L.N. 287 of 2008

VETERINARY SERVICES ACT
(CAP. 437)

CONTROL OF CERTAIN ANIMAL DISEASES (AND SPECIFICALLY THE SWINE VESICULAR DISEASE) RULES, 2008

IN the exercise of the powers conferred by article 5(1) of the Veterinary Services Act, the Minister for Resources and Rural Affairs has made the following rules:-

Title, scope and applicability.

1. (1) The title of these rules is Control of Certain Animal Diseases (and Specifically the Swine Vesicular Disease) Rules, 2008.

(2) The scope of these rules is to implement the rules found under European Union Council Directive 92/119/EEC introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease and to include the amendments made by Commission Directive 2007/10/EC as regards the measures to be taken within a protection zone following an outbreak of swine vesicular disease, repealing and replacing the Control of Certain Animal Diseases (and specifically the Swine Vesicular Disease) Rules, 2005. L.N. 366 of 2005.

(3) These rules define the general control measures to be applied in the event of an outbreak of one of the diseases listed in Schedule I.

Definitions.

2. For the purpose of these rules –

"animal" means 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;

"confirmation of infection" means the declaration by the competent authority of the presence of any of the diseases listed in Schedule I based on laboratory results and in the event of an epidemic, the competent authority may also confirm the presence of the disease on the basis of clinical or epidemiological results;

"holding" means any establishment (agricultural or other), situated in the territory of Malta, in which animals are kept or bred;

"incubation period" means 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 Schedule I for the disease in question;

"Member State" means a State which is a Member within the European Community;

"official veterinarian" means the veterinarian appointed by the competent authority;

"owner or keeper" means 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;

"the competent authority" means the Veterinary Services within the territory of Malta as provided under article 2 of the Veterinary Services Act;

"the Commission" means the European Commission within the Community;

"the Community" means the European Community as established under the Treaty establishing the European Community;

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

Notification to the competent authority in case of suspected presence of disease.

3. It is compulsory for the suspected presence in the territory of Malta of any of the diseases referred to in Schedule I to be notified immediately to the competent authority.

Official measures in the case of suspected infection or contamination.

4. (1) When animals on a holding are suspected of being infected or contaminated with one of the diseases listed in Schedule I, the official veterinarian shall immediately activate 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 and recorded 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; 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:

(i) of persons, animals of other species not susceptible to the disease and vehicles to or from the holding;

(ii) of meat or animal carcases, 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 rule 8.

(3) Until such time as the official measures laid down in sub-rule (2) are enforced, the owner or keeper of any animal in which disease is suspected shall take every appropriate measure to ensure compliance with sub-rule (2), except for paragraph (f) thereof.

(4) The competent authority may apply any of the measures provided for in sub-rule (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.

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

Measures in the case of confirmation of existence of diseases.

5. (1) Once it has been officially confirmed that one of the diseases listed in Schedule I is present on a holding, in addition to the measures laid down in rule 4(2), the competent authority shall require 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 paragraphs (a) and (b) hereof, 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 rule 16; and

(d) an epizootiological inquiry shall be carried out in accordance with rule 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 sub-rule (1)(a) and (b) hereof and shall 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 sub-rule (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 rule 16.

Animals living in the wild.

6. Where animals living in the wild are infected or suspected of being infected, appropriate action shall be taken by the competent authority which shall inform the Commission and the other Member States, of the measures it has taken.

Holdings consisting of two or more separate production units.

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 rule 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 sub-rule (1) hereof, the rules laid down in Article 18 (2) of European Union Council Directive 2003/85/EC on Community measures for the control of foot-and-mouth disease repealing European Union Council Directive 85/511/EEC and Commission Decisions 89/531/EEC and 91/665/EEC and amending European Union Council Directive 92/46/EEC shall *mutatis mutandis* apply:

Provided that these rules may be amended for the disease in question according to the European Community requirements in order to take account of the specific nature of the disease.

The epizootiological enquiry.

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, carcases, 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.

(3) The rules concerning national crisis units shall be laid down according to European Community requirements.

When other holdings are placed under official surveillance.

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 rule 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 rule 4, and such surveillance shall not be lifted until the suspected presence of disease on the holding has been officially ruled out.

