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► **B** **COUNCIL DIRECTIVE 92/119/EEC**
of 17 December 1992
introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease
(OJ L 62, 15.3.1993, p. 69)

Amended by:

		Official Journal		
		No	page	date
► <u>M1</u>	Council Directive 2002/60/EC of 27 June 2002	L 192	27	20.7.2002
► <u>M2</u>	Council Regulation (EC) No 806/2003 of 14 April 2003	L 122	1	16.5.2003
► <u>M3</u>	Commission Decision 2006/911/EC of 5 December 2006	L 346	41	9.12.2006
► <u>M4</u>	Council Directive 2006/104/EC of 20 November 2006	L 363	352	20.12.2006
► <u>M5</u>	Commission Directive 2007/10/EC of 21 February 2007	L 63	24	1.3.2007
► <u>M6</u>	Commission Decision 2007/729/EC of 7 November 2007	L 294	26	13.11.2007
► <u>M7</u>	Council Directive 2008/73/EC of 15 July 2008	L 219	40	14.8.2008
► <u>M8</u>	Council Decision 2009/470/EC of 25 May 2009	L 155	30	18.6.2009
► <u>M9</u>	Commission Implementing Decision (EU) 2018/136 of 25 January 2018	L 24	3	27.1.2018

Amended by:

► <u>A1</u>	Act concerning the conditions of accession of the Kingdom of Norway, the Republic of Austria, the Republic of Finland and the Kingdom of Sweden and the adjustments to the Treaties on which the European Union is founded (94/C 241/08)	C 241	21	29.8.1994
	(adapted by Council Decision 95/1/EC, Euratom, ECSC)	L 1	1	1.1.1995
► <u>A2</u>	Act concerning the conditions of accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded	L 236	33	23.9.2003

Corrected by:

- **C1** Corrigendum, OJ L 145, 10.6.2009, p. 49 (92/119/EEC)

▼B

COUNCIL DIRECTIVE 92/119/EEC
of 17 December 1992

**introducing general Community measures for the control of certain
 animal diseases and specific measures relating to swine vesicular
 disease**

Article 1

This Directive defines the general Community control measures to be applied in the event of an outbreak of one of the diseases listed in Annex I.

Article 2

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

1. *holding*: any establishment (agricultural or other), situated in the territory of a Member State, in which animals are kept or bred;
2. *animal*: any domestic animal of a species liable to be directly affected by the disease in question, or any wild vertebrate animal likely to participate in the epidemiology of the disease, by acting as a carrier or reservoir of infection;

▼C1

3. *vector*: any vertebrate or invertebrate animal which, by mechanical or biological means, is liable to transmit and spread the agent of the disease in question;

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4. *owner or keeper*: any person or persons, either natural or legal, having ownership of the animals, or charged with keeping the said animals, whether or not for financial reward;
5. *incubation period*: the period of time likely to elapse between exposure to the agent of the disease and the onset of clinical symptoms. The duration of this period shall be that indicated in Annex I for the disease in question;
6. *confirmation of infection*: the declaration by the competent authority of the presence of any of the diseases listed in Annex I based on laboratory results; however, in the event of an epidemic, the competent authority may also confirm the presence of the disease on the basis of clinical and/or epidemiological results;
7. *competent authority*: the central authority of a Member State responsible for carrying out veterinary checks or any veterinary authority to which it has delegated that responsibility;
8. *official veterinarian*: the veterinarian appointed by the competent authority.

Article 3

Member States shall ensure that it is compulsory for the suspected presence of any of the diseases referred to in Annex I to be notified immediately to the competent authority.

▼B*Article 4*

1. When animals on a holding are suspected of being infected or contaminated with one of the diseases listed in Annex I, Member States shall ensure that the official veterinarian immediately activates official investigation arrangements to confirm or rule out the presence of the disease in question and, in particular, must take or have taken the samples necessary for laboratory examination. To that end the animals in question may be transported to the laboratories under the supervision of the competent authority, which shall take appropriate steps to prevent the disease from spreading.
2. As soon as the suspected presence of the disease is notified, the competent authority shall have the holding placed under official surveillance and shall in particular require that:
 - (a) a census be made of all categories of animals of susceptible species and that, in respect of each of these categories, the number of animals already dead, infected or liable to be infected or contaminated be recorded; the census must be kept up to date to take account of animals born or dying during the period of suspicion; the information in the census must be kept up to date and produced on request and may be checked at each visit;
 - (b) all animals of susceptible species on the holding be kept in their living quarters or confined in some other place where they can be isolated taking into account the possible role of vectors, where appropriate;
 - (c) no animals of susceptible species enter or leave the holding;
 - (d) all movement:
 - of persons, animals of other species not susceptible to the disease and vehicles to or from the holding,
 - of meat or animal carcasses, or of animal feed, equipment, waste, droppings, litter, manure, or anything liable to transmit the disease in question
 - (e) be subject to authorization by the competent authority, which shall lay down the conditions for preventing any risk of the disease spreading; appropriate means of disinfection be installed at the entrances and exits of buildings or places housing animals of susceptible species and of the holding itself;
 - (f) an epizootiological inquiry be carried out in accordance with Article 8.
3. Until such time as the official measures laid down in paragraph 2 are enforced, the owner or keeper of any animal in which disease is suspected shall take every appropriate measure to ensure compliance with paragraph 2, except for subparagraph (f) thereof.
4. The competent authority may apply any of the measures provided for in paragraph 2 to other holdings should their location, their configuration or contacts with the holding where the disease is suspected give reason to suspect possible contamination.

