

Proposal for a Council Directive on Community measures for the control of classical swine fever

(2001/C 531 E/06)

(Text with EEA relevance)

COM(2000) 462 final — 2000/0214(CNS)

(Submitted by the Commission on 15 September 2000)

THE COUNCIL OF THE EUROPEAN UNION,

action can be taken as soon as its presence is confirmed, including depopulation of the infected holding.

Having regard to the Treaty establishing the European Community, and in particular Article 37 thereof,

(6) If an outbreak occurs it is also necessary to prevent any further spread of the disease by carefully monitoring movements of animals and the use of products liable to be contaminated, cleaning and disinfection of the infected premises, establishment of surveillance and protection zones around the outbreak and, if necessary, by vaccination.

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

(7) In case of infection, vaccinated pigs may become apparently healthy virus carriers and further spread the disease; the use of vaccines may only be authorised in emergencies.

Having regard to the opinion of the Committee of the Regions,

Whereas:

(8) Special eradication measures should be applied in case of disease in feral pigs.

(1) Council Directive 80/217/EEC of 22 January 1980 introducing Community measures for the control of classical swine fever⁽¹⁾ has been frequently and substantially amended; now that it is also to be further amended, the Directive should, for reasons of clarity and rationality, be recast as a single text.

(9) Provisions should be established to guarantee that harmonised procedures and methods are used for the diagnosis of classical swine fever, including the establishment of a Community reference laboratory as well as reference laboratories in the Member States.

(2) Since live animals are listed in Annex I of the Treaty, one of the Community's tasks in the veterinary field is to improve the state of health of pigs, thereby facilitating trade in pig and pig products to ensure the development of this sector.

(10) Provisions should be established to ensure the necessary preparedness to effectively tackle the emergency situations related to one or more outbreaks of classical swine fever.

(3) In the event of an outbreak of classical swine fever, it is necessary to establish at Community level control measures to eradicate the disease in order that the development of the pig sector is ensured and to contribute to the protection of animal health in the Community.

(11) Some of the measures so far adopted in the Community in the event of an outbreak of classical swine fever in accordance with Directive 80/217/EEC should be changed to take into account scientific advances, development of new diagnostic tools and vaccines and the experiences gained following the outbreaks of classical swine fever which recently occurred in the Community.

(4) An outbreak of classical swine fever can take on epizootic proportions, causing mortality and disturbances on a scale which threatens in particular the profitability of pig farming as a whole.

(12) In order to ensure the continuity of the coordination of the diagnostic work carried out under the auspices of the competent national laboratories, the 'Institut für Virologie der Tierärztlichen Hochschule, Hanover', designated by Council Decision 81/859/EEC⁽²⁾ should be confirmed as the Community reference laboratory. For reasons of legal certainty, Decision 81/859/EEC should be repealed.

(5) Measures should be adopted as soon as the presence of the disease is suspected so that immediate and effective

⁽¹⁾ OJ L 47, 21.2.1980, p. 11; Directive as last amended by the Act of Accession of Austria, Finland and Sweden.

⁽²⁾ OJ L 319, 7.11.1981, p. 20; Decision as amended by Decision 87/65/EEC (OJ L 34, 5.2.1987, p. 54).

(13) Since the measures necessary for the implementation of this Directive are measures of general scope within the meaning of Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ⁽¹⁾, they should be adopted by use of the regulatory procedure provided for in Article 5 of that Decision.

(14) This Directive should not affect the obligations of the Member States concerning the deadlines for transposition of the Directives set out in Part B of Annex VII,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Objectives

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

Article 2

Definitions

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

- (a) 'pig' means any animal of the *Suidae* family, including feral pigs;
- (b) 'feral pig' means a pig which is not kept or bred in a holding;
- (c) 'holding' means any agricultural or other premises located in the national territory of a Member State where pigs are being bred or kept on a permanent or temporary basis; this definition does not include slaughterhouses or means of transport;
- (d) 'Diagnostic Manual' means the classical swine fever Diagnostic Manual referred to in Article 17(3);
- (e) 'pig suspected of being infected with classical swine fever virus' means any pig or pig carcass exhibiting clinical symptoms or showing *post-mortem* lesions or reactions to laboratory tests carried out in accordance with the Diagnostic Manual indicating the possible presence of classical swine fever;
- (f) 'case of classical swine fever' or 'pig infected with classical swine fever' means any pig or pig carcass:

— in which clinical symptoms or *post-mortem* lesions of classical swine fever have been officially confirmed, or

— in which the presence of the disease has been officially confirmed as the result of a laboratory examination carried out in accordance with the Diagnostic Manual;

- (g) 'outbreak of classical swine fever' means the holding where one or more cases of classical swine fever has or have been detected;
- (h) 'primary outbreak' means the outbreak within the meaning of Article 2(d) of Council Directive 82/894/EEC ⁽²⁾;
- (i) 'classical swine fever infected area' means the area of a Member State where following the confirmation of one or more cases of classical swine fever in feral pigs, disease eradication measures are in place in accordance with Article 15 or 16;
- (j) 'primary case of classical swine fever in feral pigs' means any case of classical swine fever which is detected in feral pigs in an area in which no measures are in place in accordance with Articles 15 or 16;
- (k) 'meta-population of feral pigs' means any group or subpopulation of feral pigs with limited contacts with other groups or subpopulations;
- (l) 'susceptible feral pig population' means that part of a feral pig population which has not developed immunity against classical swine fever virus;
- (m) 'owner' means any person or persons, either natural or legal, having ownership of the pigs, or charged with keeping the said animals, whether or not for financial reward;
- (n) 'competent authority' means the competent authority within the meaning of Article 2(6) of Council Directive 90/425/EEC ⁽³⁾;
- (o) 'official veterinarian' means the veterinarian designated by the competent authority of the Member State;
- (p) 'processing' means the processing or disposal by burying or burning of high risk material in accordance with Article 3 of Council Directive 90/667/EEC ⁽⁴⁾ in such a way as to avoid the risk of spread of classical swine fever virus;
- (q) 'swill' means waste from kitchens, restaurants, catering facilities, the household of the farmer or persons attending susceptible animals or from industries using meat fit for human consumption;

⁽²⁾ OJ L 378, 31.12.1982, p. 58; Directive as last amended by Commission Decision 98/12/EC (OJ L 4, 8.1.1998, p. 63).

⁽³⁾ OJ L 224, 18.8.1990, p. 29; Directive as last amended by Directive 92/118/EEC (OJ L 62, 15.3.1993, p. 49).

⁽⁴⁾ OJ L 363, 27.12.1990, p. 51; Directive as last amended by the Act of Accession of Austria, Finland and Sweden.

⁽¹⁾ OJ L 184, 17.7.1999, p. 23.

- (r) 'marker vaccine' means a vaccine that can elicit a protective immunity distinguishable from the immune response elicited by the natural infection with the wild type virus by means of laboratory tests carried out in accordance with the Diagnostic Manual;
- (s) 'killing' means the killing of pigs within the meaning of Article 2(6) of Council Directive 93/119/EEC ⁽¹⁾;
- (t) 'slaughter' means the slaughter of pigs within the meaning of Article 2(7) of Directive 93/119/EEC;
- (u) 'area with a high density of pigs' means any geographical area with a radius of 10 km around a holding containing pigs suspected to be or known to be infected with classical swine fever virus, where there is a pig density higher than 800 pigs per km²; the holding in question must be located either in a region, as defined in accordance with point (p) of Article 2 of Council Directive 64/432/EEC ⁽²⁾, where there is a density of pigs kept in holdings higher than 300 pigs per km², or at a distance of less than 20 km from such a region;
- (v) 'contact holding' means a holding where classical swine fever could have been introduced, whether as a result of the location, movement of persons, pigs or vehicles or in any other way.

Article 3

Classical swine fever notification

1. Member States shall ensure that the presence and suspected presence of classical swine fever are compulsorily and immediately notifiable to the competent authority.
2. Without prejudice to existing Community provisions on notification of outbreaks of animal diseases, the Member State in whose territory classical swine fever is confirmed shall:
 - (a) give notification of the disease and provide information to the Commission and the other Member States in accordance with Annex I on:
 - the outbreaks of classical swine fever which are confirmed in holdings;
 - the cases of classical swine fever which are confirmed in a slaughterhouse or in means of transport;
 - the primary cases of classical swine fever which are confirmed in feral pigs;

⁽¹⁾ OJ L 340, 31.12.1993, p. 21.

⁽²⁾ OJ L 121, 29.7.1964, p. 1977/64; Directive as last amended by European Parliament and Council Directive 2000/20/EC (OJ L 163, 4.7.2000, p. 35).

