L.N. 510 of 2004

VETERINARY SERVICES ACT

(CAP. 437)

Foot-and-Mouth Disease (Control Measures) Rules, 2004

IN exercise of the powers conferred by article 5(2) of the Veterinary Services Act, the Minister for Rural Affairs and the Environment has made the following regulations:-

CHAPTER I

General provisions

Title, scope and applicability

1. (1) The title of these regulations is the Foot-and-Mouth Disease (Control Measures) Rules, 2004.

(2) The scope of these regulations is to implement the rules found under European Union Council Directive 2003/85/EC regarding measures for the control of foot-and-mouth disease to be taken in the territory of Malta.

(3) These rules set out:

(a) the minimum control measures to be applied in the event of an outbreak of foot-and-mouth disease, of whatever type of virus;

(b) certain preventative measures aimed at increasing awareness and preparedness of the competent authorities and the farming community for foot-and-mouth disease;

Provided that these rules amend the provisions found under L.N. 130/2004 entitled 'Health Rules for the Production and Placing on the market of Raw Milk, Heat-Treated Milk and Milk-Based Products Regulations, 2004'.

(4) The competent authority shall remain free to take more stringent action in the field covered by these rules.

Definitions

2. For the purposes of these rules -

'animal of a susceptible species' means any domestic or wild animal of the suborders *Ruminantia*, *Suina*, and *Tylopoda* of the order *Artiodactyla*. For specific measures, notably in application of regulation 16(4), regulation 15 and regulation 75(2), other animals, such as for example of the order *Rodentia* or *Proboscidae*, may be considered susceptible to foot-and-mouth disease in accordance with scientific evidence;

'animal suspected of being contaminated' means any animal of a susceptible species which, according to the epidemiological information collected, may have been directly or indirectly exposed to the foot-and-mouth disease virus;

'animal suspected of being infected' means any animal of a susceptible species exhibiting clinical symptoms or showing post-mortem lesions or reactions to laboratory tests which are such that the presence of foot-and-mouth disease may reasonably be suspected;

'authorisation' means a written authorisation given by the competent authorities, of which the necessary copies must be available for subsequent inspections in accordance with the appropriate legislation in Malta;

'case of foot-and-mouth disease' or 'animal infected with foot-and-mouth disease' means any animal of a susceptible species or carcass of such animal in which foot-and-mouth disease has been officially confirmed, taking into account the definitions in Schedule I, either on clinical symptoms or post-mortem lesions consistent with foot-and-mouth disease have been officially confirmed, or as the result of a laboratory examination carried out in accordance with Schedule XIII;

'Community antigen and vaccine bank' means appropriate premises designated in accordance with these regulations for the storage of Community reserves of both concentrated inactivated antigen of the foot-and-mouth disease virus for the production of foot-and-mouth disease vaccines and veterinary immunological products (vaccines) reconstituted from such antigens and authorised in accordance with European Council Directive 2001/82/EC relating to veterinary medicinal products;

'the competent authority' means the Veterinary Services within Malta as provided under article 2 of the Veterinary Services Act, or any other authority to which such responsibility has been delegated by the Veterinary Services;

'emergency slaughter' means the slaughter in emergency cases within the meaning of Article 2(7) of European Council Directive 93/119/EEC of animals which on the basis of epidemiological data or clinical diagnosis or results of laboratory testing are not considered infected or contaminated with the foot-and-mouth disease virus, including slaughter for reasons of animal welfare;

'emergency vaccination' means vaccination in accordance with rule 48(1);

'herd' means an animal or group of animals kept on a holding as an epidemiological unit; if more than one herd is kept on a holding, each of these herds shall form a distinct unit and shall have the same health status;

'holding' means any agricultural or other premises, including circuses, located in Malta where animals of susceptible species are being bred or kept on a permanent or temporary basis. However, for the purpose of rule 10(l) this definition does not include living areas for humans on such premises, unless animals of susceptible species, including those referred to in rule 75(2), are kept on a permanent or temporary basis therein, slaughterhouses, means of transport, border inspection posts or fenced areas where animals of susceptible species are kept and may be hunted, if such fenced areas are of a size which makes the measures provided for in rule 10 inapplicable;

'incubation period' means the length of the time between infection and the occurrence of clinical signs of foot-and mouth disease. Namely, for the purposes of these rules, 14 days for bovine and porcine animals, and 21 days for ovine and caprine animals and any other animal of susceptible species;

'killing' means any process which causes the death of an animal;

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

'official veterinarian' means the veterinarian designated by the competent authority of Malta;

'outbreak of foot-and-mouth disease' means a holding where animals of susceptible species are kept, which meets one or more of the criteria set out in Schedule I;

'owner' means any person or persons, either natural or legal, having ownership of an animal of a susceptible species, or charged with keeping such animals, whether or not for financial reward;

'primary case of foot-and-mouth disease in wild animals' means any case of foot-and-mouth disease which is detected in a wild animal in an area in which no measures are in place in accordance with regulation 75(3) or (4);

'primary outbreak' means an outbreak not epizootiologically linked with a previous outbreak in the same region of Malta as defined in Article 2 of European Council Directive 64/432/EEC or the first outbreak in a different region of Malta;

'processing' means one of the treatments for high risk material laid down in European Council Regulation (EC) No 1774/2002, and any implementing legislation thereof, applied in such a way as to avoid the risk of spread of foot-and-mouth disease virus;

'protective vaccination' means emergency vaccination carried out on holdings in a designated area in order to protect animals of susceptible species within this area against airborne spread or spread through fomites of foot-and-mouth disease virus and where the animals are intended to be kept alive following vaccination;

'region' means that part of the territory of Malta which is at least 2,000 square kilometres in area and which is subject to inspection by the competent authority;

'regionalisation' means the delimitation of a restricted zone in which restrictions are applied on the movements of or trade in certain animals or animal products as provided for in regulation 43 in order to prevent the spread of foot-and-mouth

disease into the free zone where no restrictions are applied in accordance with these rules;

'sub-region' means an area specified in the Annex to European Council Decision 2000/807/EC;

'suppressive vaccination' means emergency vaccination which is carried out exclusively in conjunction with a stamping-out policy in a holding or area where there is an urgent need to reduce the amount of foot-and-mouth disease virus circulating and to reduce the risk of it spreading beyond the perimeters of the holding or the area and where the animals are intended to be destroyed following vaccination;

'wild animal' means an animal of a susceptible species living outside any holding or premises referred to in rules 15 and 16.