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5. The measures referred to in paragraphs 1 and 2 shall not be withdrawn until the suspicion of the presence of the disease has been ruled out by the official veterinarian.

Article 5

1. Once it has been officially confirmed that one of the diseases listed in Annex I is present on a holding, Member States shall ensure that, in addition to the measures laid down in Article 4 (2), the competent authority requires application of the following measures:

- (a) all animals of susceptible species on the holding shall be killed on the spot, without delay. The animals which have died or been killed shall either be burnt or buried on the spot, if possible, or destroyed in a carcase disposal plant. These operations shall be carried out in such a way as to minimize the risk of disseminating the agent of the disease;
- (b) any substance or waste, such as animal feed, litter, manure or slurry, which is liable to be contaminated, shall be destroyed or treated appropriately. This treatment, carried out in accordance with the instructions of the official veterinarian, must ensure that any agent or vector of the agent of the disease is destroyed;
- (c) after carrying out operations listed in subparagraphs (a) and (b), the buildings used for housing animals of susceptible species, their surroundings, the vehicles used for transport and all equipment liable to be contaminated shall be cleaned and disinfected in accordance with Article 16;
- (d) an epizootiological inquiry shall be carried out in accordance with Article 8.

2. When recourse is had to burial, it must be deep enough to prevent carnivorous animals from digging up the carcases or waste referred to in paragraph 1 (a) and (b) above and must be in suitable ground so as to prevent contamination of water tables or any environmental nuisance.

3. The competent authority may extend the measures provided for in paragraph 1 to other neighbouring holdings should their location, their configuration or contacts with the holding where the presence of the disease has been confirmed give reason to suspect possible contamination.

4. The restocking of the holding shall be authorized by the competent authority, following the satisfactory inspection by the official veterinarian of the cleaning and disinfection operations carried out in accordance with Article 16.

Article 6

Where animals living in the wild are infected or suspected of being infected, Member States shall ensure that appropriate action is taken. Member States shall inform the Commission and the other Member States, in the Standing Veterinary Committee set up by Decision 68/361/EEC ⁽¹⁾, of the measures they have taken.

⁽¹⁾ OJ No L 255, 18.10.1968, p. 23.

▼B*Article 7*

1. In the case of holdings which consist of two or more separate production units, the competent authority may derogate from the requirements of Article 5 (1) (a) as regards healthy production units of a holding which is infected, provided that the official veterinarian has confirmed that the structure and size of these units and the operations carried out therein are such that they are completely separate as regards housing, keeping, staff, equipment and feeding, so as to prevent the spread of the agent of the disease from one unit to another.

2. Where recourse is had to paragraph 1, the rules laid down in Commission Decision 88/397/EEC ⁽¹⁾ shall apply *mutatis mutandis*. These rules may be amended for the disease in question under the procedure laid down in Article 25 in order to take account of the specific nature of the disease.

Article 8

1. The epizootiological enquiry shall deal with:

- (a) the length of time during which the disease may have existed on the holding before being notified or suspected;
- (b) the possible origin of the disease on the holding and the identification of other holdings on which there are animals of susceptible species which may have become infected or contaminated;
- (c) the movement of persons, animals, carcasses, vehicles, equipment or any other substances likely to have carried the agent of the disease to or from the holdings in question;
- (d) the presence and distribution of disease vectors as appropriate.

2. A crisis unit shall be established in order to provide full coordination of all measures necessary to ensure eradication of the disease as quickly as possible and for the purpose of carrying out the epizootiological enquiry.

The general rules concerning national crisis units and the Community crisis unit shall be laid down by the Council, acting by a qualified majority on a proposal from the Commission.

Article 9

1. Where the official veterinarian finds, or considers on the basis of confirmed data, that disease could have been introduced from other holdings onto the holding referred to in Article 4 or from the latter onto other holdings as a result of the movement of persons, animals or vehicles or in any other way, those other holdings shall be placed under official surveillance in accordance with Article 4; this surveillance shall not be lifted until the suspected presence of disease on the holding has been officially ruled out.

⁽¹⁾ Commission Decision 88/397/EEC of 12 July 1988 coordinating rules laid down by Member States in application of Article 6 of Council Directive 85/511/EEC (OJ No L 189, 20.7.1988, p. 25).

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2. Where the official veterinarian finds, or considers on the basis of confirmed data, that disease could have been introduced from other holdings on to the holding referred to in Article 5 or from the latter onto other holdings as a result of the movement of persons, animals or vehicles or in any other way, those other holdings shall be placed under official surveillance in accordance with Article 4; this surveillance shall not be lifted until the suspected presence of disease on the holding has been officially ruled out.

3. When a holding has been subject to the provisions of paragraph 2, the competent authority shall keep the provisions of Article 4 in force on the holding for at least the maximum incubation period pertaining to each disease following the likely time of introduction of infection as established by the epizootiological enquiry carried out in accordance with Article 8.

4. Where it considers that conditions permit, the competent authority may limit the measures provided for in paragraphs 1 and 2 to a part of the holding and the animals contained therein provided that the holding can satisfy the conditions set out in Article 7, or to animals of susceptible species only.

Article 10

1. Once the diagnosis of one of the diseases in question has been officially confirmed, Member States shall ensure that the competent authority establishes around the infected holding a protection zone with a minimum radius of three kilometres, itself contained in a surveillance zone with a minimum radius of 10 kilometres. The establishment of the zones must take account of geographical, administrative, ecological and epizootiological factors relating to the disease in question, and of monitoring facilities.

2. Where the zones are situated in the territory of more than one Member State, the competent authorities of the Member States concerned shall cooperate in establishing the zones referred to in paragraph 1. However, if necessary, the protection zone and the surveillance zone shall be established under the procedure provided for in Article 26.

