (13):

'However, in the case of ducks and geese reared for the production of "foie gras" and stunned, bled and plucked on the fattening farm, the *ante mortem* inspection may be carried out in the last week of fattening.'

6. The following subparagraph shall be added to Annex I, Chapter IV (14):

'In the case of ducks and geese reared for the production of "foie gras" and stunned, bled and plucked on the fattening farm, the certificate referred to in Annex IIIa must accompany the uneviscerated carcases on arrival at the cutting plant equipped with the separate room for evisceration.'

7. The following subparagraph shall be added to Annex I, Chapter V (23):

'However, ducks and geese reared and slaughtered for the production of "foie gras" may be eviscerated within 24 hours, provided that uneviscerated carcases are as soon as possible reduced to and then kept at the temperature laid down in Chapter XII (46) and transported in accordance with the rules of hygiene.'

8. The following Annex shall be added:

'ANNEX IIIa

MODEL

Health certificate for the carcases of ducks and geese reared for the production of "foie gras", stunned, bled and plucked on the fattening farm and transported to a cutting plant which is equipped with a separate room for evisceration

Competent service ..... No (1) .....

I. Identification of uneviscerated carcases

Species: .....

Number of uneviscerated carcases: .....

II. Origin of uneviscerated carcases

Address of fattening farm: .....

III. Destination of uneviscerated carcases

The uneviscerated carcases will be transported to the following cutting plant: .....

.....

by the following means of transport: .....

IV. Attestation

I, the undersigned, official veterinarian, certify that the uneviscerated carcases described above are of birds which were examined *ante mortem* on the abovementioned fattening farm at .....

(time) on ..... (date) and found to be healthy.

Done at ..... on .....

.....

(Signature of official veterinarian)'.

(1) Optional.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive on 1 February 1980, and shall forthwith notify the Commission thereof.

Article 3

This Directive is addressed to the Member States.

Done at Brussels, 22 January 1980.

For the Council

The President

G. MARCORA

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) OJ 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.

Article 3

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 heat-treatment 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.

Article 6

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 slaughterhouse 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.

Article 10

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.

Article 15

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.

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(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 1 000 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 $\log_{10}$ 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 $^1/_5$ for screening purposes. Two-fold dilutions of serum starting at $^1/_5$ 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 $\geqslant$ 50 in any pig together with clinical or epizootiological evidence giving rise to suspicion of disease shall constitute a positive diagnosis.

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

A titre of ⩾ 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.

COUNCIL DIRECTIVE

of 22 January 1980

prolonging certain derogations granted to Denmark, Ireland and the United Kingdom in respect of swine fever

(80/218/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas, under Article 1 of Directive 79/580/EEC (4), Denmark, Ireland and the United Kingdom were authorized to retain until 31 December 1979 their national provisions for ensuring protection against swine fever;

Whereas Community rules offer the only final solution to the problems caused by this disease;

Whereas the proposals which have been forwarded for this purpose by the Commission must be re-examined; whereas a sufficient period should be provided for their adoption by the Council and their implementation by the Member States prior to the expiry of the abovementioned derogations;

Whereas, therefore, these derogations should be extended until 30 June 1980,

HAS ADOPTED THIS DIRECTIVE:

Article 1

By way of derogation from Directive 64/432/EEC (5), and from Directive 72/461/EEC (6), both as last amended by Directive 79/580/EEC, Denmark, Ireland and the United Kingdom are authorized to retain their national rules relating to protection against swine fever upon introduction into their territory of swine for breeding, store and slaughter and to imports of fresh pigmeat, subject to compliance with the general provisions of the Treaty.

Article 2

This Directive shall apply from 1 January until 31 June 1980.

Article 3

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive and shall inform the Commission thereof.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 22 January 1980.