CHAPTER II

Control of outbreaks of foot-and-mouth disease

Foot-and-mouth disease notification

3. (1) In Malta:

(a) foot-and-mouth disease is listed by the competent authority as a compulsorily notifiable disease;

(b) the owner and any person attending animals, accompanying animals during transport or looking after animals shall be obliged to notify without delay to the competent authority or the official veterinarian the presence or suspected

presence of foot-and-mouth disease and keep animals infected with foot-and-mouth disease or animals suspected of being infected, away from places where other animals of susceptible species are at risk of being infected or contaminated with the foot-and-mouth disease virus;

(c) veterinary practitioners, official veterinarians, senior staff of veterinary or other official or private laboratories and any person with a occupational relation to animals of susceptible species or products derived from such animals shall be obliged to notify without delay to the competent authority any knowledge of the presence or suspected presence of foot-and-mouth disease they have obtained prior to official intervention within the framework of these rules.

(2) Without prejudice to existing European Community legislation on notification of outbreaks of animal disease, in case of an outbreak of foot-and-mouth disease or a primary case of foot-and-mouth disease in wild animals is confirmed, the competent authority shall give notification of the disease and provide information and written reports to the European Commission and the other Member States in accordance with Schedule II.

Measures in case of suspicion of an outbreak of foot-and-mouth disease

4. (1) The competent authority shall ensure that the measures provided for in sub-rules (2) and (3) hereof are carried out where a holding contains one or more animals suspected of being infected or contaminated.

(2) The competent authority shall immediately activate official investigation arrangements under its supervision to confirm or rule out the presence of the foot-and-mouth disease and, in particular, have the necessary samples taken for the laboratory

examinations required to confirm an outbreak in accordance with the definition of outbreak in Schedule I.

(3) The competent authority shall place the holding referred to in sub-regulation (1) under official surveillance as soon as the suspected infection is notified and shall in particular ensure that:

(a) a census is made of all categories of animals on the holding and that, in respect of each category of animals of susceptible species, the number of animals that are already dead and the animals suspected of being infected or of being contaminated, is recorded;

(b) the census as referred to in paragraph (a) is kept up to date to take account of those animals of susceptible species born or dying during the period of suspicion. Such information is produced by the owner on request of the competent authority and is checked by that authority at each visit;

(c) all stocks of milk, milk products, meat, meat products, carcasses, hides and skins, wool, semen, embryos, ova, slurry, manure as well as animal feed and litter on the holding are recorded and those records are maintained;

(d) no animals of susceptible species enter or leave the holding, except in cases of holdings consisting of different epidemiological production units referred to in rule 17, and that all animals of susceptible species on the holding are kept in their living quarters or another place where they can be isolated;

(e) appropriate means of disinfection are used at the entrances and exits of buildings or places housing animals of susceptible species and of the holding itself;

(f) an epidemiological inquiry is carried out in accordance with rule 13;

(g) to facilitate the epidemiological inquiry, the necessary samples shall be taken for laboratory testing in accordance with point 2.1.1.1 of Schedule III.

Movements onto and off a holding in case of suspicion of an outbreak of foot-and-mouth disease

5. (1) The competent authority shall ensure that in addition to the measures provided for in rule 4, all movement onto and off a holding where there is a suspicion of an outbreak of foot-and-mouth disease is prohibited. That prohibition shall apply in particular to:

(a) movement from the holding of meat or carcasses, meat products, milk or milk products, semen, ova or embryos of animals of susceptible species or of animal feed, utensils, objects or other substance, such as wool, hides and skins, bristles or animal waste, slurry, manure or anything liable to transmit foot-and-mouth disease virus;

(b) movement of animals of species not susceptible to foot-and-mouth disease;

(c) movement of persons onto or out of the holding;

(d) movement of vehicles onto or out of the holding.

(2) By way of derogation from the prohibition in paragraph (a) of sub-rule (1) hereof, the competent authority may in the event of difficulties in storing the milk on the holding either order that the milk shall be destroyed on the holding, or authorise the milk to be transported under veterinary supervision and only by means of transport suitably equipped to ensure no risk of spreading foot-and-mouth disease virus from the holding to

the nearest possible place for disposal or treatment ensuring destruction of the foot-and-mouth disease virus.

(3) By way of derogation from the prohibitions provided for in paragraphs (b), (c) and (d) of sub-rule (1), the competent authority may authorise such movements onto and off the holding subject to all conditions necessary in order to avoid the spread of foot-and-mouth disease virus.

Extension of measures to other holdings

6. (1) The competent authority shall extend the measures provided for in rules 4 and 5 to other holdings where their location, their construction and layout, or contacts with animals from the holding referred to in rule 4, give reason to suspect contamination.

(2) The competent authority shall apply at least the measures provided for in rules 4 and 5(1) to premises or means of transport referred to in rule 16 should the presence of animals of susceptible species give reason to suspect infection or contamination with the foot-and-mouth disease virus.

Temporary control zone

7. (1) The competent authority may establish a temporary control zone, where required by the epidemiological-situation, and in particular when that situation involves a high density of animals of susceptible species, intensive movement of animals or persons in contact with animals of susceptible species, delays in suspect status notifications, or insufficient information on the possible origin and ways of introduction of the foot-and-mouth disease virus.

(2) At least the measures provided for in rules 4(2) and (3)(a), (b) and (d) and in rule 5(1) shall be applied to holdings in the temporary control zone where animals of susceptible species are kept.

(3) The measures applied in the temporary control zone may be supplemented by a temporary ban on movements of all animals in a larger area or on the whole of the territory of Malta. However, the ban on movement of animals of species not susceptible to foot-and-mouth disease shall not exceed 72 hours, unless justified by exceptional circumstances.

Preventive eradication programme

8. (1) The competent authority may, where epidemiological information or other evidence indicates, implement a preventive eradication programme, including preventive killing of animals of susceptible species likely to be contaminated and, if necessary, of animals from epidemiologically-linked production units or adjoining holdings.

(2) In that event, the taking of samples and clinical examinations of animals of susceptible species shall be carried out at least in accordance with point 2.1.1.1 of Schedule III.

(3) The competent authority shall notify the European Commission prior to the implementation of the measures provided for in this rule.

Maintenance of measures

9. The competent authority shall not withdraw the measures provided for in rules 4 to 7 until the suspicion of foot-and-mouth disease has been officially ruled out.

Measures in case of confirmation of an outbreak of foot-and-mouth disease

10. (1) As soon as an outbreak of foot-and-mouth disease is confirmed, the competent authority shall ensure that, in addition to the measures provided for in rules 4 to 6 the following measures are also applied without delay on the holding:-

(a) All animals of susceptible species shall be killed on-the-spot. In exceptional circumstances the animals of susceptible species may be killed at the nearest suitable place for that purpose under official supervision and in such a way as to avoid the risk of spreading foot-and-mouth disease virus during transport and killing. The competent authority shall notify the European Commission about the existence of such exceptional circumstances, and the action taken.

