

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

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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.

^{F15} 5. Diagnostic laboratories

Textual Amendments

F1 Deleted by Council Directive 2008/73/EC of 15 July 2008 simplifying procedures of listing and publishing information in the veterinary and zootechnical fields and amending Directives 64/432/EEC, 77/504/EEC, 88/407/EEC, 88/661/EEC, 89/361/EEC, 89/556/EEC, 90/426/EEC, 90/427/EEC, 90/428/EEC, 90/429/EEC, 90/539/EEC, 91/68/EEC, 91/496/EEC, 92/35/EEC, 92/65/EEC, 92/66/EEC, 92/119/EEC, 94/28/EC, 2000/75/EC, Decision 2000/258/EC and Directives 2001/89/EC, 2002/60/EC and 2005/94/EC (Text with EEA relevance).

F26. Community reference laboratory

Textual Amendments

F2 Deleted by Commission Implementing Decision (EU) 2018/136 of 25 January 2018 designating the European Union reference laboratory for foot-and-mouth disease and amending Annex II to Council Directive 92/119/EEC as regards the European Union reference laboratory for swine vesicular disease (notified under document C(2018) 299) (Text with EEA relevance).

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,

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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:
- (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;
- (g) ^{F3}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;]

- (h) (i) [F⁴by 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⁽²⁾ or Commission Regulation (EC) No 2076/2005⁽³⁾;

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.]

Textual Amendments

- F3** Substituted by [Commission Directive 2007/10/EC of 21 February 2007 amending Annex II to Council Directive 92/119/EEC as regards the measures to be taken within a protection zone following an outbreak of swine vesicular disease \(Text with EEA relevance\)](#).
- F4** Inserted by [Commission Directive 2007/10/EC of 21 February 2007 amending Annex II to Council Directive 92/119/EEC as regards the measures to be taken within a protection zone following an outbreak of swine vesicular disease \(Text with EEA relevance\)](#).

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.

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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.
- [^{F45} 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*.]
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.

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

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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).

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) 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.

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- (1) [^{F3}OJ L 18, 23.1.2003, p. 11.;
- (2) [^{F4}OJ L 139, 30.4.2004, p. 55, corrected by OJ L 226, 25.6.2004, p. 22.]
- (3) [^{F4}OJ L 338, 22.12.2005, p. 83.]

Textual Amendments

- F3** Substituted by [Commission Directive 2007/10/EC](#) of 21 February 2007 amending Annex II to Council Directive 92/119/EEC as regards the measures to be taken within a protection zone following an outbreak of swine vesicular disease (Text with EEA relevance).
- F4** Inserted by [Commission Directive 2007/10/EC](#) of 21 February 2007 amending Annex II to Council Directive 92/119/EEC as regards the measures to be taken within a protection zone following an outbreak of swine vesicular disease (Text with EEA relevance).