(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 rule 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 rule 4, and such 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 sub-rule (2) hereof, the competent authority shall keep the provisions of rule 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 rule 8.

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

Protection zone.

10. (1) Once the diagnosis of one of the diseases in question has been officially confirmed, the competent authority shall establish 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:

Provided that 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 another Member State, the competent authority shall co-operate with the competent authorities of the Member States concerned in establishing the zones referred to in sub-rule (1). If necessary, the protection zone and the surveillance zone shall be established under the relevant procedure of the European Community.

(3) The decision to modify (in particular to reduce or increase, as appropriate) the boundaries of the zones laid down in sub-rule (1) or the duration of the restriction measures may be decided by the European Commission according to the relevant procedure of the European Community, taking into account:

(a) their geographical situation and ecological factors;

(b) the meteorological conditions;

(c) the presence, distribution and type of vectors;

(d) the results of the epizootiological studies carried out in accordance with rule 8;

(e) the results of laboratory tests;

(f) control measures actually applied.

Measures to be taken in the protection zone.

11. (1) The competent authority 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 those 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:

Provided that 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 rule 5 and cleaning and disinfection operations have been carried out in accordance with rule 16.

(3) Notwithstanding sub-rule (2), 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. In such cases, the competent authority shall forthwith inform the Commission and the other Member States of the measures they have taken. On expiry of the period referred to in this rule, the rules applied to the surveillance zone shall also apply to the protection zone.

Measures to be taken in surveillance zone.

12. (1) The competent authority 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:

Provided that the competent authority may grant a derogation from that prohibition for the transit of animals by road without unloading or stopping;

(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:

(i) remain inside the surveillance zone for a maximum incubation period after the most recent recorded case of disease;

(ii) thereafter, be removed from that zone to be transported under official supervision directly to a slaughterhouse designated by the competent authority for emergency slaughter;

(iii) be transported after being authorized by the competent authority and 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 official veterinarian 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 rule 5 and cleaning and disinfection operations have been carried out in accordance with rule 16.

(3) Notwithstanding sub-rule (2) hereof, 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. In such cases, the competent authority shall forthwith inform the Commission and the other Member States, of the measures they have taken.

Removal of animals from protection or surveillance zone.

13. (1) Where the prohibitions provided for in rule 11 (1)(d) and rule 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 gounds for such application,

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.

(2) All the necessary precautions shall 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.

Necessary measures to be taken by competent authority.

14. (1) The competent authority shall take all the necessary measures to keep at least persons established in the protection and surveillance zones informed of the restrictions in force and make all necessary arrangements for the appropriate implementation of those measures.

(2) Where, in a given region, the epizootic in question is exceptionally serious, all the additional measures to be taken in the territory of Malta shall be adopted according to the relevant procedure of the European Community.

Specific provisions.

15. By way of derogation from the general provisions laid down in these rules, specific provisions relating to the control and eradication measures for each respective disease are:

(a) for swine vesicular disease, set out in Schedule II for swine vesicular disease; and

(b) for each of the other diseases listed in Schedule I, adopted in accordance with the provisions adopted by the European Community in those matters.

Cleaning, disinfection and disinsectization operations.

16. The following procedure shall be observed –

(a) the disinfectants and insecticides to be used and, where appropriate, their concentrations, shall be officially approved by the competent authority;

(b) the cleaning, disinfection and disinsectization operations are carried out under official supervision –

(i) in accordance with the instructions given by the official veterinarian; and

(ii) 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 paragraph (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–

(a) for swine vesicular disease, those set out in Schedule II; and

(b) determined, in the context of preparation of the specific measures for each disease listed in Schedule I, in accordance with the requirements of the European Community.

National laboratories.

17. (1) For the purpose of implementation of these rules in the Territory of Malta, there shall be 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.

(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 territory of Malta. 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 territory of Malta;

(e) shall ensure the confirmation of positive results obtained in regional diagnostic laboratories.

(4) By way of derogation from sub-rule (1) hereof, the national laboratories competent as regards the disease in question, may provide the services of a diagnostic laboratory.

(5) The list of laboratories for swine vesicular disease is designated in Schedule II.