— the results of the epidemiological enquiry carried out in accordance with Article 8;

- (b) provide information to the Commission and the other Member States on the further cases confirmed in feral pigs in a classical swine fever infected area in accordance with the provisions laid down in Article 16(3)(a) and (4).

3. The provisions of Annex I may be supplemented or amended in accordance with the procedure referred to in Article 25(2).

Article 4

Measures in case of suspicion of classical swine fever in pigs on a holding

1. Where a holding contains one or more pigs suspected of being infected with classical swine fever virus, Member States shall ensure that the competent authority immediately sets in motion official means of investigation to confirm or rule out the presence of the said disease in accordance with the procedures laid down in the Diagnostic Manual.

When the holding is visited by an official veterinarian, a check of the register and of the pig identification marks referred to in Articles 4 and 5 of Council Directive 92/102/EEC ⁽³⁾ shall also be carried out.

2. When the competent authority considers that the suspected presence of classical swine fever in a holding cannot be ruled out, it shall have the holding placed under official surveillance and shall in particular order that:

- (a) all the pigs in the various categories on the holding are to be counted and a list compiled of the number of pigs already sick, dead or likely to be infected in each category; the list shall be updated to take account of pig births and deaths during the period of suspicion; the information on the list shall be produced upon request and may be checked at each visit;
- (b) all the pigs on the holding shall be restricted to their living quarters or be confined in some other place where they can be isolated;
- (c) no pigs may enter or leave the holding. The competent authority may, if necessary, extend the ban on leaving the holding to cover other species of animals;
- (d) no pig carcasses may leave the holding without an authorisation issued by the competent authority;

⁽³⁾ OJ L 355, 5.12.1992, p. 32; Directive as amended by the Act of Accession of Austria, Finland and Sweden.

- (e) no meat, semen, ova and embryos of pigs, animal feed, utensils, materials or waste likely to transmit classical swine fever may leave the holding without an authorisation issued by the competent authority; meat, semen, ova and embryos shall not be moved from the holding for intra-Community trade;
- (f) the movement of persons to or from the holding shall be subject to written authorisation by the competent authority;
- (g) the movement of vehicles to or from the holding shall be subject to written authorisation by the competent authority;
- (h) appropriate means of disinfection shall be used at the entrances and exits of buildings housing pigs and of the holding itself; any person entering or leaving pig holdings shall observe appropriate hygienic measures necessary to reduce the risk of spread of classical swine fever virus;
- (i) an epizootiological enquiry shall be carried out in accordance with Article 8.

3. Where required by the epidemiological situation and in particular if the holding containing suspected pigs is located in an area with a high density of pigs, the competent authority:

- (a) may apply the measures of Article 5(1) in the holding referred to in (2) of this Article; however, the competent authority may, where it considers that conditions permit, limit the application of these measures only to the pigs suspected of being infected or contaminated with classical swine fever virus and the part of the holding where they were kept, provided that these pigs have been housed, kept and fed completely separately from the other pigs in the holding. In any case, a sufficient number of samples shall be taken from the pigs when they are killed in order that the presence of classical swine fever virus can be confirmed or ruled out;
- (b) may establish a suspect-protection zone around the holding referred to in (2); some or all the measures referred to in (1) or (2) shall be applied in the pig holdings within this zone.

4. The measures provided for in (2) shall not be lifted until the suspicion of classical swine fever has been officially ruled out.

Article 5

Measures in case of confirmation of classical swine fever in pigs in a holding

1. In cases where the presence of classical swine fever is officially confirmed in a holding, Member States shall ensure

that, in addition to the measures referred to in Article 4(2), the competent authority prescribes that:

- (a) all pigs on the holding are to be killed without delay under official supervision and in such a way as to avoid the risk of spread of classical swine fever virus during transport or killing;
- (b) a sufficient number of samples are to be taken from the pigs when they are killed, in order that the manner of introduction of classical swine fever virus into the holding and the length of time during which it may have existed on the holding before the disease was notified may be established;
- (c) the carcasses of pigs which have died or have been killed are to be processed under official supervision;
- (d) meat of pigs slaughtered during the period between the probable introduction of disease to the holding and the taking of official measures shall wherever possible be traced and processed under official supervision;
- (e) semen, ova and embryos of pigs collected from the holding during the period between the probable introduction of disease into the holding and the taking of official measures shall be traced and destroyed under official supervision in such a way as to avoid the risk of spread of classical swine fever virus;
- (f) all substances and waste likely to be contaminated, such as feedingstuffs, must be subjected to a treatment ensuring the destruction of classical swine fever virus; this treatment shall be carried out in accordance with the instructions of the official veterinarian;
- (g) after the pigs have been eliminated, the buildings used for housing the pigs, the vehicles used for transporting them or their carcasses and the equipment, bedding, manure and slurry likely to be contaminated shall be cleaned and disinfected or treated in accordance with Article 12;
- (h) in the case of a primary outbreak of disease, the classical swine fever virus isolate shall be subject to the laboratory procedure laid down in the Diagnostic Manual to identify the genetic type;
- (i) an epizootiological enquiry shall be carried out in accordance with Article 8.

2. In cases where an outbreak has been confirmed in a laboratory, a zoo, a wild life park or a fenced area where pigs are kept for scientific purposes or purposes related to conservation of species or conservation of rare breeds, the Member State concerned may decide to derogate from the provisions laid down in (1) (a) and (1) (e), provided that basic Community interests are not endangered.

This decision shall immediately be notified to the Commission.

The Commission shall in all cases immediately review the situation with the Member State concerned and in the Standing Veterinary Committee at the earliest possible opportunity. If necessary, measures to prevent the spreading of the disease shall be adopted in accordance with the procedure referred to in Article 26(2), which may include emergency vaccination in accordance with the procedure laid down in Article 19.

Article 6

Measures in the event of confirmation of classical swine fever in holdings consisting of different epidemiological units

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 decide to derogate from the provisions of Article 5(1)(a) 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 referred to in (1), the Member States shall draw up detailed rules for applying it in the light of the animal health guarantees which can be given.

3. Member States which make use of this derogation shall immediately notify the Commission thereof. The Commission shall in all cases immediately review the situation with the Member State concerned and in the Standing Veterinary Committee at the earliest possible opportunity. If necessary, measures to prevent the spreading of the disease shall be adopted in accordance with the procedure laid down in Article 26(2).

Article 7

Measures in contact holdings

1. Holdings shall be considered contact holdings where the official veterinarian finds, or considers on the basis of the epidemiological enquiry carried out in accordance with Article 8, that classical swine fever may have been introduced, either from other holdings to the holding referred to in Article 4 or Article 5, or from the holding referred to in Article 4 or Article 5 to other holdings.

The provisions of Article 4 shall be applied in such holdings until the suspicion of classical swine fever has been officially ruled out.

2. The competent authority shall apply the measures provided for in Article 5(1) in the contact holdings referred to in (1) of this Article if the epidemiological situation so requires.

A sufficient number of samples shall be taken from the pigs when they are killed in order that the presence of classical swine fever virus in these holdings can be confirmed or ruled out.

3. The main criteria to be considered for the application of the measures provided for in Article 5(1)(a) in contact holdings are laid down in Annex V. These criteria may subsequently be amended or supplemented to take account of scientific developments and experiences, in accordance with the procedure referred to in Article 25(2).

Article 8

Epidemiological enquiry

Member States shall ensure that the epidemiological enquiry in relation to suspected cases or outbreaks of classical swine fever is carried out on the basis of questionnaires, prepared within the framework of the contingency plans referred to in Article 22.

Such enquiry shall deal at least with:

- (a) the length of time during which classical swine fever virus may have existed on the holding before the disease was notified or suspected;
- (b) the possible origin of classical swine fever on the holding and the identification of other holdings in which pigs may have become infected or contaminated from the same source;
- (c) the movement of persons, vehicles, pigs, carcasses, semen, meat or any material likely to have transported the virus to or from the holdings in question.

If the results of this enquiry suggest that classical swine fever may have spread from or to holdings located in other Member States, the Commission and the Member States concerned shall be immediately informed.

Article 9

Establishment of protection and surveillance zones

1. Immediately after the diagnosis of classical swine fever has been officially confirmed in pigs on a holding, the competent authority shall establish a protection zone with a radius of at least three kilometres around the outbreak site, which shall itself be included in a surveillance zone of a radius of at least ten kilometres.

The measures referred to in Articles 10 and 11 shall be applied in the respective zones.