For the Council

The President

G. MARCORA

(1) OJ No C 295, 24. 11. 1979, p. 2.
(2) OJ No C 34, 11. 2. 1980, p. 108.
(3) Opinion delivered on 12 December 1979 (not yet published in the Official Journal).
(4) OJ No L 158, 26. 6. 1979, p. 17.
(5) OJ No 121, 29. 7. 1964, p. 1977/64.
(6) OJ No L 302, 31. 12. 1979, p. 24.

COUNCIL DIRECTIVE

of 22 January 1980

amending Directive 64/432/EEC as regards tuberculosis and brucellosis

(80/219/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas bovine tuberculosis has virtually disappeared from certain regions of the Community; whereas it is necessary to reduce the cost of routine testing for tuberculosis in those regions;

Whereas, in order to reduce the time taken to restore officially tuberculosis-free status to herds in which tuberculosis has been found, the necessary methods of control must be adopted;

Whereas under Article 104 (3) of the Act of Accession, Denmark, Ireland and the United Kingdom were authorized to retain, until 31 December 1977, their national provisions for declaring a herd of cattle officially free of tuberculosis or free of brucellosis; whereas these authorizations were extended on three occasions (4) (5) (6) in the case of tuberculosis and, in the case of Ireland and the United Kingdom, on two occasions (4) (5) as regards brucellosis-free status within the meaning of Article 2 of Directive 64/432/EEC (7), as last amended by Directive 77/98/EEC (8);

Whereas these derogations were instituted and extended because of the time required to provide solutions to basic technical problems;

Whereas, for the same reasons, these derogations apart from that affecting traditional trade in live animals between Ireland and the United Kingdom should be extended for a further period of one year;

Whereas, in order to facilitate trade in certain bovine animals and until such time as the Community accelerated disease-eradication programme is completed, it is necessary to amend and to prolong certain derogations relating to brucellosis which were provided for in Article 7 (1) (C) of Directive 64/432/EEC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 64/432/EEC is hereby amended as follows:

1. The following paragraph shall be added to Article 3:

'14. By way of derogation from Annex A (I) (b), a decision may be taken in accordance with the procedure laid down in Article 12 that in a Member State or part of a Member State composed of several adjacent regions where at least 99·9 % of the bovine herds have been declared officially tuberculosis-free within the meaning of Article 2 (d) for at least 10 years, and where every year for at least six years bovine tuberculosis has not been found to be present in more than one herd per 10 000 herds in that Member State or part thereof, it being understood that all cattle which have reacted positively to a tuberculin test, and all cattle slaughtered within the territory of that Member State, must have been submitted to a post mortem examination by an official veterinarian and if necessary a bacteriological examination, the inspections for determining whether the status is to be retained may be carried out in a manner and in parts of the Member State to be decided in accordance with the same procedure.

(1) OJ No C 268, 23. 10. 1979, p. 2.
(2) OJ No C 34, 11. 2. 1980, p. 109.
(3) Opinion delivered on 21 November 1979 (not yet published in the Official Journal)
(4) OJ No L 15, 19. 1. 1978, p. 32.
(5) OJ No L 29, 3. 2. 1979, p. 27.
(6) OJ No L 158, 26. 6. 1979, p. 17.
(7) OJ No 121, 29. 7. 1964, p. 1977/64.
(8) OJ No L 26, 31. 1. 1977, p. 81.

If one of the conditions provided for in the first subparagraph ceases to be fulfilled, the Commission, after assessing the circumstances of the recrudecence of tuberculosis, and if its assessment gives grounds for so doing, shall adopt a decision in accordance with the same procedure to rescind the derogation decision taken in respect of that Member State or part of that Member State composed of several adjacent regions.'

2. In Annex A (I):

(i) under (b):

— in the second sentence, the words 'or in a region of a Member State' shall be added after the words 'Member State',

— the following sentence shall be added:

'If the percentage infected bovine herds does not exceed 0·1% during two successive supervisory periods separated by an interval of three years, the interval between subsequent tuberculin tests may be increased to four years and/or the age at which animals have to undergo these tests may be increased to 24 months.'