3. At the duly substantiated request of a Member State or on the Commission's initiative, it may be decided under the procedure laid down in Article 26, to modify (in particular to reduce or increase, as appropriate) the boundaries of the zones laid down in paragraph 1 or the duration of the restriction measures, taking into account:

- their geographical situation and ecological factors,
- the meteorological conditions,
- the presence, distribution and type of vectors,
- the results of the epizootiological studies carried out in accordance with Article 8,
- the results of laboratory tests,
- control measures actually applied.

▼B*Article 11*

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

- (a) all holdings within the zone having animals of susceptible species shall be identified;
- (b) there shall be periodic visits to holdings having animals of susceptible species, a clinical examination of those animals including, if necessary, the collection of samples for laboratory examination; a record of visits and findings must be kept, with the frequency of visits being proportional to the seriousness of the epizootic on those holdings at greatest risk;
- (c) the movement and transport of animals of susceptible species on public or private roads, excluding the service roads of holdings, shall be prohibited; the competent authority may, however, grant a derogation from that prohibition for the transit of animals by road or rail without unloading or stopping;
- (d) animals of susceptible species must remain on the holding on which they are being kept, except to be transported under official supervision directly to a slaughterhouse located in that zone for emergency slaughter or, if that zone has no slaughterhouse under veterinary supervision, to a slaughterhouse in the surveillance zone designated by the competent authority. Such transport may be authorized by the competent authority only after the official veterinarian has carried out an examination of all the animals of susceptible species on the holding and confirmed that none of the animals is suspected of being infected. The competent authority responsible for the slaughterhouse shall be informed of the intention to send animals to it.

2. The measures applied in the protection zone shall be kept in force for at least the maximum incubation period pertaining to the disease in question after animals from the infected holding have been disposed of in accordance with Article 5 and cleaning and disinfection operations have been carried out in accordance with Article 16. However, where the disease is transmitted by an insect vector, the competent authority may fix the duration of the measures and lay down provisions for the possible introduction of sentinel animals. Member States shall forthwith inform the Commission and the other Member States, within the Standing Veterinary Committee, of the measures they have taken.

On expiry of the period referred to in the first subparagraph, the rules applied to the surveillance zone shall also apply to the protection zone.

Article 12

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

- (a) all holdings having animals of susceptible species shall be identified;
- (b) the movement of animals of susceptible species on public roads shall be prohibited except for the purpose of leading them to pasture or animal buildings; the competent authority may, however, grant a derogation from that prohibition for the transit of animals by road or rail without unloading or stopping;

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- (c) the transport of animals of susceptible species within the surveillance zone shall be subject to authorization by the competent authority;
- (d) animals of susceptible species must remain inside the surveillance zone for a maximum incubation period after the most recent recorded case of disease. Thereafter, animals may be removed from that zone to be transported under official supervision directly to a slaughterhouse designated by the competent authority for emergency slaughter. Such transport may be authorized by the competent authority only after the official veterinarian has carried out an examination of all the animals of the susceptible species on the holding and confirmed that none of the animals is suspected of being infected. The competent authority responsible for the slaughterhouse shall be informed of the intention to send animals to it.

2. The measures applied in the surveillance zone shall be kept in force for a period at least equal to the maximum incubation period after animals from the holding have been disposed of in accordance with Article 5 and cleaning and disinfection operations have been carried out in accordance with Article 16. However, where the disease is transmitted by an insect vector, the competent authority may fix the duration of the measures and lay down provisions for the possible introduction of sentinel animals. Member States shall forthwith inform the Commission and the other Member States, within the Standing Veterinary Committee, of the measures they have taken.

Article 13

Where the prohibitions provided for in Articles 11 (1) (d) and 12 (1) (d) are maintained beyond 30 days because of the occurrence of further cases of the disease and as a result problems arise in keeping the animals, the competent authority may, following an application by the owner explaining the grounds for such application, by the owner explaining the grounds for such applications authorize the removal of the animals from a holding within the protection zone or the surveillance zone, provided that:

- (a) the official veterinarian has verified the facts;
- (b) an inspection of all animals on the holding has been carried out;
- (c) the animals to be transported have undergone a clinical examination, with negative result;
- (d) each animal has been marked by ear marking or has been identified by any other approved method;
- (e) the holding of destination is located either in the protection zone or within the surveillance zone.

All the necessary precautions must be taken, in particular by cleaning and disinfecting lorries after transport, to avoid the risk of spreading the agent of the disease in the course of such transport.

Article 14

1. Member States shall ensure that the competent authority takes all the necessary measures to keep at least persons established in the protection and surveillance zones informed of the restrictions in force and makes all necessary arrangements for the appropriate implementation of those measures.

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2. Where, in a given region, the epizootic in question is exceptionally serious, all the additional measures to be taken by the Member States concerned shall be adopted under the procedure laid down in Article 26.

Article 15

By way of derogation from the general provisions laid down in this Directive, specific provisions relating to the control and eradication measures for each respective disease:

- are, for swine vesicular disease, set out in Annex II for swine vesicular disease,
- are, for each of the other diseases listed in Annex I, adopted by the Council, acting by a qualified majority on a proposal from the Commission.