2. When establishing zones, the competent authority must take account of:

- (a) the results of the epidemiological enquiry carried out in accordance with Article 8;
- (b) the geographical situation, particularly natural boundaries;

- (c) the location and proximity of holdings;
- (d) patterns of trade in breeding and slaughter pigs and the availability of slaughterhouses;
- (e) the facilities and personnel available to control any movement of pigs within the zones, in particular if the pigs to be killed have to be moved away from their holding of origin.
3. If a zone includes parts of the territory of several Member States, the competent authorities of the Member States concerned shall collaborate to establish the zone.
4. The competent authority shall take all necessary measures, including the use of prominent signs and warning notices and use of media resources, such as the press and television, to ensure that all persons in the protection and surveillance zones are fully aware of the restrictions in force in accordance with Articles 10 and 11, and shall take such measures as they consider appropriate to ensure the adequate enforcement of these measures.

Article 10

Measures in the established protection zone

1. Member States shall ensure that the following measures are applied in the protection zone:
- (a) a census of all the holdings shall be made as soon as possible; after the establishment of the protection zone these holdings shall be visited by an official veterinarian within not more than seven days for a clinical examination of the pigs and for a check of the register and of the pig identification marks referred to in Articles 4 and 5 of Directive 92/102/EEC;
- (b) the movement and transport of pigs on public or private roads, excluding the service roads of holdings, shall be prohibited unless approved by the competent authority to allow the movements referred to in (f). This prohibition shall not apply to the transit of pigs by road or rail without unloading or stopping. However, in accordance with the procedure referred to in Article 26(2), a derogation may be granted for slaughter pigs coming from outside the protection zone and on their way to a slaughterhouse situated in the said zone;
- (c) trucks and other vehicles and equipment, which are used to transport pigs or other livestock or material which may be contaminated (e.g. carcasses, feedingstuff, manure, slurry, etc.) shall be cleaned, disinfected and treated as soon as possible after contamination, in accordance with the provisions and procedures laid down in Article 12. No truck or vehicle, which has been used in the transport of pigs may leave the zone without being cleaned and disinfected and then inspected and authorised by the competent authority;
- (d) no other species of animal may enter or leave a holding without the authorisation of the competent authority;
- (e) all dead or diseased pigs on a holding shall be immediately notified to the competent authority, which shall carry out appropriate investigations in accordance with the procedures laid down in the Diagnostic Manual;
- (f) pigs may not be removed from the holding in which they are kept for at least 30 days after the completion of the preliminary cleaning and disinfection of the infected holdings. After 30 days, subject to the conditions set out in (3), the competent authority may authorise the removal of pigs from the said holding to be directly transported to:
- a slaughterhouse designated by the competent authority, preferably within the protection or surveillance zone for the purpose of immediate slaughter;
 - a rendering plant or a suitable place where the pigs are immediately killed and their carcasses are processed under official supervision; or
 - under exceptional circumstances, to other premises located within the protection zone;
- (g) semen, ova and embryos of pigs shall not leave the holdings situated within the protection zone;
- (h) any person entering or leaving pig holdings shall observe appropriate hygienic measures necessary to reduce the risk of spread of classical swine fever virus.
2. Where the prohibitions provided for in paragraph 1 are maintained beyond 30 days because of further outbreaks of the disease and as a result animal welfare or other problems that arise in keeping the pigs, subject to the conditions set out in (3), the competent authority may, following a reasoned application by the owner, authorise removal of pigs from a holding within the protection zone, to be directly transported to:
- (a) a slaughterhouse designated by the competent authority, preferably within the protection or surveillance zone for the purpose of immediate slaughter;
 - (b) a rendering plant or a suitable place where the pigs are immediately killed and their carcasses are processed under official supervision; or
 - (c) under exceptional circumstances, to other premises located within the protection zone.

3. When reference is made to this paragraph, the competent authority may authorise removal of pigs from the holding concerned, on condition that:

(a) a clinical examination of the pigs in the holding and in particular those to be moved, including the taking of the body temperature of a proportion thereof, and a check of the register and the pig identification marks referred to in Articles 4 and 5 of Directive 92/102/EEC, have been carried out by an official veterinarian;

(b) the checks and examinations above have shown no evidence of classical swine fever and compliance with the provisions of Directive 92/102/EEC;

(c) the pigs are transported in vehicles sealed by the competent authority;

(d) the vehicle and equipment which have been involved in the transport of the pigs are immediately cleaned and disinfected after the transport in accordance with the provisions referred to in Article 12;

(e) if the pigs are to be slaughtered or killed, a sufficient number of samples shall be taken from the pigs in order that the presence of classical swine fever virus in these holdings can be confirmed or ruled out;

(f) if the pigs are to be transported to a slaughterhouse:

— the competent authority responsible for the slaughterhouse shall be informed of the intention to send pigs to it and notifies the dispatching competent authority of their arrival;

— on arrival at the slaughterhouse these pigs shall be kept and slaughtered separately from other pigs;

— during *ante* and *post-mortem* inspection carried out at the designated slaughterhouse, the competent authority shall take into account any signs relating to the presence of classical swine fever;

— the fresh meat from these pigs shall be either processed or marked with the special stamp referred to in Article 5a of Council Directive 72/461/EEC⁽¹⁾ and subsequently treated in accordance with the rules laid down in Article 4(1) of Council Directive 80/215/EEC⁽²⁾. This shall be done at an establishment designated by the competent authority. The meat shall be sent to the said establishment on condition that the consignment is sealed before departure and remains sealed throughout the transport.

⁽¹⁾ OJ L 302, 31.12.1972, p. 24; Directive as last amended by the Act of Accession of Austria, Finland and Sweden.

⁽²⁾ OJ L 47, 21.2.1980, p. 4; Directive as last amended by the Act of Accession of Austria, Finland and Sweden.

4. The measures in the protection zone shall continue to be applied at least until:

(a) cleaning and disinfection in the infected holdings have been carried out;

(b) pigs on all holdings have undergone clinical and laboratory examinations carried out in accordance with the Diagnostic Manual in order to detect the possible presence of classical swine fever virus.

The examinations referred to in (b) shall not take place before 30 days have elapsed after the completion of preliminary cleaning and disinfection measures on the infected holdings.

Article 11

Measures in the established surveillance zone

1. Member States shall ensure that the following measures are applied in the surveillance zone:

(a) a census shall be taken of all pig holdings;

(b) the movement and transport of pigs on public or private roads, excluding the service roads of holdings, shall be prohibited, unless approved by the competent authority. This prohibition shall not apply to the transit of pigs by road or rail, without unloading or stopping;

(c) trucks and other vehicles and equipment, which are used to transport pigs or other livestock or material which may be contaminated (e.g. carcasses, feedingstuff, manure, slurry, etc.) shall be cleaned, disinfected and treated as soon as possible after contamination, in accordance with the provisions and procedures laid down in Article 12. No truck or vehicle, which has been used in the transport of pigs may leave the zone without having been cleaned and disinfected;

(d) no other species of animal may enter or leave a holding during the first seven days after establishment of the zone without the authorisation of the competent authority;

(e) all dead or diseased pigs on a holding shall be immediately notified to the competent authority, which shall carry out appropriate investigations in accordance with the procedures laid down in the Diagnostic Manual;

(f) pigs may not be removed from the holding in which they are kept for at least 21 days after the completion of the preliminary cleaning and disinfection of the infected holdings. After 21 days, subject to the conditions set out in Article 10(3), the competent authority may authorise the removal of the pigs from the said holding to be directly transported to:

— a slaughterhouse designated by the competent authority, preferably within the protection or surveillance zone for the purpose of immediate slaughter,

— a rendering plant or a suitable place where the pigs are immediately killed and their carcasses are processed under official supervision; or

— under exceptional circumstances, to other premises located within the protection or surveillance zone.

However, if the pigs are to be transported to a slaughterhouse, at the request of a Member State, accompanied by appropriate justification, and in accordance with the procedure referred to in Article 26(2), derogations to the provisions laid down in Article 10(3)(e) and (f), fourth indent, may be authorised, in particular with respect to the marking of meat of these pigs and its subsequent use, and the destination of the processed products;

(g) semen, ova and embryos of pigs shall not leave the holdings situated within the surveillance zone;

(h) any person entering or leaving pig holdings shall observe appropriate hygienic measures necessary to reduce the risk of spread of classical swine fever virus.

2. Where the prohibitions provided for in paragraph 1 are maintained beyond 30 days because of further outbreaks of the disease and where as a result animal welfare or other problems arise in keeping the pigs, subject to the conditions set out in Article 10(3), the competent authority may, following a reasoned application by the owner, authorise removal of pigs from a holding within the surveillance zone to be directly transported to:

(a) a slaughterhouse designated by the competent authority, preferably within the protection or surveillance zone for the purpose of immediate slaughter;

(b) a rendering plant or a suitable place where the pigs are immediately killed and their carcasses are processed under official supervision; or

(c) under exceptional circumstances, to other premises located within the protection or surveillance zone.