(ii) the following subparagraph shall be added:

'If in an officially tuberculosis-free herd, an animal is deemed to have reacted positively to a routine tuberculin test, or a clinical case of tuberculosis has been diagnosed at routine post mortem examination of an animal from an officially tuberculosis-free herd, the officially tuberculosis-free status of the herd must be suspended until such time as all the remaining animals over six weeks of age have reacted negatively to at least two official intradermal tuberculin tests in accordance with Annex B, the first one carried out at least two months after elimination of the animal from the herd and the second one at least 42 days after the first.'

3. Annex B shall be replaced by the Annex to this Directive.

4. In Article 7 (1):

(a) under C:

— in the second sentence, the words 'if over 30 days old' shall be inserted between the words 'animals' and 'must',

— in the second subparagraph the date '31 December 1979' shall be replaced by '31 December 1981';

(b) the following point shall be added:

'E. Bovine animals which have not undergone the sero-agglutination test prescribed in C and D above, provided that they satisfy the following conditions:

(i) in the case of bovine animals intended for meat production:

— they are less than 42 days of age, or have been castrated before the age of four months,

— they are moved under supervision, if necessary via a weaning unit, to an approved fattening holding and do not leave that holding except to go for slaughter;

(ii) in the case of bovine animals for slaughter, they are moved under official supervision directly to the slaughterhouse.

These provisions shall apply until 31 December 1981.'

5. In Annex A (II) (A), the following paragraph shall be added:

'7. The tests provided for in paragraphs 1 to 6 shall not be required for male animals castrated before the age of four months.'

Article 2

For the purpose of testing tuberculins known as 'synthetic' tuberculins, a Member State which, at the date of adoption of this Directive, makes use of a standard tuberculin conforming with the international standard for old tuberculin may, by way of derogation from Annex B (1) to Directive 64/432/EEC, continue to apply this method until more advanced international standards are introduced.

Article 3

The Council, acting on a proposal from the Commission, and before 1 January 1984, shall designate the Community laboratories and the manner of their operation in accordance with Annex B (27) to Directive 64/432/EEC.

Under the procedure laid down in Article 12 of Directive 64/432/EEC the Standing Veterinary Committee shall designate the tuberculins to be tested and the examinations to be carried out, and may amend the list of laboratories where these examinations must be carried out.

Article 4

This Directive shall apply:

— from 1 January 1980 as regards Article 1 (4),

— by 31 December 1980 at the latest as regards the other provisions.

Article 5

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive.

They shall forthwith inform the Commission thereof.

2. Until the date on which they are able to comply with this Directive, and until 31 December 1980 at the latest:

— Denmark, Ireland and the United Kingdom are hereby authorized to retain the methods applied in their territory whereby a herd of cattle becomes considered to be officially tuberculosis-free within the meaning of Article 2 of Directive 64/432/EEC,

— Ireland and the United Kingdom are hereby authorized to retain the methods applied in their territory whereby a herd of cattle becomes considered to be brucellosis-free within the meaning of Article 2 of Directive 64/432/EEC subject to the application of the provisions of that Directive relating to the presence of animals vaccinated against brucellosis.

The provisions relating to the tests laid down for animals traded within the Community shall continue to apply.

Article 6

This Directive is addressed to the Member States.

Done at Brussels, 22 January 1980.

For the Council

The President

G. MARCORA

ANNEX

'ANNEX B

Standards for the manufacture and use of bovine and avian tuberculins

1. Officially supervised tuberculin tests must be carried out with PPD or HCSM tuberculins.

2. Manufacturers' working standards for the control of bovine PPD and HCSM tuberculins must be calibrated in Community tuberculin units (CTU) following biological assay against the appropriate EEC standard tuberculin.

3. Manufacturers' working standards for the control of avian tuberculins must be calibrated in international units following biological assay against the EEC standard for PPD of avian tuberculin.

4. The EEC standard for PPD of bovine tuberculin is that supplied by the Centraal Diergeneeskundig Instituut, Afdeling Rotterdam, the Netherlands.