Article 16

1. Member States shall ensure that:
 - (a) the disinfectants and insecticides to be used and, where appropriate, their concentrations, are officially approved by the competent authority;
 - (b) the cleaning, disinfection and disinsectization operations are carried out under official supervision:
 - in accordance with the instructions given by the official veterinarian,
 - and
 - in such a way as to eliminate any risk of spread or survival of the agent of the disease;
 - (c) on completion of the operations in (b), the official veterinarian makes sure that the measures have been carried out properly and that an appropriate period, of not less than 21 days, has elapsed to ensure that the disease in question has been completely eliminated before animals of susceptible species are re-introduced.
2. The procedures for cleaning and disinfecting an infected holding:
 - are, for swine vesicular disease, those set out in Annex II,
 - are determined, in the context of preparation of the specific measures for each disease listed in Annex I, in accordance with the procedure laid down in the second indent of Article 15.

Article 17

1. Member States shall ensure that in each Member State there is designated:
 - (a) a national laboratory with facilities and expert personnel enabling it to show at all times, and especially when the disease in question first appears, the type, sub-type and variant of the relevant virus and to confirm results obtained in regional diagnostic laboratories;
 - (b) a national laboratory at which reagents used in regional diagnostic laboratories are tested.

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2. The national laboratories designated for each of the diseases referred to shall be responsible for coordinating diagnostic standards and methods, and for the use of reagents.

3. The national laboratories designated for each of the diseases referred to shall be responsible for coordinating the diagnostic standards and methods laid down by each laboratory for diagnosis of the disease in question within the Member State. To this end, they:

- (a) may provide diagnostic reagents to national laboratories;
- (b) shall control the quality of all diagnostic reagents used in the Member State;
- (c) shall periodically arrange comparative tests;
- (d) shall hold isolates of the virus of the disease in question from cases confirmed in the Member State;
- (e) shall ensure the confirmation of positive results obtained in regional diagnostic laboratories.

4. However, by way of derogation from paragraph 1, Member States which do not have a national laboratory competent as regards the disease in question, may use the services of a national laboratory with competence in the matter of another Member State.

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5. Member States shall maintain up-to-date lists of the national laboratories referred to in paragraph 1 and make them available to the other Member States and to the public.

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6. The national laboratories designated for each of the diseases referred to shall cooperate with the respective Community reference laboratories referred to in Article 18.

7. The detailed rules for implementing this Article shall be adopted by the Commission under the procedure laid down in Article 25.

Article 18

1. The Community reference laboratory for swine vesicular disease is indicated in Annex II.

2. The Community reference laboratories for each of the other diseases listed in Annex I shall be designated in accordance with the procedure laid down in the second indent of Article 15 in the context of preparation of the specific measures for each disease.

3. Without prejudice to Decision 90/424/EEC, and in particular Article 28 thereof, the functions and duties of the laboratories referred to in paragraphs 1 and 2 of this Article shall be those laid down in Annex III.

▼B*Article 19*

1. Vaccination against the diseases listed in Annex I may not be carried out except as a supplement to control measures taken when the disease in question broke out, in accordance with the following provisions:

(a) the decision to introduce vaccination as a supplement to control measures shall be taken by the Commission, in cooperation with the Member State concerned, under the procedure laid down in Article 26;

(b) this decision shall be based on the following criteria in particular:

- the concentration of animals of the species concerned in the affected zone,
- the characteristics and composition of each vaccine used,
- the procedures for supervision of the distribution, storage and use of vaccines,
- the species and age of the animals which may or must be vaccinated,
- the areas in which vaccination may or must be carried out,
- the duration of the vaccination campaign.

2. In the case referred to in paragraph 1:

(a) the vaccination or re-vaccination of animals of susceptible species on the holdings referred to in Article 4 shall be prohibited;

(b) hyper-immune serum injection shall be prohibited.

3. In the event of recourse to vaccination, the following rules shall apply:

(a) all vaccinated animals must be identified by a clear and legible mark in accordance with a method approved by the procedure laid down in Article 25;

(b) all vaccinated animals must remain within the vaccination zone unless sent to a slaughterhouse designated by the competent authority for immediate slaughter, in which case the movement of animals may be authorized only after the official veterinarian has carried out an examination of all the susceptible animals on the holding and confirmed that none of the animals is suspected of being infected.

4. When the vaccination operations have been completed, movements of animals of susceptible species from the vaccination zone may be permitted under the procedure laid down in Article 26, after a period determined by the same procedure.

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5. Member States shall inform the Commission on a regular basis, within the Standing Veterinary Committee, of progress as regards the vaccination measures.

6. However, by way of derogation from paragraph 1, the decision to introduce emergency vaccination may be taken by the Member State concerned, following notification of the Commission, provided that the fundamental interests of the Community are not affected. That decision, which must in particular take into account the degree of concentration of the animals in certain regions, of the need to protect individual breeds and of the geographical area in which vaccination is carried out, shall forthwith be re-examined, under the procedure laid down in Article 26, by the Standing Veterinary Committee, which may decide to retain, modify or extend the measures or to bring them to an end.

Article 20

1. Each Member State shall draw up a contingency plan applicable to all the diseases listed in Annex I, specifying the national measures to be implemented in the event of an outbreak of any of these diseases.

This plan must allow access to facilities, equipment, personnel and all other appropriate materials necessary for the rapid and efficient eradication of the outbreak.

2. The general criteria to be applied for drawing up the contingency plans are laid down in points 1 to 5 and 10 of Annex IV, with points 6 to 9 representing criteria to be adapted according to the disease concerned. Member States may however confine themselves to applying the criteria laid down in points 6 to 9 where the criteria in points 1 to 5 and 10 were already adopted when plans were submitted for the application of control measures for another disease.

3. Contingency plans drawn up in accordance with the criteria listed in Annex IV shall be submitted to the Commission:

- (i) no later than six months after this Directive is brought into effect as regards swine vesicular disease;
- (ii) no later than six months after implementation of the specific measures for each of the other diseases listed in Annex I.