3. The measures in the surveillance zone shall continue to be applied at least until:

(a) cleaning and disinfection in the infected holdings have been carried out;

(b) pigs on all holdings have undergone clinical and, where necessary, laboratory examinations as laid down in the Diagnostic Manual in order to detect the eventual presence of classical swine fever virus.

The examinations referred to in (b) shall not take place before 20 days have elapsed after the completion of preliminary cleaning and disinfection measures on the infected holdings.

Article 12

Disinfection

1. Member States shall ensure that:

(a) the disinfectants to be used and their concentrations are officially approved by the competent authority;

(b) the cleaning and disinfection operations are carried out under official supervision in accordance with:

— the instructions given by the official veterinarian; and

— the principles and procedures for cleaning, disinfecting and treatment laid down in Annex II.

2. The principles and procedures for cleaning and disinfecting laid down in Annex II may subsequently be amended or supplemented to take account of scientific developments and experiences, in accordance with the procedure referred to in Article 25(2).

Article 13

Repopulation of pig holdings following disease outbreaks

1. The reintroduction of pigs to the holding referred to in Article 5 shall not take place until at least 30 days after completion of the cleaning and disinfection operations in accordance with Article 12.

2. The reintroduction of pigs shall take account of the type of farming practised on the holding concerned and must conform to one of the following procedures:

(a) as regards open-air pig holdings, the reintroduction of pigs shall start with the introduction of sentinel pigs which have been checked and found negative for the presence of antibodies against classical swine fever virus or come from holdings situated outside the restriction zone. The sentinel pigs shall be placed, in accordance with the requirements of the competent authority, throughout the infected holding and be sampled 40 days after having been placed on the holding, and tested for the presence of antibodies, in accordance with the Diagnostic Manual.

If none of the pigs has developed antibodies against classical swine fever virus, full repopulation may take place;

(b) as regards all other forms of rearing, the reintroduction of pigs shall either take place in accordance with the measures provided for in (a) or shall be based on total repopulation, provided that:

— all the pigs arrive within a period of twenty days and come from holdings situated outside the restriction zone;

— pigs in the repopulated herd are subjected to a serological examination in accordance with the Diagnostic Manual. Sampling for that examination shall be carried out at the earliest 40 days after the arrival of the last pigs;

- no pig may leave the holding before the negative results of the serological examination are available.

Article 14

Measures in case of classical swine fever in pigs in a slaughterhouse or means of transport

Should a case of classical swine fever be detected in a slaughterhouse or means of transport, the competent authority shall ensure that:

- (a) all susceptible animals in the slaughterhouse or in the means of transport are killed without delay;
- (b) the carcasses, offal and animal waste of possibly infected and contaminated animals are processed under official supervision;
- (c) cleaning and disinfection of buildings and equipment, including vehicles, takes place under the supervision of the official veterinarian in accordance with Article 12;
- (d) an epidemiological inquiry is carried out as provided in Article 8 *mutatis mutandis*;
- (e) the classical swine fever virus isolate is subject to the laboratory procedure laid down in the Diagnostic Manual to identify the genetic type of virus;
- (f) the measures referred to in Article 7 are applied in the holding where the infected pigs or carcasses came from and in the other contact holdings;
- (g) no animals are reintroduced for slaughter or transport until at least 24 hours after completion of the cleaning and disinfection operations completed in accordance with Article 12.

Article 15

Measures to be adopted in case of suspicion and confirmation of classical swine fever in feral pigs

1. Immediately after the competent authority of a Member State has information that feral pigs are suspected of being infected, it shall take all appropriate measures to confirm or rule out the presence of the disease, by giving information to the owners of pigs and to hunters, and by investigations of all feral pigs shot or found dead, including laboratory testing.

2. As soon as confirmation of a primary case of classical swine fever in feral pigs has taken place, the competent authority of a Member State shall immediately:

- (a) establish an expert group including veterinarians, hunters, wild life biologists and epidemiologists. The expert group shall assist the competent authority in:

- studying the epidemiological situation and defining an infected area;

- establishing appropriate measures to be applied in the infected area in addition to the ones referred to in (b) and (c); these measures may include suspension of hunting and a ban in feeding feral pigs;

- drawing up the eradication plan to be submitted to the Commission in accordance with Article 16;

- carrying out audits to verify the effectiveness of the measures adopted to eradicate classical swine fever from the infected area;

- (b) place under official surveillance pig holdings in the defined infected area and shall in particular order that:

- an official census be carried out of all categories of pigs on all holdings; the census shall be kept up to date by the owner. The information in the census shall be produced on request and may be checked at each inspection. However, as regards open-air pig holdings, the first census carried out may be done on the basis of an estimate;

- all pigs on the holding be kept in their living quarters or some other place where they can be isolated from feral pigs. The feral pigs must not have access to any material which may subsequently come in contact with the pigs on the holding;

- no pigs enter or leave the holding save where authorised by the competent authority having regard to the epidemiological situation;

- appropriate means of disinfection be used at the entrance and exits of buildings housing pigs and of the holding itself;

- appropriate hygienic measures be applied by all persons coming in contact with feral pigs, to reduce the risk of spread of classical swine fever virus;

- all dead or diseased pigs with classical swine fever symptoms on a holding be tested for the presence of classical swine fever;

- no part of any feral pig, whether shot or found dead, as well as any material or equipment which could be contaminated with classical swine fever virus shall be brought into a pig holding;

- pigs, their semen, embryos or ova shall not be moved from the area for intra-Community trade;

- (c) arrange that all feral pigs shot or found dead in the defined infected area are inspected by an official veterinarian and examined for classical swine fever in accordance with the Diagnostic Manual. Carcasses of all animals found positive shall be processed under official supervision. Where such testing proves negative as regards classical swine fever, Member States shall apply the measures laid down in Article 11(2) of Council Directive 92/45/EEC ⁽¹⁾. Parts not intended for human consumption shall be processed under official supervision;
- (d) ensure that the classical swine fever virus isolate is subject to the laboratory procedure indicated in the Diagnostic Manual to identify the genetic type of virus.

3. If a case of classical swine fever has occurred in feral pigs in an area of a Member State close to the territory of another Member State, the Member States concerned shall collaborate in the establishment of disease control measures.

Article 16

Plans for the eradication of classical swine fever from a feral pig population

1. Without prejudice to the measures laid down in Article 15, Member States shall submit to the Commission within 90 days from the confirmation of the primary case of classical swine fever in feral pigs a written plan of the measures taken to eradicate the disease in the area defined as infected and of the measures applied on the holdings in that area.

The Commission shall examine the plan in order to determine whether it permits the desired objective to be attained. The plan, if necessary with amendments, shall be approved in accordance with the procedure referred to in Article 26(2).

The plan may subsequently be amended or supplemented to take account of developments in the situation.

If these amendments concern the re-definition of the infected area, Member States shall ensure that the Commission and the other Member States are informed of these amendments without delay.

If the amendments concern other provisions of the plan, Member States shall submit the amended plan to the Commission for examination and eventual approval in accordance with the procedure referred to in Article 26(2).

2. After the measures provided for in the plan mentioned in paragraph 1 have been approved, they shall replace the initial measures laid down in Article 15, on a date which shall be decided upon when approval is given.

3. The plan mentioned in paragraph 1 shall contain information on:

- (a) the results of the epidemiological investigations and controls carried out in accordance with Article 15 and the geographical distribution of the disease;

- (b) a defined infected area within the territory of the Member State concerned. When defining the infected area, the competent authority shall take into account:

- the results of the epidemiological investigations carried out and the geographical distribution of the disease;
- the feral pig population in the area;
- the existence of major natural or man-made obstacles to movements of feral pigs;

- (c) the organisation of close cooperation between biologists, hunters, hunting organisations, the wildlife services and veterinary services (animal health and public health);

- (d) the information campaign to be enforced to increase hunters' awareness of the measures they have to adopt in the framework of the eradication plan;

- (e) specific efforts made to determine the number and location of feral pig meta-populations in and around the infected area;

- (f) the approximate number of meta-populations of feral pigs and their size in and around the infected area;

- (g) specific efforts made to determine the extent of the infection in the feral pig population, by investigation of feral pigs shot by hunters or found dead, and by laboratory testing, including age-stratified epidemiological investigations;

- (h) the measures adopted to reduce spread of disease due to feral pig movements and/or contact between meta-populations of feral pigs; these measures may include a prohibition of hunting;

- (i) the measures adopted to reduce the susceptible feral pig population and in particular young piglets;

- (j) the requirements to be complied with by hunters in order to avoid any spread of the disease;

- (k) the method of removal of feral pigs found dead or shot, which shall be based on:

- processing under official supervision; or
- inspection by an official veterinarian and laboratory tests as provided for in the Diagnostic Manual. Carcasses of all animals found positive shall be processed under official supervision. Where such testing proves negative as regards classical swine fever, Member States shall apply the measures laid down in Article 11(2) of Directive 92/45/EEC. Parts not intended for human consumption shall be processed under official supervision;

⁽¹⁾ OJ L 268, 14.9.1992, p. 35; Directive as last amended by Directive 97/79/EC (OJ L 24, 30.1.1998, p. 31).