5. The EEC standard for bovine HCSM tuberculin is that supplied by the Institut Pasteur, Paris, France.

6. The EEC standard for avian tuberculin is that supplied by the Central Veterinary Laboratory, Weybridge, Surrey, England.

7. Bovine tuberculins must be prepared with one of the mycobacterium bovis strains indicated below:

   (a) AN5;

   (b) Vallee.

8. Avian tuberculins must be prepared with one of the mycobacterium avium strains indicated below:

   (a) D4ER;

   (b) TB56.

9. The pH of tuberculins must be between 6·5 and 7·5.

10. Antimicrobial preservatives or other substances that may be added to a tuberculin shall have been shown, to the satisfaction of the State institute responsible for the official testing of the tuberculin, not to impair the safety and effectiveness of the product.

    The following are the maximum permitted concentrations for phenol and glycerol:

    (a) phenol: 0·5 % M/v;

    (b) glycerol: 10 % v/v.

11. Provided the tuberculins are stored at a temperature between 2 and 8 °C, protected from light, they may be used up to the end of the following periods subsequent to the last satisfactory potency test:

    (a) liquid PPD tuberculins: two years,
    lyophilized PPD tuberculins: eight years;

    (b) HCSM tuberculins diluted: two years.

12. The State institutes listed below shall be responsible for the official testing of tuberculins in their respective countries:

(a) Germany:	Paul-Ehrlich Institut, Frankfurt/Main;
(b) Belgium:	Instituut voor Hygiëne en Epidemiologie, J. Wytsmanstraat 14, B-1050 Brussels;
(c) France:	Laboratoire national des médicaments vétérinaires, Fougères;
(d) Grand Duchy of Luxembourg:	institute of the supplying country;
(e) Italy:	Istituto superiore di sanità, Rome;
(f) Netherlands:	Centraal Diergeneeskundig Instituut, Afdeling Rotterdam;
(g) Denmark:	Statens Veterinære Serumlaboratorium, Copenhagen V;
(h) Ireland:	institute of the supplying country;
(i) United Kingdom:	The Central Veterinary Laboratory, Weybridge, Surrey.

13. Official testing must be carried out on each batch of bottled tuberculins ready for use.

14. Tuberculins shall be tested by biological and chemical methods.

15. Tuberculins must be sterile. Tests for sterility shall be carried out according to the specifications of the European Pharmacopeia.

16. A test for the absence of toxic or irritant properties shall be carried out according to the specifications of the European Pharmacopeia.

17. Tuberculins must be chemically analyzed to determine the concentration of glycerol and/or phenol and also the concentration of any other preservative which may have been added.

18. A test of non-sensitization to tuberculin must be carried out according to the specifications of the European Pharmacopeia.

19. The potency of tuberculins must be assessed by biological methods. These methods must be used for HCSM and PPD tuberculins; they are based on the comparison with standard tuberculins of the tuberculins to be tested.

20. The protein content of PPD tuberculin must be estimated by the Kjeldahl method. The nitrogen is converted into tuberculo-protein content by multiplying by a factor of 6·25.

21. The EEC standard for bovine HCSM has a potency of 65 000 Community tuberculin units (CTU) per ml and is dispensed in ampoules containing 5 ml of tuberculin.

22. The EEC standard for bovine PPD has a potency of 50 000 Community tuberculin units (CTU) per mg of PPD and is dispensed lyophilized in ampoules containing 1·8 mg of PPD, i.e. 0·00002 mg PPD has a potency equal to one Community tuberculin unit.

23. The EEC standard for avian PPD has a potency of 50 000 international units (i.u.) per mg of the dried material of the purified protein derivative and is dispensed in the lyophilized in ampoules containing 10 mg of PPD plus 26·3 mg of salts, i.e. 0·0000726 mg of the standard has a potency equal to one international unit.