(b) The official veterinarian shall ensure that before or during the killing of the animals of susceptible species all appropriate samples needed for the epidemiological inquiry referred to in rule 13 have been taken in accordance with point 2.1.1.1 of Schedule III, and in sufficient numbers. The competent authority may decide that rule 4(2) shall not apply in cases of appearance of a secondary source which is epidemiologically linked with a primary source for which samples have already been taken in accordance to that rule, provided that appropriate and sufficient numbers of samples needed for the epidemiological inquiry referred to in rule 13 have been taken.

(c) The carcasses of animals of susceptible species which have died on the holding and the carcasses of animals which have been killed in accordance with paragraph (a) shall be processed without undue delay under official supervision in such a way that there is no risk of spreading foot-and-mouth disease virus. Where particular circumstances require the carcasses to be buried or burned, on site or off site, such operations shall be carried out in

conformity with the instructions prepared in advance in the framework of the contingency plans referred to in rule 67.

(d) All products and substances referred to in rule 4(3)(c) shall be isolated until contamination can be ruled out, or treated in accordance with the instructions of the official veterinarian in such a way as to ensure the destruction of any foot-and-mouth disease virus, or processed.

(2) After the killing and processing of the animals of susceptible species and the completion of the measures provided for in sub-rule 1(d), the competent authority shall ensure that:

(a) the buildings used for housing animals of susceptible species, their surroundings and the vehicles used for their transportation, as well as all other buildings and equipment likely to be contaminated shall be cleaned and disinfected in accordance with rule 11;

(b) in addition, where there is a reasonable suspicion that the living area for humans or the office area of the holding are contaminated with the foot-and-mouth disease virus, these areas shall also be disinfected by appropriate means;

(c) restocking of animals is carried out in accordance with Schedule V.

Cleansing and disinfection

11. (1) The competent authority shall ensure that cleansing and disinfection operations, as integral parts of the measures provided for in these rules, are adequately documented and are carried out under official supervision and in accordance with the instructions given by the official veterinarian, using disinfectants and working

concentrations of such disinfectants officially authorised and registered for placing on the market by the competent authority as veterinary hygiene biocidal products in accordance with European Union Directive 98/8/EC, in order to ensure destruction of the foot-and-mouth disease virus.

(2) The competent authority shall ensure that cleansing and disinfection operations, which shall include appropriate pest control, are carried out in a way to reduce as much as possible any adverse environmental impact that may arise from such operations.

(3) The competent authority shall endeavour to ensure that any disinfectants used, in addition to being able to disinfect effectively, also have the lowest possible adverse impacts on the environment and public health in accordance with best available technology.

(4) The competent authority shall ensure that cleansing and disinfection operations are carried out in accordance with Schedule IV.

Tracing and treatment of products and substances in contact with animals of an outbreak

12. The competent authority shall ensure that the products and substances referred to in rule 4(3)(c) of animals of susceptible species collected from a holding where an outbreak of foot-and-mouth disease has been confirmed and semen, ova and embryos collected from animals of susceptible species present on that holding, during the period between the probable introduction of the disease to the holding and the implementation of official measures, shall be traced and processed or, in the case of substances other than semen, ova and embryos, be treated under official supervision and in such a way as to ensure destruction of foot-and-mouth disease virus and to avoid any risk of it spreading further.

Epidemiological inquiry

13. (1) The competent authority shall ensure that epidemiological inquiries in relation to outbreaks of foot-and-mouth disease are carried out by specifically trained veterinarians on the basis of questionnaires, prepared within the framework of the contingency plans provided for in rule 67, to ensure standardised, speedy and targeted inquiries. Such inquiries shall deal at least with:

(a) the length of time during which the foot-and-mouth disease may have been present on a holding before being suspected or notified;

(b) the possible origin of the foot-and-mouth disease virus on a holding and the identification of other holdings where there are animals suspected of being infected or animals suspected of being contaminated from the same source;

(c) the possible extent to which animals of susceptible species other than bovine and porcine animals may have been infected or contaminated;

(d) the movement of animals, persons, vehicles and the substances referred to in rule 4(3)(c) likely to have carried the foot-and-mouth disease virus to or from the holdings in question.

(2) The competent authority shall inform and regularly update the European Commission and the other Member States about the epidemiology and spread of the foot-and-mouth disease virus.

Additional measures in case of confirmation of outbreaks of foot-and-mouth disease

14. (1) The competent authority may order that, besides the animals of susceptible species, animals of species not susceptible to foot-and-mouth disease on the holding

where an outbreak of foot-and-mouth disease has been confirmed shall also be killed and processed of in such a way as to avoid any risk of spreading the foot-and-mouth disease virus.

Provided that the provisions of this sub-rule do not apply to animals of species not susceptible to foot-and-mouth disease which may be isolated, effectively cleansed and disinfected, and provided that they are individually identified, in the case of equidae in accordance with European Community legislation, so as to allow the control of their movement.

(2) The competent authority may apply the measures provided for in rule 10(1)(a) on epidemiologically-linked production units or adjoining holdings, where epidemiological information or other evidence give reason to suspect a possible contamination of those holdings. The intention to make use of those provisions shall be notified to the European Commission, where possible, prior to implementation. In this event, the measures regarding taking of samples and clinical examinations of animals shall be carried out at least as set out in point 2.1.1.1 of Schedule III.

(3) The competent authority shall, immediately upon confirmation of the first outbreak of foot-and-mouth disease, prepare all arrangements necessary for emergency vaccination in an area of at least the size of the surveillance zone established in accordance with rule 19.

(4) The competent authority may apply the measures provided for in rules 7 and 8.

Measures to be in the vicinity or within certain specific premises

15. (1) Where an outbreak of foot-and-mouth disease threatens to infect animals of susceptible species in a laboratory, zoo, wildlife park, and fenced area or in bodies, institutes or centres approved in accordance with Article 13(2) of European Directive

92/65/EEC and where animals are kept for scientific purposes or purposes related to conservation of species or farm animal genetic resources, the competent authority shall ensure that all appropriate bio-security measures are taken to protect such animals from infection. Those measures may include restricting access to public institutions or making such access subject to special conditions.

(2) Where an outbreak of foot-and-mouth disease is confirmed in one of the premises referred to in sub-rule (1), the competent authority may decide to derogate from rule 10(1)(a), provided that basic European Community interests, and in particular the animal health status of other Member States, are not endangered and that all necessary measures are in place to prevent any risk of spreading foot-and-mouth disease virus.

(3) The decision referred to in sub-rule (2) shall immediately be notified to the European Commission. In the case of farm animal genetic resources, this notification shall include a reference to the list of premises established in accordance with rule 72(2)(f), by which the competent authority has identified these premises in advance as breeding nucleus of animals of susceptible species indispensable for the survival of a breed.