(l) the epidemiological enquiry which is carried out on each feral pig, whether shot or found dead. This enquiry must include the completion of a questionnaire which supplies information about:

- the geographical area where the animal was found dead or shot;
- the date on which the animal was found dead or shot;
- the person who found or shot the animal;
- the age and sex of the pig;
- if shot: symptoms before shooting;
- if found dead: the state of the carcass;
- laboratory findings;

(m) surveillance programmes and prevention measures applicable to the holdings situated in the defined infected area, including the transport and movement of animals within, from and to the area; these measures shall at least include the ban of moving pigs, their semen, embryos or ova from the area for intra-Community trade;

(n) other criteria to be applied for lifting the measures taken to eradicate the disease in the defined area and the measures applied to holdings in the area;

(o) the authority charged with supervising and coordinating the departments responsible for implementing the plan;

(p) the system established in order that the expert group appointed in accordance with Article 15(2)(a), can review on a regular basis the results of the eradication plan;

(q) the disease monitoring measures that shall be enforced after a period of at least twelve months has elapsed from the last confirmed case of classical swine fever in feral pigs in the defined infected area; these monitoring measures shall stay in place for at least twelve months and shall at least include the measures already enforced in accordance with (g), (k) and (l).

4. A report concerning the epidemiological situation in the defined area and the results of the eradication plan shall be transmitted to the Commission and to the other Member States every six months.

More detailed rules relating to the information that is to be provided by the Member States on this matter may be adopted in accordance with the procedure referred to in Article 25(2).

Article 17

Diagnostic procedures and bio-safety requirements

1. Member States shall ensure that:

- (a) diagnostic procedures, sampling and laboratory testing to detect the presence of classical swine fever are carried out in accordance with the Diagnostic Manual;
- (b) a national laboratory is responsible for coordinating standards and methods of diagnosis in each Member State in accordance with the provisions of Annex III.

2. The national laboratories referred to in (1)(b) shall liaise with the Community reference laboratory as mentioned in Annex IV. Without prejudice to the provisions of Decision 90/424/EEC, and in particular Article 28 thereof, the powers and duties of the laboratory shall be those appearing in the said Annex.

3. In order to ensure uniform procedures to diagnose classical swine fever, within two months from the date when this Directive enters into force and in accordance with the procedure referred to in Article 25(2), a classical swine fever Diagnostic Manual shall be approved, establishing at least:

(a) minimum bio-safety requirements and quality standards to be observed by the classical swine fever diagnostic laboratories and for the transport of samples;

(b) criteria and procedures to be followed when clinical or *post-mortem* examinations are carried out to confirm or exclude the presence of classical swine fever;

(c) criteria and procedures to be followed for collection of samples from live pigs or their carcasses, to confirm or exclude classical swine fever by laboratory examinations, including sampling methods for serological or virological screenings carried out in the framework of the application of the measures provided for in this Directive;

(d) laboratory tests to be used for the diagnosis of classical swine fever, including:

- tests for the differential diagnosis between classical swine fever virus and other *Pestiviruses*, and
- if available and suitable, tests to distinguish the antibody pattern elicited by a marker vaccine from the one elicited by the wild type of classical swine fever virus;
- criteria for the evaluation of the results of the laboratory tests;

(e) laboratory techniques for the genetic typing of classical swine fever virus isolates.

4. In order that appropriate bio-safety conditions are guaranteed to protect animal health, the classical swine fever virus, its genome and antigens and vaccines for research, diagnosis or manufacture shall be manipulated or used out only in places, establishments or laboratories approved by the competent authority.

The list of approved places, establishments or laboratories shall be transmitted to the Commission within six months from the date laid down in Article 29, second subparagraph and kept updated hereafter.

5. The provisions of Annexes III and IV and the Diagnostic Manual may be supplemented or amended in accordance with the procedure referred to in Article 25(2).

Article 18

Use, manufacture and sale of classical swine fever vaccines

1. Member States shall ensure that:

- (a) the use of classical swine fever vaccines is prohibited;
- (b) the manipulation, manufacture, storage, supply, distribution and sale of classical swine fever vaccines in the territory of the Community are carried out under official control.

2. If necessary, rules relating to the production, packaging, distribution and state of the stocks of classical swine fever vaccines in the Community may be adopted in accordance with the procedure referred to in Article 25(2).

Article 19

Emergency vaccination in pig holdings

1. Notwithstanding Article 18(1)(a), when classical swine fever has been confirmed in pig holdings and the epidemiological data available suggest that it threatens to spread, emergency vaccination may be introduced in pig holdings in accordance with the procedures and provisions laid down in paragraphs 2 to 9 of this Article.

2. Without prejudice to the provisions of Article 5(2), the main criteria to be considered for the application of emergency vaccination are laid down in Annex VI. These criteria may subsequently be amended or supplemented to take account of scientific developments and experiences, in accordance with the procedure referred to in Article 25(2).

3. Where a Member State intends to introduce vaccination, it shall submit to the Commission an emergency vaccination plan, which shall at least include information on:

- (a) the disease situation which has led to the request for emergency vaccination;

- (b) the extent of the geographical area in which emergency vaccination is to be carried out and the number of pig holdings in this area;
- (c) categories of pigs and the approximate number of pigs to be vaccinated;
- (d) the vaccine to be used;
- (e) the duration of the vaccination campaign;
- (f) the identification and registration of the vaccinated animals;
- (g) measures for the movement of pigs and their products;
- (h) the criteria that will be considered to decide if vaccination or the measures referred to in Article 7(2) will be applied in contact holdings;
- (i) other matters appropriate to the emergency, including the clinical and laboratory examinations to be carried out on samples taken in the vaccinated holdings and in the other holdings located in the vaccination area, in particular if a marker vaccine is to be used.

The Commission shall immediately examine the plan in collaboration with the Member State concerned. In accordance with the procedure referred to in Article 26(2), the emergency vaccination plan may be approved or amendments and additions may be requested before approval is given.

In accordance with the procedure referred to in Article 26(2), the emergency vaccination plan may subsequently be amended or supplemented to take account of developments in the situation.

4. Any Member State which carries out emergency vaccination shall ensure that during the vaccination period:

- (a) no live pigs leave the vaccination area, unless to be transported to a slaughterhouse designated by the competent authority and situated within the vaccination area or close to that area for immediate slaughter or to a rendering plant or to a suitable place where they are immediately killed and their carcasses are processed under official supervision;
- (b) all fresh pig meat produced from pigs vaccinated during the emergency vaccination is either processed or marked and treated in accordance with the provisions referred to in Article 10(3)(f), fourth indent;
- (c) semen, ova and embryos collected from the pigs to be vaccinated during the thirty days prior to vaccination are traced and destroyed under official supervision.

5. The provisions laid down in (4) shall apply for a minimum of six months following completion of the vaccination operations in the affected area.

6. In accordance with the procedure referred to in Article 26(2) and before the end of the six-month period referred to in (5), measures shall be taken to ban:

- (a) sero-positive pigs from leaving the holding where they are kept, except for immediate slaughter;
- (b) the collection of semen, embryos or ova from sero-positive pigs;
- (c) piglets of sero-positive sows from leaving their holding of origin unless being transported to:
 - a slaughterhouse for immediate slaughter;
 - a holding designated by the competent authority, from which they are to be sent directly to the slaughterhouse;
 - a holding after obtaining a negative result from a serological test for antibodies against the classical swine fever virus.

7. By way of derogation from the provisions laid down in (3), the decision to introduce emergency vaccination may be taken by a Member State if the following conditions are met:

- (a) the emergency vaccination plan must be submitted and the decision to adopt vaccination must be notified to the Commission before the starting of the vaccination operations;
- (b) in addition to the information referred to in (3), the plan must prescribe that all the pigs in the holdings where the vaccine is to be used will be slaughtered or killed as quickly as possible after completion of the vaccination operations in accordance with the provisions laid down in 4 (a), and the fresh meat produced from these pigs will be either processed or marked and treated in accordance with the provisions laid down in Article 10(3)(f), fourth indent.