(6) The national laboratories designated for each of the diseases referred to shall cooperate with the respective Community reference laboratories.

(7) The detailed rules for implementing this Article shall be adopted in accordance with the requirements of the European Community and under the procedure laid down in article 5(1) of the Veterinary Services Act.

Vaccination.

18. (1) Vaccination against the diseases listed in Schedule 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 competent authority in cooperation with the Commission and under its approval;

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

(i) the concentration of animals of the species concerned in the affected zone;

(ii) the characteristics and composition of each vaccine used;

(iii) the procedures for supervision of the distribution, storage and use of vaccines;

(iv) the species and age of the animals which may or must be vaccinated;

(v) the areas in which vaccination may or must be carried out;

(vi) the duration of the vaccination campaign.

(2) In the cases referred to in sub-rule (1) hereof:

(a) the vaccination or re-vaccination of animals of susceptible species on the holdings referred to in rule 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 Community;

(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 relevant procedure of the Community.

(5) The competent authority shall inform the Commission, on a regular basis, of progress as regards the vaccination measures.

(6) By way of derogation from sub-rule (1), the decision to introduce emergency vaccination may be taken by the competent authority, 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 relevant procedure of the Community and it may be decided to retain, modify or extend the measures or to bring them to an end.

Contingency plan.

19. (1) The competent authority shall draw up a contingency plan applicable to all the diseases listed in Schedule 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 Schedule III, with points 6 to 9 representing criteria to be adopted according to the disease concerned:

Provided that the competent authority may confine itself 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 Schedule III shall be submitted to the Commission:

(4) The contingency plans shall be –

(a) examined by the Commission in order to determine whether they permit the desired objective to be attained and shall suggest to the competent authority any amendments required in particular to ensure that they are compatible with those of the other Member States;

(b) approved by the Commission, if necessary amended, in accordance with the relevant procedure of the Community;

(c) 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.

Particular and specific Control measures for each disease listed in Schedule I.

20. (1) 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 Schedule I to these rules.

(2) Malta 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.

(3) Following the information procedure referred to in sub-rule 2 and rule 19, these shall apply mutatis mutandis.

Necessary measures to ensure uniform application of these rules.

21. (1) Commission experts may, in collaboration with the competent authorities, and in so far as is necessary to ensure uniform application of these rules, 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 these rules. The Commission shall inform the competent authority of the result of the checks carried out.

(2) Whenever a check is being carried out in Malta the competent authority shall give all the necessary assistance to the experts in carrying out their duties.

(3) The detailed rules for implementing this Article shall be determined in accordance with the procedure laid down in rule 22.

Provisions to apply whenever reference to this rule is being made.

22. (1) Whenever reference is being made to this rule, Articles 5 and 7 of European Union Decision 1999/468/EC shall apply.

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

SCHEDULE 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
African swine fever	40 days
Lumpy skin disease	28 days
Rift valley fever	30 days

SCHEDULE II

SPECIFIC MEASURES TO CONTROL CERTAIN DISEASES

In addition to the general provisions laid down in these rules, 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 these rules, 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 relevant procedure of the Community.

4. Confirmation of the presence of swine vesicular disease

By way of derogation from rule 2(6), 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.

5. **Diagnostic laboratories**

Austria: Institut für Fischkunde, Veterinärmedizinische Universität, Wien.
Belgium: Institut national de recherches vétérinaires, Groeselenberg 99, B-1180 Bruxelles.
Denmark: Statens Veterinære Institut for Virusforskning, Lindholm.

Finland: Eläinlääkintä- ja elintarvikelaitos, Helsinki —Anstalten för veterinärmedicin och livsmedel, Helsingfors.

Germany: Bundesforschungsanstalt für Viruskrankheiten der Tiere, Paul-Ehrlich-Straße, 7400 Tübingen.

France: Laboratoire central de recherche vétérinaire, Maisons-Alfort.

Greece: Ινστιτούτο Λοιμωδών και Παρασιτικών Νοσημάτων, Νεαπόλεως *21*, Αγία Παρασκευή·

Ireland: Institute for Animal Health, Pirbright, Woking, Surrey.

Italy: Istituto zooprofilattico sperimentale della Lombardia e dell'Emilia Romagna, Brescia.