Measures to be applied in slaughterhouses, border inspection posts and means of transportation

16. (1) Where a case of foot-and-mouth disease is confirmed in a slaughterhouse, a border inspection post established in accordance with European Union Council Directive 91/496/EEC or in a means of transport, the competent authority shall ensure that the following measures are carried out in relation to the affected premises or means of transport:

(a) all animals of susceptible species in such premises or means of transport shall be killed without delay;

(b) the carcasses of the animals referred to in paragraph (a) shall be processed under official supervision in such a way as to avoid the risk of foot-and-mouth disease virus spreading;

(c) other animal waste, including offal, of infected or suspected of being infected and contaminated animals shall be processed under official supervision in such a way as to avoid the risk of foot-and-mouth disease virus spreading;

(d) dung, manure and slurry shall be subject to disinfection and shall only be removed for treatment in accordance with point 5 of Section II in Part A of Chapter III of Annex VIII to European Regulation No 1774/2002;

(e) cleansing and disinfection of buildings and equipment, including vehicles or means of transport, shall take place under the supervision of the official veterinarian in accordance with rule 11 and with the instructions laid down by the competent authority;

(f) an epidemiological inquiry shall be carried out in accordance with rule 13.

(2) The competent authority shall ensure that the measures provided for in rule 18 are applied in contact holdings.

(3) The competent authority shall ensure that no animals are reintroduced for slaughter, inspection or transport in the premises or means of transport referred to in sub-rule (1) until at least 24 hours after completion of the cleansing and disinfection operations referred to in sub-rule (1)(e).

(4) Where required by the epidemiological situation, in particular where contamination of animals of susceptible species in holdings adjacent to the premises or means of transport referred to in sub-rule (1) must be suspected, the competent authority shall ensure that by way of derogation from the definition of a 'holding' in rule 2, second sentence, an outbreak is declared on the premises or means of transport referred to in sub-regulation (1), and the measures provided for in rules 10 and 19 are applied.

Holdings consisting of different epidemiological production units

17. (1) In the case of holdings which consist of two or more separate production units, the competent authority may, in exceptional cases and after considering the risks, derogate from rule 10(1)(a) as regards production units of such holdings not affected by foot-and-mouth disease.

(2) The derogation provided for in sub-rule (1) shall only be granted after the official veterinarian has confirmed at the time of the official investigation referred to in rule 4(2), that the following conditions to prevent the spread of foot-and-mouth disease virus between the production units referred to in sub-rule (1), have been in place for at least two incubation periods prior to the date the outbreak of foot-and-mouth disease was identified on the holding:

(a) the structure, including the administration, and size of the premises allow a complete separation of housing and keeping for the distinct herds of animals of susceptible species, including separate air space;

(b) the operations on the different production units, and in particular stable and pasture management, feeding, removal of dung or manure are completely separated and carried out by different personnel;

(c) the machinery, working animals of species not susceptible to foot-and-mouth disease, equipment, installations, instruments and disinfection facilities used in the production units are completely separate.

(3) In relation to milk, a derogation from rule 10(1)(d) may be granted to a holding producing milk provided that:

(a) such holding complies with the conditions set out in sub-rule (2), and

(b) milking in each unit is carried out separately, and

(c) depending on the intended use, the milk is subject to at least one of the treatments described in Part A or Part B of Schedule IX.

(4) Where a derogation is granted in accordance with sub-rule (1), the competent authority shall lay down in advance detailed rules for applying such derogation. The competent authority shall notify the European Commission of the derogation and provide details of the measures taken.

Contact holdings

18. (1) Holdings shall be recognised as contact holdings where the official veterinarian finds, or considers on the basis of confirmed data, that the foot-and-mouth disease virus may have been introduced as a result of the movement of persons, animals, products of animal origin, vehicles or in any other way either from other holdings onto a holding referred to in rules 4(1) or 10(1) or from a holding referred to in rules 4(1) or 10(1) to other holdings.

(2) Contact holdings shall be subject to the measures provided for in rules 4(3) and 5 and these measures shall be maintained until the suspected presence of foot-and-

mouth disease virus on these contact holdings has been officially ruled out in accordance with the definition in Schedule I and the survey requirements provided for in point 2.1.1.1 of Schedule III.

(3) The competent authority shall prohibit the removal of all animals from contact holdings during a period corresponding to the incubation period specified for the species which has to undergo an 'emergency slaughter' in terms of the definition in rule 2 hereof. However, the competent authority may, by way of derogation from regulation 4(3)(d), authorise the transport of animals of susceptible species under official supervision directly to the closest possible designated slaughterhouse for emergency slaughter. Prior to granting such derogation, the official veterinarian shall at least carry out the clinical examinations provided for in point 1 of Schedule III.

(4) Where the competent authority considers that the epidemiological situation permits, it may limit the recognition as a contact holding provided for in sub-rule 1, to one identified epidemiological production unit of the holding and to the animals contained therein, provided that the epidemiological production unit complies with rule 17.

(5) Where an epidemiological link between an outbreak of foot-and-mouth disease and premises or means of transportation referred to in rules 15 and 16 respectively cannot be excluded, the competent authority shall ensure that the measures provided for in rule 4(2) and (3) and in regulation 5 shall apply to such premises or means of transportation. The competent authority may decide to apply the measures provided for in rule 8.

Establishment of protection and surveillance zones

19. (1) The competent authority shall ensure that, without prejudice to measures provided for in rule 7, at least the measures laid down in sub- rules (2), (3) and (4) below are taken immediately after an outbreak of foot-and-mouth disease is confirmed.

(2) The competent authority shall establish a protection zone based on a minimum radius of 3 kilometres and a surveillance zone based on a minimum radius of 10 kilometres centred on the outbreak of foot-and-mouth disease referred to in sub-rule (1). The geographical delimitation of those zones shall take account of administrative boundaries, natural barriers, supervision facilities and technological progress which makes it possible to predict the probable dispersion of the foot-and-mouth disease virus by air or any other means. That delimitation shall be reviewed, if necessary, in the light of such elements.

(3) The competent authority shall ensure that the protection and surveillance zones are marked by posting signs of sufficient size on roads entering the zones.

(4) In order to ensure full coordination of all measures necessary to eradicate foot-and-mouth disease as quickly as possible, national and local disease control centres as referred to in rules 69 and 71 shall be established. For the purpose of carrying out the epidemiological inquiry as provided for in rule 13, those centres shall be assisted by an expert group as provided for in rule 73.

(5) The competent authority shall without delay trace animals dispatched from the zones during the period of at least 21 days before the estimated date of earliest infection on a holding in the protection zone and they shall inform the competent authorities in other Member States and the European Commission about their results from tracing of animals.

(6) The competent authority shall collaborate in tracing fresh meat, meat products, raw milk and raw milk products derived from animals of susceptible species originating in the protection zone and produced between the date of estimated introduction of the foot-and-mouth disease virus until the date the measures provided for in sub-rule (2) come into force. Such fresh meat, meat products, raw milk and raw milk products shall be

treated in accordance with rules 23, 24 and 25 respectively or detained until possible contamination with the foot-and-mouth disease virus is officially ruled out.