When this decision is taken, the vaccination plan shall be immediately reviewed in the Standing Veterinary Committee. In accordance with the procedure referred to in Article 26(2), the plan may be approved or amendments and additions may be requested before approval is given.

8. Notwithstanding the provisions laid down in (5) and (6), the measures provided for in (4) may be lifted after:

- (a) all the pigs in the holdings where vaccine has been used have been slaughtered or killed in accordance with the provisions laid down in (4) (a), and the fresh meat produced from these pigs has been either processed or marked and treated in accordance with the provisions laid down in Article 10(3)(f), fourth indent;
- (b) all the holdings where vaccinated pigs had been kept have been cleansed and disinfected in accordance with Article 12.

Where the measures provided for in (4) are lifted, Member States shall also ensure that:

- (a) reintroduction of pigs in the holdings above shall not take place until at least 10 days after completion of the cleaning and disinfection operations, and after all pigs in the

holdings where vaccine has been applied have been slaughtered or killed;

- (b) after reintroduction, pigs on all holdings in the vaccination area shall undergo clinical and, where necessary, laboratory examinations as laid down in the Diagnostic Manual in order to detect the possible presence of classical swine fever virus. In case of pigs re-introduced in holdings where the vaccine had been applied, these examinations shall not take place until at least 40 days have elapsed after the reintroduction, during which time pigs shall not be allowed to move from the holding.

9. In those cases where a marker vaccine has been used during the vaccination campaign, derogations from the provisions referred to in (4), (5) and (6) may be authorised in accordance with the procedure referred to in Article 26(2), in particular with respect to the marking of meat of the vaccinated pigs and its subsequent use, and the destination of the processed products. Such authorisation shall be subject to the following conditions:

- (a) the vaccination plan shall have been approved before the starting of the vaccination operations in accordance with the provisions referred to in (3);
- (b) a specific request shall have been submitted by the Member State concerned, accompanied by a comprehensive report on the implementation of the vaccination campaign, its results and the overall epidemiological situation; and
- (c) an on-the-spot check on the implementation of the vaccination campaign shall have been carried out in accordance with the procedures referred to in Article 21.

The adoption of the derogations referred to in the first paragraph shall be based on the risk that classical swine fever virus is spread by movements or trade of the vaccinated pigs, their offspring or their products.

Article 20

Emergency vaccination of feral pigs

1. Notwithstanding Article 18(1)(a), when classical swine fever has been confirmed in feral pigs and the epidemiological data available suggest that it threatens to spread, emergency vaccination of feral pigs may be introduced in accordance with the procedures and provisions laid down in paragraphs 2 and 3.

2. Where a Member State intends to introduce vaccination, it shall submit to the Commission an emergency vaccination plan, which shall include information on:

- (a) the disease situation which has led to the request for emergency vaccination;
- (b) the extent of the geographical area in which emergency vaccination is to be carried out. In any case, this area shall be part of the infected area defined in accordance with Article 16(3)(b);
- (c) the type of vaccine to be used and the procedure of vaccination;

- (d) the special efforts to be carried out to vaccinate the young;
- (e) the expected duration of the vaccination campaign;
- (f) the approximate number of feral pigs to be vaccinated;
- (g) the measures adopted to avoid a high turn-over of the feral pig population;
- (h) the measures adopted to avoid any spread of vaccine virus to pigs kept in holdings, if applicable;
- (i) the expected results of the vaccination campaign and the parameters that will be considered to verify its effectiveness;
- (j) the authority charged with supervising and coordinating the departments responsible for implementing the plan;
- (k) the system established in order that the expert group appointed in accordance with Article 15(2)(a), can review on regular basis the results of the vaccination campaign;
- (l) other matters appropriate to the emergency.

The Commission shall immediately examine the plan in collaboration with the Member State concerned, in particular to ensure its consistency with the measures applied in accordance with the eradication plan provided for in Article 16(1).

If the vaccination area is close to the territory of another Member State where measures to eradicate classical swine fever from feral pigs are also in place, consistency between the vaccination plan and the measures applied in such other Member State shall also be ensured.

In accordance with the procedure referred to in Article 26(2), the emergency vaccination plan may be approved or amendments and additions may be requested before approval is given.

In accordance with the procedure above, the emergency vaccination plan may subsequently be amended or supplemented to take account of developments in the situation.

3. A report concerning the results of the vaccination campaign shall be transmitted by the Member State concerned to the Commission and the other Member States every six months, together with the report referred to in Article 16(4).

Article 21

On-the-spot checks

Veterinary experts from the Commission may, in collaboration with the authorities of the Member State concerned and, in so far as it is necessary to ensure uniform application of this Directive, make on-the-spot checks in accordance with the procedures laid down in Commission Decision 98/139/EC⁽¹⁾.

⁽¹⁾ OJ L 38, 12.2.1998, p. 10.

Article 22

Contingency plans

1. Each Member State shall draw up a contingency plan specifying the national measures to be implemented in the event of an outbreak of classical swine fever.

This plan shall allow access to facilities, equipment, personnel and all other appropriate materials necessary for the rapid and efficient eradication of the outbreak. It shall give a precise indication of the vaccine requirements which each Member State concerned considers it needs in the event of emergency vaccination.

2. The criteria and requirements to be applied *mutatis mutandis* for drawing up the contingency plan shall be those laid down in Community legislation laying down the criteria and requirements to be applied when drawing up contingency plans for the control of foot-and-mouth disease.

In accordance with the procedure referred to in Article 25(2), those criteria and requirements may be amended or supplemented taking into account the specific nature of classical swine fever and progress made in the development of disease control measures.

3. The Commission shall examine the plans in order to determine whether they permit the desired objective to be attained and shall suggest to the Member State concerned any amendments required, in particular to ensure that they are compatible with those of the other Member States.

The plans, if necessary amended, shall be approved in accordance with the procedure referred to in Article 25(2).

The plans may subsequently be amended or supplemented, in accordance with the procedure referred to in Article 25(2), to take into account developments in the situation. In any case, every five years each Member State shall update the plan and submit it to the Commission for approval in accordance with the procedure referred to in Article 25(2).

Article 23

Disease control centres

In order to provide full coordination of all measures necessary for a quick eradication of classical swine fever, Member States shall ensure that with regard to the establishment, function, responsibilities and duties of disease control centres and expert groups, the provisions referred to in Community legislation for the control of foot-and-mouth disease shall apply *mutatis mutandis*.

Article 24

Control of swill feeding

Member States shall ensure that with regard to swill feeding the provisions referred to in Community legislation for the control of foot-and-mouth disease shall apply *mutatis mutandis*.

*Article 25***Normal regulatory procedure**

1. The Commission shall be assisted by the Standing Veterinary Committee established by Council Decision 68/361/EEC ⁽¹⁾.

2. Where reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7 thereof.

The period referred to in Article 5(6) of Decision 1999/468/EC shall be three months.

*Article 26***Accelerated regulatory procedure**

1. The Commission shall be assisted by the Standing Veterinary Committee established by Decision 68/361/EEC.

2. Where reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7 thereof.

The period referred to in Article 5(6) of Decision 1999/468/EC shall be 15 days.

*Article 27***Repeals**

1. Directive 80/217/EEC, as amended by the acts listed in Annex VII, Part A are hereby repealed as from the date laid down in Article 29, second subparagraph, without prejudice to the obligation of the Member States concerning the deadlines for transposition of the said Directives set out in Annex VII, Part B.

References to the repealed Directive 80/217/EEC shall be construed as references to this Directive and shall be read in accordance with the correlation table set out in Annex VIII.

2. Directive 81/859/EEC is hereby repealed.

*Article 28***Transitional provisions**

1. By way of derogation from the first subparagraph of Article 27(1), Annexes I and IV to Directive 80/217/EEC shall continue to apply for the purposes of this Directive pending the entry into force of the Decision approving the Diagnostic Manual referred to in Article 17(3) of this Directive.

2. Plans to eradicate classical swine fever from feral pigs, approved in accordance with Article 6a of Directive

80/217/EEC and in place at the date of entry into force of this Directive, shall continue to apply for the purposes of this Directive.

However, Member States shall, within 90 days of the date laid down in Article 29, second subparagraph, submit to the Commission amendments to these plans, taking into account the provisions laid down in Article 16(3).

The plans, amended as necessary, shall be approved in accordance with the procedure referred to in Article 26(2).

3. Contingency plans for the control of classical swine fever, approved in accordance with Article 14b of Directive 80/217/EEC and in place at the date of entry into force of this Directive, shall continue to apply for the purposes of this Directive.