4. The Commission shall examine the contingency 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 Commission shall approve the plans, if necessary amended, in accordance with the procedure laid down in Article 25.

The plans may subsequently be amended or supplemented, in accordance with the same procedure, to take into account developments in the situation and the specific nature of the disease in question.

▼B*Article 21*

By way of derogation from the conditions provided for in Articles 19 and 20 as regards the contingency measures to be adopted by the Member States and so as to take account of the natural, geographical constraints particular to the French Overseas Departments, the Azores and Madeira and their remoteness from the central part of the Community's territory, the Member State concerned shall be authorized to apply particular control measures specific to each of the diseases listed in Annex I to this Directive.

The Member State concerned shall, within the Standing Veterinary Committee, inform the Commission and the other Member States of the measures it has taken in this respect and in particular of the control measures implemented to ensure that animals from the territories in question or products from such animals are not dispatched to the other territories of the Community.

Following the information procedure referred to in the second paragraph, Article 20 shall apply *mutatis mutandis*.

Article 22

Commission experts may, in collaboration with the competent authorities, and in so far as is necessary to ensure uniform application of this Directive, make on-the-spot checks. In order to do this, they may check a representative percentage of holdings to see whether the competent authorities are checking that these holdings are fulfilling the requirements of this Directive. The Commission shall inform the Member States of the result of the checks carried out.

A Member State in whose territory a check is being carried out shall give all the necessary assistance to the experts in carrying out their duties.

The detailed rules for implementing this Article shall be determined in accordance with the procedure laid down in Article 25.

Article 23

1. The conditions governing the Community's financial contribution to the measures connected with the application of this Directive are laid down in Decision 90/424/EEC.

▼M8

▼B*Article 24*

1. Annexes I, III and IV shall be amended, as and when required, by the Council acting by a qualified majority on a proposal from the Commission, in particular in order to take into account developments in research and in diagnostic procedures.

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2. The Commission may, in accordance with the procedure laid down in Article 25, amend Annex II, in particular in order to take into account technological and scientific developments and diagnostic methods.

▼ M2*Article 25*

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health set up pursuant to Article 58 of Regulation (EC) No 178/2002 ⁽¹⁾.

2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC ⁽²⁾ shall apply.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its Rules of Procedure.

▼ B*Article 26*

1. Where the procedure laid down in this Article is to be followed, the matter shall without delay be referred to the Standing Veterinary Committee by its chairman, either on his own initiative or at the request of a Member State.

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2. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the Chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The Chairman shall not vote.

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► A1 3. ◀ (a) The Commission shall adopt the measures and shall implement them immediately, where they are in accordance with the opinion of the Committee.

(b) 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 a proposal to the Council 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 matter is referred to it, the Commission shall adopt the proposed measures and shall implement them immediately unless the Council has voted against the measures by a simple majority.

⁽¹⁾ OJ L 31, 1.2.2002, p. 1.

⁽²⁾ OJ L 184, 17.7.1999, p. 23.

▼B*Article 27*

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 October 1993. They shall forthwith inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

2. Member States shall communicate to the Commission the texts of the main provisions of national law which they adopt in the field governed by this Directive.

3. The setting of the deadline for transposition into national law at 1 October 1993 shall be without prejudice to the abolition of veterinary checks at frontiers provided for in Directive 90/425/EEC.

Article 28

This Directive is addressed to the Member States.

▼B*ANNEX I***LIST OF COMPULSORILY NOTIFIABLE DISEASES**

Disease	Maximum incubation period
Rinderpest	21 days
Peste des petits ruminants	21 days
Swine vesicular disease	28 days
Bluetongue	40 days
Epizootic haemorrhagic disease of deer	40 days
Sheep and goat pox (Capripox)	21 days
Vesicular stomatitis	21 days
► <u>M1</u> African swine fever ◀	40 days
Lumpy skin disease	28 days
Rift valley fever	30 days

▼B*ANNEX II***SPECIFIC MEASURES TO CONTROL CERTAIN DISEASES**

In addition to the general provisions laid down in this Directive, the following specific provisions shall be applicable to swine vesicular disease.

1. Description of the disease

A disease of swine that is clinically indistinguishable from foot-and-mouth disease, causing vesicles on the snout, lips, tongue and the coronary bands of the digits. The disease varies considerably in severity and may infect a pig herd without manifesting itself by clinical lesions. The virus is able to survive for long periods outside the body even in fresh meat; it is extremely resistant to normal disinfectants and noted for its persistence and stability over a pH range from 2,5 to 12. Particularly thorough cleaning and disinfection are, therefore, necessary.

2. Incubation period

For the purpose of this Directive, the maximum incubation period shall be considered to be 28 days.

3. Diagnostic procedures for the confirmation and differential diagnosis of swine vesicular disease

The detailed methods for the collection of materials for diagnosis, the laboratory diagnostic tests, detection of antibodies and evaluation of the results of laboratory testing shall be decided in accordance with the procedure laid down in Article 25 before the Directive enters into force.

4. Confirmation of the presence of swine vesicular disease

By way of derogation from Article 2 (6) of this Directive, the presence of the disease shall be confirmed:

- (a) on holdings on which swine vesicular disease virus is isolated either from the pigs or from the environment;
- (b) on holdings containing pigs which are seropositive for swine vesicular disease provided those pigs or others on the holdings show lesions characteristic of swine vesicular disease;
- (c) on holdings containing pigs which show clinical signs of disease or are seropositive, provided there is a direct epidemiological connection with a confirmed outbreak;
- (d) on other herds in which seropositive pigs are detected. In the latter case the competent authority shall, before confirming the presence of the disease, undertake further investigations, in particular resampling and retesting with an interval of 28 days at least between collections of samples. The provisions of Article 4 shall continue to apply until such further investigations are completed. If subsequent investigations show no evidence of the disease, although the pigs are still seropositive, the competent authority shall ensure that the pigs tested are killed and destroyed under its supervision or slaughtered under its supervision in a slaughterhouse it has designated in its national territory.