Measures to be applied to holdings in the protection zone

20. (1) The competent authority shall ensure that at least the following measures are applied in the protection zone without delay:

(a) the registration of all holdings with animals of susceptible species and the establishment of a census of all animals present on these holdings shall be carried out as soon as possible and kept up to date;

(b) all holdings with animals of susceptible species shall periodically undergo a veterinary inspection, carried out in such a way as to avoid the spread of foot-and-mouth disease virus possibly present on the holdings, which shall include in particular the relevant documentation, notably the records referred to in paragraph (a) and the measures applied to prevent the introduction or escape of foot-and-mouth disease virus and which may include clinical inspection as described in point 1 of Schedule III or taking of samples from animals of susceptible species in accordance with point 2.1.1.1 of Schedule III;

(c) animals of susceptible species shall not be removed from the holding on which they are kept.

(2) By way of derogation from sub-rule (1)(c), animals of susceptible species may be transported, under official supervision for the purpose of emergency slaughter, directly to a slaughterhouse situated inside the same protection zone or, if that zone has no slaughterhouse to a slaughterhouse outside the zone designated by the competent

authority in means of transport cleansed and disinfected under official control after each transport operation.

(3) The movement referred to in the sub-rule (1) shall only be authorised if the competent authority is satisfied, on the basis of a clinical examination in accordance with point 1 of Schedule III by the official veterinarian of all the animals of susceptible species present on the holding and after evaluation of epidemiological circumstances, that there is no reason to suspect the presence of infected or contaminated animals on the holding. The meat of such animals shall be subject to the measures provided for in rule 23.

Movement and transport of animals and their products in the protection zone

21. The competent authority shall ensure that the following activities are prohibited within the protection zone:

(a) movement between holdings and transport of animals of susceptible species;

(b) fairs, markets, shows and other gatherings of animals, including collection and dispersion of susceptible species;

(c) itinerant service for breeding of animals of susceptible species;

(d) artificial insemination of and collection of ova and embryos from animals of susceptible species.

Additional measures and derogations

22. (1) The competent authority may extend the prohibitions in rule 21 to:

(a) movement or transport of animals of non-susceptible species between holdings situated within the zone or out of or into the protection zone;

(b) transit of animals of all species through the protection zone;

(c) events with gatherings of people with possible contact with animals of susceptible species, where there is a risk of spreading the foot-and-mouth disease virus;

(d) artificial insemination of, or collection of ova and embryos from, animals of species not susceptible to foot-and-mouth disease;

(e) movement of means of transport designed for the transportation of animals;

(f) the slaughter on the holding of animals of susceptible species for private consumption;

(g) transport of goods referred to in rule 31 to holdings keeping animals of susceptible species.

(2) The competent authority may authorise:

(a) the transit of animals of all species through the protection zone undertaken exclusively via major highways;

(b) the transport of animals of susceptible species which have been certified by the official veterinarian as coming from holdings outside the protection zone and transported on designated routes directly to designated slaughterhouses for immediate slaughter, provided that the means of transport

are cleansed and disinfected after delivery under official supervision at the slaughterhouse and such decontamination of transport is recorded in the logbook of the means of transport;

(c) the artificial insemination of animals on a holding carried out by the personnel of that holding by use of semen collected from animals on that holding or semen stored on that holding or semen delivered from a semen collection centre to the outside perimeter of that holding;

(d) the movement and transport of equidae taking into account the conditions set out in Schedule VI;

(e) the transport, under certain conditions, of goods referred to in rule 31 to holdings keeping animals of susceptible species.

Measures in relation to fresh meat produced in the protection zone

23. (1) The competent authority shall ensure that the placing on the market of fresh meat, minced meat and meat preparations, derived from animals of susceptible species originating in the protection zone, shall be prohibited.

(2) The competent authority shall ensure that the placing on the market of fresh meat, minced meat and meat preparations from animals of susceptible species produced in establishments situated in the protection zone, shall be prohibited.

(3) The competent authority shall ensure that fresh meat, minced meat and meat preparations as referred to in sub-rule (1), shall be marked in accordance with European Union Council Directive 2002/99/EC and subsequently transported in sealed containers to an establishment designated by the competent authorities for transformation into meat products treated in accordance with point 1 in Part A of Schedule VII of these rules.

(4) By way of derogation, the prohibition provided for in sub-rule (1) shall not apply to fresh meat, minced meat and meat preparations which were produced on a date at least 21 days before the estimated date of earliest infection on a holding in the protection zone and which since production have been stored and transported separately from such meats produced after that date. Such meats must be readily distinguished from meats not eligible for dispatch outside the protection zone by means of a clear mark established in conformity with European Community legislation.

(5) By way of derogation, the prohibition provided for in sub-rule (2), shall not apply to fresh meat, minced meat or meat preparations obtained from establishments situated in the protection zone under the following conditions:

(a) the establishment shall be operated under strict veterinary control;

(b) only fresh meat, minced meat or meat preparations as described in sub-rule (4), or fresh meat, minced meat or meat preparations obtained from animals reared and slaughtered outside the protection zone or from animals transported to the establishment and slaughtered therein in accordance with the provisions in rule 22(2)(b) shall be processed in the establishment;

(c) all such fresh meat, minced meat or meat preparations, must bear the health mark in accordance with Chapter XI of Annex I to European Union Council Directive 64/433/EEC or in the case of meat from other biungulates the health mark provided for in Chapter III of Annex I to European Union Council Directive 91/495/EEC, or in the case of minced meat and meat preparations the health mark as provided for in Chapter VI of Annex I to European Union Council Directive 94/65/EC;

(d) during the whole production process all such fresh meat, minced meat or meat preparations must be clearly identified, and transported and stored separately from fresh meat, minced meat or meat preparations which are not eligible for dispatch outside the protection zone in accordance with these rules.

(6) Compliance with the conditions in sub-rule (5) shall be certified by the competent authority for fresh meat, minced meat and meat preparations intended for intra-European Community trade. The competent authority shall supervise the control of compliance undertaken by the local veterinary authority and, in the case of intra-European Community trade, communicate to other Member States and the European Commission a list of those establishments which it has approved for the purpose of such certification.

(7) Derogation from the prohibition provided for in sub-rule (1) may be granted subject to specific conditions adopted in accordance with European Union legislation, in particular with regard to the health marking of meat produced from animals of susceptible species originating in protection zones maintained for more than 30 days.

Measures in relation to meat products produced in the protection zone

24. (1) The competent authority shall ensure that the placing on the market of meat products produced from meat derived from animals of susceptible species originating in the protection zone shall be prohibited.