4. However, Member States shall, within six months of the date laid down in Article 29, second subparagraph, submit to the Commission amendments to these plans, taking into account the provisions laid down in Article 22.

The plans, amended as necessary, shall be approved in accordance with the procedure referred to in Article 25(2).

*Article 29***Transposition into national legislation and application**

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 March 2001 at the latest. They shall forthwith inform the Commission thereof.

Member States shall apply the provisions of this Directive as from 1 April 2001.

When Member States adopt the provisions referred to in the first paragraph, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

*Article 30***Entry into force**

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Communities*.

*Article 31***Addressees**

This Directive is addressed to the Member States.

⁽¹⁾ OJ L 255, 18.10.1968, p. 23.

ANNEX I

Notification of disease and further epidemiological information to be provided by the Member State where classical swine fever has been confirmed

1. Within 24 hours from the confirmation of each primary outbreak, primary case in feral pigs or case in a slaughterhouse or means of transport, the Member State concerned must notify by means of the Animal Disease Notification System established in accordance with Article 5 of Council Directive 82/894/EEC:
 - (a) the date of dispatch;
 - (b) the time of dispatch;
 - (c) the name of Member State;
 - (d) the name of disease;
 - (e) the number of the outbreak or case;
 - (f) the date on which classical swine fever was suspected;
 - (g) the date of confirmation;
 - (h) the methods used for confirmation;
 - (i) whether the disease has been confirmed in feral pigs or in pigs in a holding, slaughterhouse or means of transport;
 - (j) the geographical location where the outbreak or the case of classical swine fever has been confirmed;
 - (k) the disease control measures applied.
2. In case of primary outbreaks or cases in slaughterhouses or means of transport, in addition to the data referred to in (1), the Member State concerned must also forward the following information:
 - (a) the number of susceptible pigs in the outbreak, slaughterhouse or means of transport;
 - (b) the number of dead pigs of each category on the holding, slaughterhouse or means of transport;
 - (c) for each category, the morbidity of the disease and the number of pigs in which classical swine fever has been confirmed;
 - (d) the number of pigs killed in the outbreak, slaughterhouse or means of transport;
 - (e) the number of carcasses processed;
 - (f) in case of an outbreak, its distance from the nearest pig farm;
 - (g) if classical swine fever was confirmed in a slaughterhouse or means of transport, the location of the holding or holdings of origin of the infected pigs or carcasses.
3. In case of secondary outbreaks, the information referred to in (1) and (2) must be forwarded within the time limit laid down in Article 4 of Council Directive 82/894/EEC.
4. The Member State concerned shall ensure that the information to be provided in relation to any outbreak or case of classical swine fever in a holding, slaughterhouse or means of transport in accordance with (1), (2) and (3), is followed as soon as possible by a written report to the Commission and the other Member States including at least:
 - (a) the date on which the pigs on the holding, slaughterhouse or means of transport were killed and their carcasses processed;
 - (b) the results of the tests carried out on samples taken when pigs were killed;

- (c) where the derogation provided for in Article 6(1) has been applied, the number of pigs killed and processed and the number of pigs which are to be slaughtered at a later date and the time limit laid down for their slaughter;
- (d) any information relating to the possible origin of the disease or the origin of the disease if this has been ascertained;
- (e) in case of a primary outbreak or a case of classical swine fever in a slaughterhouse or means of transport, the genetic type of virus responsible for the outbreak or the case;
- (f) in case pigs have been killed in contact holdings or in holdings containing pigs suspected of being infected with classical swine fever virus, information on:
 - the date of killing and the number of pigs of each category killed in each holding;
 - the epidemiological link between the outbreak or case of classical swine fever and each contact holding or the reasons that have induced to suspect classical swine fever in each suspected holding;
 - the results of the laboratory tests carried out on the samples taken from the pigs in the holdings and when they were killed.

In case pigs in contact holdings were not killed, information must be provided on the reasons for this decision.

ANNEX II

Principles and procedures for cleansing and disinfection

1. General principles and procedures:

- (a) the cleansing and disinfection operations are carried out under official supervision and in accordance with the instructions given by the official veterinarian;
- (b) the disinfectants to be used and their concentrations are officially approved by the competent authority to ensure destruction of classical swine fever virus;
- (c) the activity of disinfectants should be checked before use, as activity of certain disinfectants is diminished by prolonged storage;
- (d) the choice of disinfectants and of procedures for disinfection should be made taking into account the nature of the premises, vehicles and objects which are to be treated;
- (e) the conditions under which degreasing agents and disinfectants are used must ensure that their efficacy is not impaired. In particular technical parameters provided by the manufacturer, such as pressure, minimum temperature and required contact time must be observed;
- (f) irrespective of the disinfectant used, the following general rules should apply:
 - thorough soaking of bedding and litter as well as faecal matter with the disinfectant;
 - washing and cleaning by careful brushing and scrubbing of the ground, floors, ramps and walls after the removal or dismantling, where possible, of equipment or installations otherwise impairing the effective cleansing and disinfection procedures;
 - then, further application of disinfectant for a minimum contact time as stipulated in the manufacturers recommendations;
- (g) where washing is carried out with liquids applied under pressure re-contamination of the previously cleansed parts must be avoided;

- (h) washing, disinfecting or destroying of equipment, installations, articles or compartments likely to be contaminated should be included;
- (i) following the disinfection procedures re-contamination must be avoided;
- (j) cleansing and disinfection required in the framework of this directive must be documented in the holding or vehicle register and where official approval is required be certified by the supervising official veterinarian.

2. Special provisions on cleansing and disinfection of infected holdings:

(a) preliminary cleansing and disinfection:

- during the killing of the animals all necessary measures shall be taken to avoid or minimise the dispersion of classical swine fever virus. This shall include *inter alia* the installation of temporary disinfection equipment, supply of protective clothing, showers, decontamination of used equipment, instruments and facilities and the interruption of power supply to the ventilation;
- carcasses of killed animals must be sprayed with disinfectant and removed from the holding for destruction in covered and leak-proof containers;
- as soon as the carcasses of the pigs have been removed for disposal, those parts of the holding in which these animals were housed and any parts of other buildings, yards, etc. contaminated during killing, slaughter or post-mortem examination should be sprayed with disinfectants approved for use in accordance with Article 12;
- any tissue or blood which may have been spilled during slaughter or post-mortem or gross contamination of buildings, yards, utensils, etc. should be carefully collected and disposed of with the carcasses;
- the used disinfectant shall remain on the surface for at least 24 hours;

(b) final cleansing and disinfection:

- grease and dirt should be removed from all surfaces by the application of a degreasing agent and the surfaces washed with cold water,
- after washing with cold water, further spraying with disinfectant should be applied,
- after seven days the premises should be treated with a degreasing agent, rinsed with cold water, sprayed with disinfectant and rinsed again with cold water.

3. Disinfection of contaminated bedding, manure and slurry:

- (a) manure and used bedding should be stacked to heat, sprayed with disinfectant and left for at least 42 days;
- (b) slurry should be stored for at least 42 days after the last addition of infective material, unless the competent authorities authorise a reduced storage period for slurry which was effectively treated in accordance with the instructions given by the official veterinarian so as to ensure the destruction of the virus.

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ANNEX III

List and duties of national classical swine fever laboratories

1. The national classical swine fever laboratories are as follows:

Belgium

Institut National de recherches vétérinaires, 1180 Bruxelles

Denmark

Statens veterinære Institut for Virusforskning, Lindholm, 4771 Kalvehave

Germany

Bundesforschungsanstalt für Viruskrankheiten der Tiere, 17498 Insel Riems

Greece

Veterinary Institute of Infectious and parasitic diseases, 15310 Ag. Paraskevi

Spain

Centro de Investigación en Sanidad Animal, 28130 Valdeolmos (Madrid)

France

AFSSA-Ploufragan, Zoopole des Côtes d'Armor, 22440 Ploufragan

Ireland

Veterinary Research Laboratory, Abbotstown, Castleknock, Dublin 15

Italy

Istituto Zooprofilattico Sperimentale dell'Umbria e delle Marche, 06100 Perugia

Luxembourg

Laboratoire de Médecine Vétérinaire de l'État, 1020 Luxembourg

The Netherlands

Instituut voor Veehouderij en Diergezondheid (ID-DLO), 8200 AB Lelystad

Austria

Bundesanstalt für Virusseuchenbekämpfung bei Haustieren, 1233 Vienna

Portugal

Laboratório Nacional de Investigação Veterinária, 1500 Lisboa

Finland

Eläinlääkintä ja elintarvikelaitos, 00231 Helsinki

Sweden

Statens veterinärmedicinska anstalt, 75189 Uppsala

United Kingdom

Central Veterinary Laboratory, New Haw, Weybridge, Surrey KT15 3NB

2. The national classical swine fever laboratories shall be responsible for ensuring that in each Member State the laboratory testing to detect the presence of classical swine fever and the identification of the genetic type of virus isolates are carried out in accordance with the Diagnostic Manual. To this end they may make special agreements with the Community Reference Laboratory or with other national laboratories.
3. The national classical swine fever laboratory in each Member State shall be responsible for coordinating the standards and diagnostic methods in each classical swine fever diagnostic laboratory within the Member State. To this end:
- they may provide diagnostic reagents to individual laboratories;
 - they shall control the quality of all diagnostic reagents used in that Member State;
 - they shall arrange comparative tests periodically;
 - they shall hold isolates of classical swine fever virus from cases and outbreaks confirmed in that Member State.