The competent authority shall ensure that on arrival at the slaughterhouse the pigs are kept and slaughtered separately from other pigs and that their meat is exclusively used on the national market.

▼M7

▼M9

▼B**7. Protection zone**

1. The size of the protection zone shall be as defined in Article 10 of this Directive.

2. In the case of swine vesicular disease, by way of derogation, the measures in Article 11 of this Directive shall be replaced by the following:
 - (a) all holdings within the zone having animals of susceptible species shall be identified;

 - (b) there shall be periodic visits to holdings having animals of susceptible species, a clinical examination of those animals including, if necessary, the collection of samples for laboratory examination; a record of visits and findings must be kept; with the frequency of the visits being proportional to the seriousness of the epizootic on those holdings at greatest risk;

 - (c) the movement and transport of animals of susceptible species on public or private roads, excluding the service roads of holdings, shall be prohibited. The competent authority may, however, derogate from this prohibition for the transit of animals by road and rail without unloading or stopping;

 - (d) however, in accordance with the procedure laid down in Article 25, an exemption may be granted for slaughter pigs coming from outside the protection zone and on their way to a slaughterhouse situated in that zone;

 - (e) trucks and other vehicles and equipment which are used within the protection zone to transport pigs or other livestock or material which may be contaminated (e.g. feedingstuff, manure, slurry, etc.) may not leave:
 - (i) a holding situated within the protection zone;

 - (ii) the protection zone;

 - (iii) a slaughterhouse,without having been cleaned and disinfected in accordance with the procedures laid down by the competent authority. Those procedures shall provide in particular that no truck or vehicle which has been used in the transport of pigs may leave the zone without being inspected by the competent authority;

 - (f) pigs may not be removed from a holding in which they are kept for 21 days after completion of the preliminary cleaning and disinfection of infected holdings as laid down in Article 16; after 21 days, authorization may be given to remove pigs from the said holding;

▼ B

- (i) directly to a slaughterhouse designated by the competent authority, preferably within the protection or surveillance zone, provided that:

- an inspection of all the pigs on the holding has been carried out,
- a clinical examination of the pigs to be moved to slaughter has been carried out,
- each pig has been marked by ear marking or has been identified by any other approved method,
- the pigs are transported in vehicles sealed by the competent authority.

The competent authority responsible for the slaughterhouse shall be informed of the intention to send pigs to it.

On arrival at the slaughterhouse, the pigs shall be kept and slaughtered separately from other pigs. The vehicle and equipment which have been involved in the transport of the pigs shall be cleaned and disinfected before leaving the slaughterhouse.

During the pre-slaughter and *post mortem* inspection carried out at the designated slaughterhouse, the competent authority shall take into account any signs relating to the presence of the swine vesicular disease virus.

In the case of pigs slaughtered under these provisions, a statistically representative sample of bloods shall be collected. In the case of a positive result which leads to the confirmation of swine vesicular disease, the measures in 9 (3) will apply;

- (ii) under exceptional circumstances, directly to other premises located within the protection zone, provided that:

- an inspection of all the pigs on the holdings has been carried out,
- a clinical examination of the pigs to be moved has been carried out, with negative results,
- each pig has been marked by ear marking or has been identified by any other approved method;

▼ M5

- (g) meat from the pigs referred to in point (f)(i):

- (i) shall not enter into intra-Community or international trade and shall bear the health mark for fresh meat provided for in Annex II to Council Directive 2002/99/EC ⁽¹⁾;
- (ii) shall be obtained, cut, transported and stored separately from meat intended for intra-Community and international trade and shall be used in such a way as to avoid it being introduced into meat products intended for intra-Community or international trade, unless it has undergone a treatment set out in Annex III to Directive 2002/99/EC;

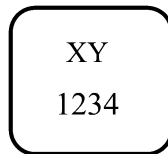
⁽¹⁾ OJ L 18, 23.1.2003, p. 11.

▼M5

- (h) (i) by way of derogation from point (g), for meat from the pigs referred to in point (f)(i) Member States may decide to use an other identification mark than the special identification mark set out in Annex II to Directive 2002/99/EC, provided that it is clearly distinguishable from other identification marks to be applied to pig meat in accordance with Regulation (EC) No 853/2004 of the European Parliament and of the Council ⁽¹⁾ or Commission Regulation (EC) No 2076/2005 ⁽²⁾;

Member States that decide to use the alternative identification mark shall inform the Commission thereof in the framework of the Standing Committee on the Food Chain and Animal Health.

- (ii) for the purpose of (i) the identification mark must be legible and indelible, the characters easily readable and clearly displayed. The identification mark must have following shape and contain following indications:



XY means the relevant country code provided for in point 6 of Part B of Section I of Annex II to Regulation (EC) No 853/2004.

1234 means the approval number of the establishment referred to in point 7 of Part B of Section I of Annex II to Regulation (EC) No 853/2004.

▼B

3. The measures in the protection zone shall continue to be applied at least until:
- (a) all measures laid down in Article 16 of this Directive have been carried out;
 - (b) all the holdings in the zone have undergone:
 - (i) a clinical examination of the pigs which has revealed that they have no signs of disease suggesting the presence of swine vesicular disease; and
 - (ii) a serological examination of a statistical sample of the pigs without the detection of antibodies to swine vesicular disease. The programme for serological screening shall take into account the transmission of swine vesicular disease and the way in which pigs are kept. The programme shall be fixed under the procedure laid down in Article 25 of this Directive before the date of entry on which it is brought into effect.