24. Tuberculins submitted by manufacturers for testing by the State institutes listed in paragraph 12 must have been tested for potency by biological assay against the appropriate standards as listed in paragraphs 2 and 3.

25. (a) Potency testing on guinea pigs

Albino guinea-pigs weighing between 400 and 600 g must be used. These guinea-pigs must be in good health at the time of injection of the tuberculin. Not less than eight guinea-pigs shall be used for each assay. The assay should be made not less than one month after sensitization.

(aa) For the assay of bovine tuberculins, guinea-pigs shall be sensitized by one of the following methods:

1. the injection of heat-killed Mycobacterium bovis strain AN5 in oil adjuvant,

2. the injection of living Mycobacterium bovis strain AN5 in physiological saline,

3. the injection of BCG vaccine.

(bb) For the assay of avian tuberculins guinea-pigs shall be sensitized by injection of 2 mg of heat-killed avian-type tubercular bacilli suspended in 0·5 ml of sterile liquid paraffin or by the injection of live avian-type tubercular bacilli in physiological saline. The avian-type strain D4 must be used for this purpose.

(cc) Each tuberculin under test shall be assayed against the appropriate standard tuberculin by an intradermal assay using groups of guinea-pigs suitably sensitized.

The hair shall be clipped from both sides of each guinea-pig. The assay shall be carried out by comparing the reactions induced by a series of intracutaneous injections of doses of not more than 0·2 ml of dilutions of the standard tuberculin in isotonic buffered saline solution containing Tween 80, 0·0005 %, with a corresponding series of injections of the tuberculin under test. Dilutions shall be arranged in geometric series, and injected into guinea-pigs according to a randomized Latin square design (four sites on each side of an eight-point assay is used). The diameters of the reactions at each site should be measured and recorded after 24 to 28 hours.

For each sample of tuberculin under test, an estimate of relative potency against the appropriate standard and its fiducial limits shall be made by statistical methods, using the diameters of the reactions and the logarithms of the doses as metameters. The bovine tuberculin under test is of acceptable potency if its estimated potency guarantees per bovine dose 2 000 Community tuberculin units (± 25 %) in cattle. The potency of each tuberculin under test shall be expressed as appropriate in Community tuberculin units or international units per ml.

(b) Potency testing on cattle

Periodic potency testing of bovine tuberculins may be carried out on naturally or artificially infected tuberculous cattle. These potency tests, on groups of tuberculous cattle, shall be carried out by intradermal four or six-point assay of the tuberculin under test against the appropriate standard and the potency of the tuberculin shall be estimated by statistical methods as in the guinea-pig assay.

26. The following requirements shall apply to the labelling of tuberculin containers and packages:

The label on the containers and the label on the package shall state:

— the name of the preparation,

— for liquid preparations, the total volume in the container,

— the number of Community or international units per ml or per mg,

— the manufacturer's name,

— the batch number,

— the nature and quantity of the reconstituting liquid for the freeze-dried preparation.

The label on the container or the label on the package shall state:

— the expiry date,

— the conditions of storage,

— the name and, if possible, the proportions of any added substance,

— the strain of bacillus from which the tuberculin has been made.

27. Community laboratories designated in accordance with Article 3 will be made responsible for the additional examination of routine issue field tuberculins used in the Member States to ensure that the potency of each of these tuberculins is adequate in relation to the appropriate Community standard tuberculin. These examinations must be carried out, in tuberculous bovines, in suitably sensitized guinea-pigs and by appropriate chemical tests.

28. The following shall be recognized as official intradermal tuberculin tests:

(a) The single intradermal test — this test requires a single injection of bovine tuberculin.

(b) The intradermal comparative test — this test requires one injection of bovine tuberculin and one injection of avian tuberculin given simultaneously.

29. The dose of tuberculin injected shall be:

1. not less than 2 000 CTU of bovine tuberculin;

2. not less than 2 000 IU of avian tuberculin.

The volume of each injection dose shall not exceed 0·2 ml.