ANNEX IV

Community reference laboratory for classical swine fever

1. The Community reference laboratory for classical swine fever is: Institut für Virologie, der Tierärztlichen Hochschule Hanover, Bünteweg 17, 30559 Hanover, Germany.
 2. The functions and duties of the Community reference laboratory for classical swine fever shall be:
 - (a) To coordinate, in consultation with the Commission, the methods employed in the Member States for diagnosing classical swine fever, specifically by:
 - storing and supplying cell cultures for use in diagnosis;
 - typing, storing and supplying strains of classical swine fever virus for serological tests and the preparation of anti-sera;
 - supplying standardised sera, conjugate sera and other reference reagents to the national laboratories in order to standardise the tests and reagents employed in the Member States;
 - building up and holding a classical swine fever virus collection;
 - organising periodic comparative tests of diagnostic procedures at Community level;
 - collecting and collating data and information on the methods of diagnosis used and the results of tests carried out;
 - characterising isolates of the virus by the most up-to-date methods available to allow greater understanding of the epizootiology of classical swine fever;
 - keeping abreast of developments in classical swine fever surveillance, epizootiology and prevention throughout the world;
 - retaining expertise on the virus causing classical swine fever and other pertinent viruses to enable rapid differential diagnosis;
 - acquiring a thorough knowledge of the preparation and use of the products of veterinary immunology used to eradicate and control classical swine fever;
 - (b) to make the necessary arrangements for training or re-training experts in laboratory diagnosis with a view to harmonising diagnostic techniques;
 - (c) to have trained personnel available for emergency situations occurring within the Community;
 - (d) to perform research activities and whenever possible coordinate research activities directed towards an improved control of classical swine fever.
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ANNEX V

Main criteria to be considered for the decision to kill pigs in contact holdings

Criteria	Decision	
	For killing	Against killing
Clinical signs suggesting classical swine fever in the contact holdings	Yes	No
Movements of pigs from the outbreak to contact holdings after the likely time of introduction of virus in the infected holding	Yes	No
Location of contact holdings in an area with a high density of pigs	Yes	No
Likely shedding of virus from the outbreak before application of eradication measures	Massive/unknown	Limited
Location of contact holdings within 500 meters ⁽¹⁾ from the outbreak	Yes	No
Proximity of contact holdings to more than one outbreak	Yes	No
Number of pigs in the outbreak and/or in contact holdings	High	Low

⁽¹⁾ In case of areas with a very high density of pigs, a longer distance must be considered.

ANNEX VI

Main criteria to be considered for the decision to apply emergency vaccination in pig holdings

Criteria	Decision	
	For vaccination	Against vaccination
Number/incidence slope of outbreaks in the previous 10-20 days	High/rising rapidly	Low/shallow or slow rise
Location of holdings where vaccination might be applied in an area with a high density of pigs	Yes	No
Likelihood of further outbreaks in the area for the next two months or more	Highly likely	Not likely
Shortage of rendering capacity	Yes	No

ANNEX VII

PART A

Directive 80/217/EEC and its successive amending acts

(referred to in Article 27)

Directive 80/1101/EEC ⁽¹⁾	
Directive 80/1274/EEC ⁽²⁾	only Article 2
Directive 81/476/EEC ⁽³⁾	only concerning the references made in Articles 1 and 2 to the provisions of Directive 80/217/EEC
Directive 84/645/EEC ⁽⁴⁾	
Directive 85/586/EEC ⁽⁵⁾	only concerning the references made in Article 5 to the provisions of Directive 80/217/EEC
Directive 87/486/EEC ⁽⁶⁾	
Directive 91/685/EEC ⁽⁷⁾	
Decision 93/384/EEC ⁽⁸⁾	

⁽¹⁾ OJ L 325, 1.12.1980, p. 17.⁽²⁾ OJ L 375, 31.12.1980, p. 75.⁽³⁾ OJ L 186, 8.7.1981, p. 20.⁽⁴⁾ OJ L 339, 27.12.1984, p. 33.⁽⁵⁾ OJ L 372, 31.12.1985, p. 44.⁽⁶⁾ OJ L 280, 3.10.1987, p. 21.⁽⁷⁾ OJ L 377, 31.12.1991, p. 1.⁽⁸⁾ OJ L 166, 8.7.1993, p. 34.

PART B

Deadlines for transposition into National law

Directive	Deadline for transposition
80/217/EEC	1 July 1981
80/1101/EEC	
80/1274/EEC	1 July 1981
81/476/EEC	
84/645/EEC	31 March 1985
85/586/EEC	1 January 1986
87/486/EEC	31 December 1987
91/685/EEC	1 July 1992

ANNEX VIII

Correlation table

This Directive	Directive 80/217/EEC
Article 1	Article 1
Article 2(a), (b), (e), (f), (m), (n), (o), (q)	Article 2(a), (e), (g), (h), (l), (j), (k), (m)
Article 2(c), (d), (g), (h), (i), (j), (k), (l), (p), (r), (s), (t), (u), (v), (w)	—
Article 3(1)	Article 3
Article 3(2) and (3)	Article 12
Article 4(1) and (2)	Article 4(1)
Article 4(3)	—
Article 4(4)	Article 4(2)
Article 5(1), (a), (c), (d), (f), (g), (i)	Article 5(1), except the seventh indent
Article 5(1) (b), (e), (h) and (2)	—
Article 6	Article 6
Article 7(1) and (2), first subparagraph	Article 5(2), Article 10(1)
Article 7(2), second subparagraph and (3)	—
Article 8, first subparagraph and second sentence in the second subparagraph (b)	—
Article 8, except the subparagraph and sentence above	Article 7
Article 9(1) except (g) and (h)	Article 9(1)
Article 9(1) (g) and (h)	—
Article 9(2), (3) and (4)	Article 9(2), (3) and (10)
Article 10(1) except (g) and (h), (2) and (3)	Article 9(4)
Article 10(1)(g) and (h)	—
Article 10(4)	Article 9(5)
Article 11(1) and (2)	Article 9(6)
Article 11(3)	Article 9(7)
Article 12(1)	Article 12
Article 12(2)	—
Article 13, except (1)(b)	Article 5(1), seventh indent
Article 13(1)(b)	—
Article 14	—
Article 15(1)	Article 6a(1)
Article 15(2)(a) and (b), fifth and eighth indents	—
Article 15(2)(b), except the fifth and eighth indents	Article 6a(2)

This Directive	Directive 80/217/EEC
Article 15(2)(c)	Article 6a(2a)
Article 15(2)(d) and (3)	—
Article 16(1), except the fourth subparagraph, and (2)	Article 6a(3) and (4)
Article 16(3)(b), (c), (g), (j), (k), (l), (n)	Article 6a(5)
Article 16(1), fourth subparagraph, (3) (a), (d), (e), (f), (h), (i), (o), (p), (q) and (4)	—
Article 17(1), (2)	Article 11
Article 17(3), (4) and (5)	—
Article 18	Article 14(1)(a), 1(c) and (5)
Article 19(1), (3), except (h) and (i), (4), except (c), (5) and (6), except (b)	Article 14(2), (3) and (4)
Article 19(2), (3)(h) and (i), (4) (c), (7), (8) and (9)	—
Article 20	—
Article 21	Article 14(a)
Article 22(1), (2) and (3)	Article 14(b)(1), (2), (4)
Article 23	—
Article 24	—
Article 25	Article 16
Article 26	Article 16(a)
Article 27	—
Article 28	—
Article 29	—
Article 30	—
Article 31	Article 20
Annex I	—
Annex II, point 1, point 2, first and second indents, and point 3(b)	—
Annex II, points 2, except the first and second indents and 3(b)	Annex V
Annex III, points 1 and 3	Annex II
Annex III, point 2	—
Annex IV	Annex VI
Annex V	—
Annex VI	—
Annex VII	—