The examination and sampling referred to in (i) and (ii) shall not take place before 28 days have elapsed after the completion of preliminary cleaning and disinfection measures at the infected holding.

4. On expiry of the period referred to in point 3, the rules applied to the surveillance zone shall also apply to the protection zone.

⁽¹⁾ OJ L 139, 30.4.2004, p. 55, corrected by OJ L 226, 25.6.2004, p. 22.

⁽²⁾ OJ L 338, 22.12.2005, p. 83.

▼M5

5. Where the prohibitions provided for in point 2(f) are maintained beyond 30 days because of the occurrence of further cases of the disease and as a result problems arise in keeping the animals, the competent authority may, following an application by the owner explaining the grounds for such application and provided that the official veterinarian has verified the facts, authorise the removal of the animals from a holding within the protection zone. Points 2(f) and (h) shall apply *mutatis mutandis*.

▼B**8. Surveillance zone**

1. The size of the surveillance zone shall be as laid down in Article 10.
2. In the case of swine vesicular disease, the measures laid down in Article 12 shall be replaced by the following:
 - (a) all holdings having animals of susceptible species shall be identified;
 - (b) any movement of pigs other than direct to a slaughterhouse from a holding in the surveillance zone shall be permitted, provided that no pigs have moved into that holding in the previous 21 days; the owner or the person responsible for the animals must keep a record of all pig movements;
 - (c) the movement of pigs from the surveillance zone may be authorized by the competent authority, provided that:
 - an inspection of all pigs on the holding has been carried out with the 48 hours preceding the movement,
 - a clinical examination of the pigs to be moved has been carried out with negative results in the 48 hours preceding the movement,
 - a serological examination of a statistical sample of the pigs to be moved has been carried out without the detection of antibodies to swine vesicular disease within the 14 days preceding the movement. However, in the case of pigs for slaughter, the serological examination may be carried out on the basis of blood samples taken at the slaughterhouse of destination designated by the competent authority in its territory. In the event of positive results confirming the presence of swine vesicular disease, the measures provided for in point 9 (3) shall be applied,
 - each pig has been marked with an individual eartag or by any other approved method of identification,
 - trucks and other vehicles and equipment used for the transport of the pigs must be cleaned and disinfected after each transport operation;
 - (d) trucks and other vehicles and equipment used for the transport of the pigs or other livestock or material that may be contaminated and which are used within the surveillance zone shall not leave that zone without having been cleaned and disinfected in accordance with the procedures laid down by the competent authority.
3. (a) The size of the surveillance zone may be amended in accordance with the provisions laid down in Article 10 (3).
- (b) The measures in the surveillance zone shall be applied at least until:
 - (i) all the measures laid down in Article 16 have been carried out;
 - (ii) all the measures required in the protection zone have been carried out.

▼B**9. General common measures**

Additional measures in the case of swine vesicular disease shall be applied as follows:

1. in cases where the presence of swine vesicular disease is officially confirmed, Member States shall ensure that, in addition to the measures laid down in Articles 4 (2) and 5 of this Directive, meat of pigs slaughtered during the period between the probable introduction of disease to the holding and the implementation of official measures is, wherever possible, traced and destroyed under official supervision in such a way as to avoid the risk of swine vesicular disease virus spreading;
2. when the official veterinarian has reason to suspect that pigs on any holding may have been contaminated as a result of the movement of any person, animal or vehicle or in any other way, pigson the holding shall remain under the movement restrictions referred to in Article 9 of this Directive at least until the holding has undergone:
 - (a) a clinical examination of the pigs, with negative results;
 - (b) a serological examination of a statistical sample of the pigs without the detection of antibodies to swine vesicular disease in accordance with 7 (3) (b) (ii).

The examination referred to in (a) and (b) shall not take place until 28 days have elapsed since the possible contamination of the premises as the result of the movement of persons, animals, or vehicles, or in any other way.

3. Should the presence of swine vesicular disease be confirmed in a slaughterhouse, the competent authority shall ensure that:
 - (a) all pigs in the slaughterhouse are slaughtered without delay;
 - (b) the carcasses and offal of infected and contaminated pigs are destroyed under official supervision in such a way as to avoid the risk of swine vesicular disease virus spreading;
 - (c) cleaning and disinfection of buildings and equipment, including vehicles, take place under the supervision of the official veterinarian, in accordance with instructions laid down by the competent authority;
 - (d) an epidemiological enquiry is carried out in accordance with Article 8 of the Directive;
 - (e) no pigs are re-introduced for slaughter until at least 24 hours after completion of the cleaning and disinfection operations carried out in accordance with (c).

10. Cleansing and disinfection of infected holdings

In addition to the measures laid down in Article 16 of this Directive, the following measures shall also apply:

1. Procedure for preliminary cleaning and disinfection

- (a) As soon as the carcasses of the pigs have been removed for disposal, those parts of the premises in which the pigs have been housed and any other parts of the premises which have been contaminated during slaughter should be sprayed with disinfectant, approved in compliance with Article 16, at the concentration appropriate for swine vesicular disease. The disinfectant used should remain on the surface for at least 24 hours.
- (b) Any tissue or blood which may have been spilled during slaughter should be carefully collected and disposed of with the carcasses (slaughter should always be carried out on an impervious surface).