(2) By way of derogation, the prohibition in sub-rule (1) shall not apply to meat products which have either undergone one of the treatments as set out in point 1 in Part A of Schedule VII or which have been produced from meats referred to in rule 23(4).

Measures in relation to milk and milk products produced in the protection zone

25. (1) The competent authority shall ensure that the placing on the market of milk derived from animals of susceptible species originating in the protection zone and of milk products produced from such milk shall be prohibited.

(2) The competent authority shall ensure that the placing on the market of milk and milk products from animals of susceptible species produced in an establishment situated in the protection zone shall be prohibited.

(3) By way of derogation, the prohibition provided for in sub-rule (1) shall not apply to milk and milk products derived from animals of susceptible species originating in the protection zone which were produced on a date at least 21 days before the estimated date of earliest infection on a holding in the protection zone and which since production have been stored and transported separately from milk and milk products produced after that date.

(4) By way of derogation, the prohibition provided for in sub-rule (1) shall not apply to milk derived from animals of susceptible species originating in the protection zone and milk products produced from such milk which have undergone one of the treatments as set out in Parts A or B of Schedule IX, depending on the use of the milk or milk products. The treatment shall be carried out under the conditions set out in sub-rule (6) in establishments referred to in sub-rule 5 or, if there is no establishment situated in the protection zone, in establishments situated outside the protection zone under the conditions set down in sub-rule 8.

(5) By way of derogation, the prohibition provided for in sub-rule (2) shall not apply to milk and milk products which have been prepared in establishments situated in the protection zone under the conditions set out in sub-rule (6).

(6) Establishments referred to in sub-rules (4) and (5) shall comply with the following conditions:

(a) the establishment shall be operated under permanent and strict official control;

(b) all milk used in the establishment shall either comply with sub-rules (3) and (4) or the raw milk shall be obtained from animals outside the protection zone;

(c) during the whole production process the milk shall be clearly identified and transported and stored separately from raw milk and raw milk products which are not destined for dispatch outside the protection zone;

(d) transport of raw milk from holdings situated outside the protection zone to the establishments shall be carried out in vehicles which were cleaned and disinfected prior to the transport operation, and which have had no subsequent contact with holdings in the protection zone keeping animals of susceptible species.

(7) Compliance with the conditions in sub-rule 6 shall be certified by the competent authority for milk intended for intra-European Community trade. The competent authority shall supervise the control of compliance undertaken by the local veterinary authority and, in the case of intra-European Community trade, communicate to other Member States and the European Commission a list of those establishments which it has approved for the purpose of such certification.

(8) Transport of raw milk from holdings situated within the protection zone to establishments situated outside the protection zone and the processing of that milk shall be subject to the following conditions:

(a) processing in establishments situated outside the protection zone of raw milk produced from animals of susceptible species kept within the protection zone shall be authorised by the competent authorities;

(b) the authorisation shall include instructions on and designation of the transport route to the designated establishment;

(c) transport shall be carried out in vehicles which were cleaned and disinfected prior to the transport operation, which are constructed and maintained in such a way that there is no leakage of milk during transport and which are equipped to avoid aerosol dispersion during the loading and unloading of the milk;

(d) before leaving the holding from where milk of animals of susceptible species was collected the connection pipes, tyres, wheel cases, the lower parts of the vehicle and any spillage of milk are cleansed and disinfected and after the last disinfection and before leaving the protection zone the vehicle had no subsequent contact with holdings in the protection zone keeping animals of susceptible species;

(e) the means of transport are strictly assigned to a defined geographical or administrative area, they are marked accordingly and may only be moved to another area after cleansing and disinfection under official supervision.

(9) The collection and transport of samples of raw milk of animals of susceptible species from holdings situated in the protection zone to a laboratory other than a veterinary diagnostic laboratory approved for diagnosis of foot-and-mouth disease and the processing of the milk in such laboratories shall be forbidden.

Measures in relation to semen, ova and embryos collected from animals of susceptible species in the protection zone

26. (1) The competent authority shall ensure that the placing on the market of semen, ova and embryos derived from animals of susceptible species originating in the protection zone shall be prohibited.

(2) By way of derogation, the prohibition provided for in sub-rule (1) shall not apply to frozen semen, ova and embryos collected and stored at least 21 days before the estimated date of earliest infection with the foot-and-mouth disease virus on a holding in the zone.

(3) Frozen semen collected in accordance with European Community legislation after the date of infection referred to in sub-rule (2), shall be stored separately and shall only be released after:

(a) all the measures relating to the outbreak of foot-and-mouth disease have been removed in accordance with rule 36, and

(b) all animals accommodated in the semen collection centre have undergone a clinical examination, and samples taken in accordance with point 2.2 of Schedule III have been subjected to a serological test to substantiate the absence of infection in the semen collection centre concerned, and

(c) the donor animal has been subjected with negative result to a serological test for the detection of antibodies against the foot-and-mouth disease virus on a sample taken not earlier than 28 days after the collection of the semen.

Transport and distribution of dung and manure of animals of susceptible species produced in the protection zone

27. (1) The competent authority shall ensure that the transport and distribution of dung or manure from holdings and premises or means of transport referred to in rule 16 situated in the protection zone where animals of susceptible species are kept, shall be prohibited within the protection zone.

(2) By way of derogation from the prohibition in sub-rule (1) the competent authority may authorise the removal of manure of animals of susceptible species from a holding situated in the protection zone to a designated plant for treatment in accordance with point 5 of Section II in Part A of Chapter III of Annex VIII to European Regulation 1774/2002 or for intermediate storage.

(3) By way of derogation from the prohibition in sub-rule (1) the competent authority may authorise the removal of manure of animals of susceptible species from holdings situated in the protection zone which are not subject to the measures provided for in rules 4 or 10 for distribution on designated fields under the following conditions:

(a) the entire volume of manure has been produced at least 21 days before the estimated date of earliest infection on a holding in the protection zone and the manure or dung is distributed close to the ground and in sufficient distance from holdings keeping animals of susceptible species and immediately incorporated into the ground, or

(b) in the case of manure from bovine animals or pigs:

(i) an examination by an official veterinarian of all the animals on the holding has ruled out the presence of animals suspected of being infected with the foot-and-mouth disease virus, and

(ii) the entire volume of manure has been produced at least 4 days prior to the examination referred to in sub-paragraph (i), and

(iii) the manure is incorporated into the ground on designated fields close to the holding of origin and in sufficient distance to other holdings keeping animals of susceptible species in the protection zone.

(4) The competent authority shall ensure that any authorisation to remove dung or manure from a holding keeping animals of susceptible species is subject to stringent measures to avoid spread of the foot-and-mouth disease virus, in particular by ensuring cleansing and disinfection of the leak-proof transport vehicles after loading and before leaving the holding.