30. Tuberculin tests shall be carried out by injecting tuberculin(s) into the skin of the neck. The injection sites shall be situated at the border of the anterior and middle thirds of the neck. When both avian and bovine tuberculins are injected in the same animal, the site for injection of avian tuberculins shall be about 10 cm from the crest of the neck and the site for the injection of bovine tuberculin about 12·5 cm lower on a line roughly parallel with the line of the shoulder or on different sides of the neck; in young animals in which there is not room to separate the sites sufficiently on one side of the neck, one injection shall be made on each side of the neck at identical sites in the centre of the middle third of the neck.

31. The technique of tuberculin testing and interpretation of reactions shall be as follows:

(a) Technique:

Injection sites shall be clipped and cleansed. A fold of skin within each clipped area shall be taken between the forefinger and thumb and measured with calipers and recorded. A short sterile needle, bevel edge outwards, with graduated syringe charged with tuberculin attached shall be inserted obliquely into the deeper layers of the skin. The dose of tuberculin shall then be injected. A correct injection shall be confirmed by palpating a small pealike swelling at each site of injection. The skin-fold thickness of each injection site shall be remeasured 72 hours after injection and recorded.

(b) Interpretation of reactions:

The interpretation of reactions shall be based on clinical observations and the recorded increases(s) in skin-fold thickness at the sites of injection 72 hours after injection of tuberculin(s).

(ba) Negative reaction: If only limited swelling is observed, with an increase of not more than 2 mm in the thickness of the fold of skin without clinical signs such as diffuse or extensive oedema, exudation, necrosis, pain or inflammation of the lymphatic ducts in that region or of the lymph nodes.

(bb) Inconclusive reaction: If no clinical signs such as mentioned in (ba) are observed and if the increase in skin-fold thickness is more than 2 mm and less than 4 mm.

(bc) Positive reaction: If clinical signs such as mentioned in (ba) are observed or there is an increase of 4 mm or more in the thickness of the fold of skin at the injection site.

32. The interpretation of official intradermal tuberculin tests shall be as follows:

(a) single intradermal test:

positive: a positive bovine reaction as defined in paragraph 31 (bc);

inconclusive: an inconclusive reaction as defined in paragraph 31 (bb);

negative: a negative bovine reaction as defined in paragraph 31 (ba).

Animals inconclusive to the single intradermal test shall be subjected to another test after a minimum of 42 days.

Animals which are not negative to this second test shall be deemed to be positive to the test.

Animals positive to the single intradermal test may be subjected to an intradermal comparative test;

(b) intradermal comparative test for the establishment and maintenance of officially tuberculosis-free herd status:

positive: a positive bovine reaction which is more than 4 mm greater than the avian reaction, or the presence of clinical signs;

inconclusive: a positive or inconclusive bovine reaction which is from 1 to 4 mm greater than the avian reaction, and the absence of clinical signs;

negative: a negative bovine reaction, or a positive or inconclusive bovine reaction but which is equal to or less than a positive or inconclusive avian reaction and the absence of clinical signs in both cases.

Animals inconclusive to the intradermal comparative test shall be subjected to another test after a minimum of 42 days. Animals which are not negative to this second test shall be deemed to be positive to the test;

(c) officially tuberculosis-free herd status may be suspended until such time as the status of the following animals is resolved:

1. animals which have been deemed to be inconclusive to the single intradermal tuberculin test;
2. animals which have been deemed to be positive to the single intradermal tuberculin test but are awaiting retest with an intradermal comparative test;
3. animals which have been deemed to be inconclusive to the intradermal comparative test.

33. Animals destined for intra-Community trade must be subjected to a single intradermal test within 30 days prior to movement. Any animal which shows an increase in skin-fold thickness greater than 2 mm or the presence of clinical signs must not be entered into intra-Community trade.

Animals from herds referred to in 32 (c) shall not be permitted to enter intra-Community trade until such time as the health status of the animals referred to therein has been clarified.'