▼B*2. Procedure for further cleaning and disinfection*

- (a) All manure, bedding, contaminated food, etc., should be removed from the buildings, stacked and sprayed with an approved disinfectant. Slurry should be treated by a method suitable for killing the virus.
- (b) All portable fittings should be removed from the premises and cleansed and disinfected separately.
- (c) Grease and other dirt should be removed from all surfaces by soaking with a degreasing agent and then washing with water under pressure.
- (d) A further application of disinfectant should then be made by spraying all surfaces.
- (e) Sealable rooms should be fumigated.
- (f) Repairs to damaged floors, walls etc. should be agreed following inspection by an official veterinarian, and carried out immediately.
- (g) Completed repairs should be inspected to ensure that they have been done satisfactorily.
- (h) All parts of the premises which are completely free of combustible material may be heat-treated using a flame gun.
- (i) All surfaces should be sprayed with an alkaline disinfectant having a pH greater than 12,5 or any other approved disinfectant. The disinfectant should be washed off after 48 hours.

3. Procedure for final cleaning and disinfection

Treatment with flame gun or alkaline disinfectant (point 2 (h) or (i)) should be repeated after 14 days.

11. Restocking of infected holdings

In addition to the measures laid down in Article 5 (4) of this Directive, the following measures shall apply:

1. Restocking should not commence until four weeks after completion of the first full disinfection of the premises, i.e. step 3 of the cleaning and disinfection procedures.
2. The re-introduction of pigs shall take account of the type of farming practised on the holding and must conform to one of the following procedures:
 - (a) in the case of outdoor pig holdings, restocking shall start with the introduction of a limited number of sentinel piglets which have been checked and found negative for the presence of antibodies against swine vesicular disease virus. The sentinel piglets shall be placed, in accordance with the requirements of the competent authority, throughout the infected holding and will be examined clinically 28 days after having been placed on the holding, and sampled for serological testing.

If none of the piglets shows clinical evidence of swine vesicular disease nor has developed antibodies against the virus of the disease, full restocking may take place;

▼B

- (b) for all other forms of rearing, the re-introduction of pigs shall take place either in accordance with the measures provided for in paragraph (a) or by full restocking, provided that:
- all the pigs arrive within a period of eight days and come from holdings situated outside areas restricted as a result of swine vesicular disease, and are seronegative,
 - no pig may leave the holding for a period of 60 days after the arrival of the last pigs,
 - the repopulated herd is subjected to a clinical and serological examination in accordance with the requirements of the competent authority. That examination may be carried out at the earliest 28 days after the arrival of the last pigs.
12. By 1 October 1997 at the latest, the Commission shall submit to the Council a report drawn up on the basis of an opinion from the Scientific Veterinary Committee on developments in research and diagnosis procedures as well as technical and scientific developments regarding swine vesicular disease, together with any appropriate proposals in the light of that report's findings. The Council shall act on such proposals by a qualified majority not later than six months after their submission.

▼B*ANNEX III***COMMUNITY REFERENCE LABORATORIES FOR THE DISEASES CONCERNED**

The functions and duties of the Community reference laboratories for the diseases concerned shall be:

1. to coordinate, in consultation with the Commission, the methods employed in the Member States for diagnosing the disease concerned, specifically by:
 - (a) typing, storing and supplying strains of the virus of the relevant disease for serological tests and the preparation of antisera;
 - (b) supplying standard sera and other reference reagents to the national reference laboratories in order to standardize the tests and reagents used in the Member States;
 - (c) building up and retaining a collection of virus strains and isolates of the relevant disease;
 - (d) organizing periodic comparative tests of diagnostic procedures at Community level;
 - (e) collecting and collating data and information on the methods of diagnosis used and the results of tests carried out in the Community;
 - (f) characterizing isolates of the virus of the relevant disease by the most up-to-date methods to allow greater understanding of the epizootiology of the disease;
 - (g) keeping abreast of developments in the surveillance, epizootiology and prevention of the relevant disease throughout the world;
 - (h) retaining expertise on the relevant disease virus and other pertinent viruses to enable rapid differential diagnosis;
 - (i) acquiring a thorough knowledge of the preparation and use of the products of veterinary immunology used to eradicate and control the relevant disease;
2. to assist actively in the diagnosis of outbreaks of the relevant disease in Member States by receiving virus isolates for confirmatory diagnosis, characterization and epizootiological studies;
3. to facilitate the training or retraining of experts in laboratory diagnosis with a view to the harmonization of diagnostic techniques throughout the Community.

*ANNEX IV***MINIMUM CRITERIA FOR THE CONTINGENCY PLANS**

Contingency plans shall meet at least the following criteria:

1. the establishment of a crisis centre on a national level, which shall coordinate all control measures in the Member State concerned;
2. a list shall be provided of local disease control centres with adequate facilities to coordinate the disease control measures at a local level;
3. detailed information shall be given on the staff involved in control measures, their skills and their responsibilities;
4. each local disease control centre must be able to contact rapidly persons/ organizations which are directly or indirectly involved in an outbreak;
5. equipment and materials shall be available to carry out the disease control measures properly;
6. detailed instructions shall be provided on action to be taken on suspicion and confirmation of infection or contamination, including means of disposal of carcasses;
7. training programmes shall be established to maintain and develop skills in field and administrative procedures;
8. diagnostic laboratories must have facilities for *post mortem* examination, the necessary capacity for serology, histology, etc., and must maintain the skills for rapid diagnosis. Arrangements must be made for rapid transportation of samples;
9. details shall be provided of the quantity of vaccine against the disease in question estimated to be required in the event of recourse to emergency vaccination;
10. provisions shall be made to ensure the legal powers necessary for the implementation of the contingency plans.