Luxembourg: Institut national de recherches vétérinaires, Groeselenberg 99, B-1180 Bruxelles.

Netherlands: Centraal Diergeneeskundig Institut, Lelystad.

Portugal: Laboratório Nacional de Investigação Veterinária, Lisboa.

Spain: Laboratorio de Alta Seguridad Biológica (INIA), 28130 Madrid.

Sweden: Statens veterinärmedicinska anstalt, Uppsala.

United Kingdom: Institute for Animal Health, Pirbright, Woking, Surrey.

Czech Republic: Státní veterinární ústav Praha, Sídlištní 24/136,165 03 Praha 6.

Estonia: Veterinaar - ja Toidulaboratoorium, Kreutzwaldi 30, 51006 Tartu.

Cyprus: Istituto Zooprofilattico Sperimentale della Lombardia e dell' Emilia Romagna, Via Bianchi 9, IT - 25124 Brescia.

Latvia: Valsts veterinarmedicinas diagnostikas centrs, Lejupes iela 3, LV-1076 Riga.

Lithuania: Nacionaline veterinarijos laboratorija, J. Kairiukšèio g. 10, LT-2021 Vilnius.

Hungary: Országos Állategészségügyi Intézet (OÁI), Pf. 2., Tábornok u. 2., HU-1581 Budapest.

Malta: Institute for Animal Health, Pirbright Laboratory, Ash Road, Pirbright, Woking, Surrey GU24 ONF, United Kingdom.

Poland: Laboratorium Zak³adu Pryszczycy Pañstwowego Instytutu Weterynaryjnego, ul. Wodna 7, PL-98- 220 Zduñska Wola.

Slovenia: Institute for Animal Health, Pirbright Laboratory, Ash Road, Pirbright, Woking, Surrey GU24 ONF, United Kingdom.

Slovakia: Institute for Animal Health, Pirbright Laboratory, Ash Road, Pirbright, Woking, Surrey GU24 ONF, United Kingdom.

6. **Community reference laboratory**

AFRC Institute for Animal Health,Pirbright Laboratory, Ash Road, Pirbright, Woking, Surrey GU24 ONF, United Kingdom.

7. **Protection zone**

1. The size of the protection zone shall be as defined in rule 10.

2. In the case of swine vesicular disease, by way of derogation, the measures in rule 11 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 requirements of the Community, 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:

(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) fresh 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;

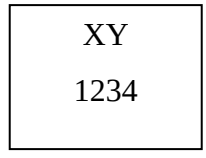
(ii) shall be obtained, cut, transported and stored separately from meat intended for intra-Community and international trade and shall be used in such a way as to avoid it being introduced into meat products intended for intra-Community or international trade, unless it has undergone a treatment set out in Annex III to Directive 2002/99/EC.

(h) (i) by way of derogation from point (g), for meat from pigs referred to in point (f) (i) Member States may decide to use another 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 the Council or Commission Regulation (EC) No 2076/2005;

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.

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

(a) all measures laid down in rule 16 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 that fixed by the Community.

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.

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.*

8. **Surveillance zone**

1. The size of the surveillance zone shall be as laid down in rule 10.

2. In the case of swine vesicular disease, the measures laid down in rule 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:

(i) an inspection of all pigs on the holding has been carried out with the 48 hours preceding the movement,

(ii) a clinical examination of the pigs to be moved has been carried out with negative results in the 48 hours preceding the movement,

(iii) 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,

(iv) each pig has been marked with an individual eartag or by any other approved method of identification,

(v) 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 rule 10 (3).

(b) The measures in the surveillance zone shall be applied at least until:

(i) all the measures laid down in rule 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 rules 4 (2) and 5, 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, pigs on the holding shall remain under the movement restrictions referred to in rule 9 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 carcases 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 rule 8;

(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 rule 16, the following measures shall also apply-

1. Procedure for preliminary cleaning and disinfection -

(a) As soon as the carcases 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 rule 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 carcases (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 rule 5(4), 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:

(i) 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,

(ii) no pig may leave the holding for a period of 60 days after the arrival of the last pigs,

(iii) 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.

SCHEDULE 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.

SCHEDULE 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 territory of Malta;

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 carcases;

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.

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