Measures in relation to hides and skins from animals of susceptible species in the protection zone

28. (1) The competent authority shall ensure that the placing on the market of hides and skins of animals of susceptible species originating in the protection zone, shall be prohibited.

(2) By way of derogation, the prohibition as provided for in sub-rule (1) shall not apply to hides and skins which either:

(a) were produced at least 21 days before the estimated date of infection on the holding referred to in rule 10(1), and that have been stored separately from hides and skins produced after that date; or

(b) comply with the requirements laid down in point 2 in Part A of Schedule VII.

Measures in relation to sheep wool, ruminant hair and pig bristles produced in the protection zone

29. (1) The competent authority shall ensure that the placing on the market of sheep wool, ruminant hair and pig bristles originating in the protection zone shall be prohibited.

(2) By way of derogation, the prohibition as provided for in sub- rule (1) shall not apply to unprocessed wool, hair and bristles which:

(a) were produced at least 21 days before the estimated date of infection on the holding referred to in rule 10(1) and have been stored separately from wool, hair and bristles produced after that date; or

(b) comply with the requirements laid down in point 3 in Part A of Schedule VII.

Measures in relation to other animal products produced in the protection zone

30. (1) The competent authority shall ensure that the placing on the market of animal products derived from animals of susceptible species not referred to in rules 23 to 29 shall be prohibited.

(2) By way of derogation, the prohibitions provided for in sub-regulation 1 shall not apply to products referred to in sub-rule (1) which:

(a) either have been produced at least 21 days before the estimated date of infection on the holding referred to in rule 10(1) and have been stored and transported separately from products produced after that date, or

(b) have undergone the treatment in accordance with point 4 in Part A of Schedule VII, or

(c) for specific products, comply with the appropriate requirements in points 5 to 9 in Part A of Schedule VII, or

(d) are composite products which are not subject to further treatment containing products of animal origin which either have undergone a treatment ensuring destruction of possible foot-and-mouth disease virus or have been obtained from animals not subject to restrictions under the provisions of these regulations, or

(e) are packed products intended for use as in-vitro diagnostic or laboratory reagents.

Measures in relation to feed, forage, hay and straw produced in the protection zone

31. (1) The competent authority shall ensure that the placing on the market of feed, forage, hay and straw originating in the protection zone shall be prohibited.

(2) By way of derogation, the prohibition provided for in sub-rule (1) shall not apply to feed, forage, hay and straw:

(a) produced at least 21 days before the estimated date of infection on holdings referred to in rule 10(1), and stored and transported separately from feed, forage, hay and straw produced after that date; or

(b) intended for use within the protection zone, subject to authorisation by the competent authorities; or

(c) produced on premises not keeping animals of susceptible species; or

(d) produced in establishments not keeping animals of susceptible species and sourcing the raw material from premises referred to in paragraph (c) or from premises situated outside the protection zone.

(3) By way of derogation, the prohibition provided for in sub-rule 1 shall not apply to forage and straw produced on holdings keeping animals of susceptible species which comply with the requirements in point 1 in Part B of Schedule VII.

Granting of derogations and additional certification

32. (1) Any derogation from the prohibitions provided for in rules 22 to 31 shall be granted by a specific decision of the competent authority only after it has satisfied itself that all relevant requirements have been met for a sufficient period before the products leave the protection zone, and that there is no risk of spreading the foot-and-mouth disease virus.

(2) Any derogation from the prohibitions provided for in rules 23 to 31 requires, in the case of intra-European Community trade, additional certification by the competent authority.

(3) Detailed rules for the implementation of the measures provided for in sub-rule (2) may be adopted in accordance with the European Community legislation.

Additional measures applied by the competent authority in the protection zone

33. In addition to the measures applicable in the protection zone in accordance with these regulations, the competent authority may take additional national measures

which are deemed necessary and proportionate to contain the foot-and-mouth disease virus taking into account the particular epidemiological, animal husbandry, commercial and social conditions prevailing in the affected area. The competent authority shall inform the European Commission and the other Member States about such additional measures.

Removal of measures in the protection zone

34. (1) The competent authority shall ensure that the measures applied in the protection zone are maintained until the following requirements have been met:

(a) at least 15 days have elapsed since the killing and safe disposal of all the animals of susceptible species from the holding referred to in rule 10(1) and the completion of the preliminary cleansing and disinfection on that holding, carried out in accordance with rule 11;

(b) a survey has been concluded with negative results in all holdings keeping animals of susceptible species and situated within the protection zone.

(2) After the removal of the measures specific to the protection zone, the measures applied in the surveillance zone as provided for in rules 35 to 40, shall continue to apply for at least 15 days until those measures are removed in accordance with rule 42.

(3) The survey referred to in sub-rule (1)(b) shall be carried out to substantiate the absence of infection and at least in compliance with the criteria of point 1 of Schedule III and shall include the measures provided for in point 2.3 of Schedule III based on the criteria set out in points 2.1.1. and 2.1.3. of Schedule III.

Measures to be applied to holdings in the surveillance zone

35. (1) The competent authority shall ensure that the measures provided for in rule 20(1) are applied in the surveillance zone.

(2) By way of derogation from the prohibition provided for in rule 20(1)(c) and where there is no or insufficient slaughter capacity available within the surveillance zone, the competent authorities may authorise the removal from holdings situated in the surveillance zone of animals of susceptible species for transporting them directly and under official supervision for slaughter to a slaughterhouse located outside the surveillance zone, subject to the following conditions:

(a) the records referred to in rule 20(1) have been subjected to official control, and the epidemiological situation of the holding does not indicate any suspicion of infection or contamination with the foot-and-mouth disease virus, and

(b) all the animals of susceptible species on the holding have been subjected with negative result to an inspection by the official veterinarian, and

(c) a representative number of animals, taking into account the statistical parameters in point 2.2 of Schedule III, has been subjected to thorough clinical examination to rule out the presence or suspicion of clinically infected animals, and

(d) the slaughterhouse is designated by the competent authority and located as near to the surveillance zone as possible, and

(e) the meat produced from such animals shall be subject to the treatment specified in rule 37.

Movement of animals of susceptible species within the surveillance zone

36. (1) The competent authority shall ensure that animals of susceptible species shall not be removed from holdings within the surveillance zone.

(2) By way of derogation, the prohibition provided for in sub-rule (1) shall not apply to movement of animals for one of the following purposes:

(a) for leading them without coming into contact with animals of susceptible species of different holdings to pasture situated within the surveillance zone not earlier than 15 days after the last outbreak of foot-and-mouth disease has been recorded in the protection zone;

(b) for transporting them directly, and under official supervision, for the purpose of slaughter to a slaughterhouse located inside the same zone;

(c) for transporting them in accordance with rule 35(2);

(d) for transporting them in accordance with rule 22(2)(a) and (b).

(3) Movements of animals provided for in sub-rule (2)(a) shall be authorised by the competent authority only after an examination by an official veterinarian of all the animals of susceptible species on the holding, including testing of samples taken in accordance with point 2.2 of Schedule III, has ruled out the presence of animals suspected of being infected or animals suspected of being contaminated.

(4) Movements of animals provided for in sub-rule (2)(b) shall be authorised by the competent authority only after the measures provided for in rule 37(2)(a) and (b) have been completed with satisfactory results.

(5) The competent authority shall without delay trace animals of susceptible species dispatched from the surveillance zone during a period of least 21 days before the estimated date of earliest infection on a holding in the surveillance zone and they shall inform the competent authorities in other Member States about their results from tracing animals.

Measures to be applied to fresh meat of animals of susceptible species originating in the surveillance zone and meat products produced from such meat

37. (1) The competent authority shall ensure that the placing on the market of fresh meat, minced meat and meat preparations derived from animals of susceptible species originating in the surveillance zone and of meat products produced from such meats shall be prohibited.

(2) The competent authority shall ensure that the placing on the market of fresh meat, minced meat, meat preparations and meat products from animals of susceptible species produced in establishments situated in the surveillance zone shall be prohibited.

(3) By way of derogation, the prohibition provided for in sub-rule (1) shall not apply to fresh meat, minced meat and meat preparations which were produced on a date at least 21 days before the estimated date of earliest infection on a holding in the corresponding protection zone and which since production have been stored and transported separately from such meats produced after that date. Such meats must be readily distinguished from meats not eligible for dispatch outside the surveillance zone by means of clear mark established in conformity with European Community legislation.

(4) By way of derogation, the prohibition provided for in sub-rule (1) shall not apply to fresh meat, minced meat and meat preparations which were produced from animals transported to the slaughterhouse under conditions at least as strict as provided

for in rule 35(2)(a) to (e) under the condition that the meat is subject to the measures provided for in sub-rule 5.

(5) By way of derogation, the prohibition provided for in sub-rule (2), shall not apply to fresh meat, minced meat or meat preparations obtained from establishments situated in the surveillance zone under the following conditions:

(a) the establishment shall be operated under strict veterinary control;

(b) only fresh meat, minced meat or meat preparations as described in sub-rule 4 and subject to the additional conditions provided for in Part B of Schedule VIII or obtained from animals reared and slaughtered outside the surveillance zone or obtained from animals transported in accordance with the provisions in rule 22(2)(b) shall be processed in the establishment;

(c) all such fresh meat, minced meat or meat preparations must bear the health mark in accordance with Chapter XI of Annex I to European Union Council Directive 64/433/EEC or in the case of meat from other biungulates the health mark provided for in Chapter III of Annex I to European Union Council Directive 91/495/EEC, or in the case of minced meat and meat preparations the health mark as provided for in Chapter VI of Annex I to European Union Council Directive 95/65/EC;

(d) during the whole production process all such fresh meat, minced meat or meat preparations must be clearly identified, and transported and stored separately from fresh meat, minced meat or meat preparations which are not eligible for dispatch outside the surveillance zone in accordance with these rules.

(6) By way of derogation, the prohibition provided for in sub-rule (1), shall not apply to meat products produced from fresh meat obtained from animals of susceptible species originating in the surveillance zone which was marked with the health mark provided for European Union Council Directive 2002/99/EC and transported under official supervision to a designated establishment for treatment in accordance with point 1 in Part A of Schedule VII.

(7) By way of derogation, the prohibition provided for in sub-rule (2), shall not apply to meat products produced in establishments situated in the surveillance zone and either complying with the provisions in sub-rule (6), or produced from meat complying with sub-rule (5).

(8) Compliance with the conditions in sub-rules (5) and (7) shall be certified by the competent authority for fresh meat, minced meat and meat preparations intended for intra-European Community trade. The competent authority shall supervise the control of compliance undertaken by the Veterinary Services and in the case of intra-European Community trade communicate to other Member States and the European Commission a list of those establishments which it has approved for the purpose of such certification.

(9) Derogation from the prohibition provided for in sub-rule (1) may be granted subject to specific conditions adopted in accordance with European Community legislation, in particular with regard to the health marking of meat produced from animals of susceptible species originating in surveillance zone maintained for more than 30 days.

Measures to be applied to milk and milk products of animals of susceptible species produced in the surveillance zone

38. (1) The competent authority shall ensure that placing on the market of milk derived from animals of susceptible species originating in the surveillance zone and of milk products produced from such milk shall be prohibited.

(2) The competent authority shall ensure that the placing on the market of milk and milk products from animals of susceptible species produced in the surveillance zone shall be prohibited.

(3) By way of derogation, the prohibition provided for in sub-rule (1) shall not apply to milk and milk products derived from animals of susceptible species originating in the surveillance zone which were produced on a date at least 21 days before the estimated date of earliest infection on a holding in the corresponding protection zone and which since production have been stored and transported separately from milk and milk products produced after that date.

(4) By way of derogation, the prohibition provided for in sub-rule (1) shall not apply to milk derived from animals of susceptible species originating in the surveillance zone and milk products produced from such milk which have undergone one of the treatments as set out in Parts A or B of Schedule IX depending on the use of the milk or milk products. The treatment shall be carried out under the condition set out in sub-rule (6) in establishments referred to in sub-rule (5) or, if there is no establishment situated in the surveillance zone, in establishments designated by the competent authorities and situated outside the protection and surveillance zones.

(5) By way of derogation, the prohibition provided for in sub-rule (2) shall not apply to milk and milk products which have been prepared in establishments situated in the surveillance zone under the conditions set out in sub-rule (6).

(6) Establishments referred to in sub-rules (4) and (5) shall comply with the following conditions:

(a) the establishment shall be operated under strict veterinary control;

(b) all milk used in the establishment shall either comply with sub-rule (4) or be obtained from animals outside the surveillance and protection zone;

(c) throughout the production process the milk shall be clearly identified and transported and stored separately from milk and milk products which are not destined for dispatch outside the surveillance zone;

(d) transport of raw milk from holdings situated outside the protection and surveillance zone to the establishments shall be carried out in vehicles which were cleaned and disinfected prior to the transport operation, and which have had no subsequent contact with holdings in the protection and surveillance zones keeping animals of susceptible species.

(7) Compliance with the conditions in sub-rule (6) shall be certified by the competent authority for milk intended for intra-European Community trade. The competent authority shall supervise the control of compliance undertaken by the Veterinary Services and, in the case of intra-European Community trade, communicate to other Member States and the European Commission a list of those establishments which it has approved for the purpose of such certification.

(8) Transport of raw milk from holdings situated within the surveillance zone to establishments situated outside the protection and surveillance zones and the processing of that milk shall be subject to the following conditions:

(a) processing in establishments situated outside the protection and surveillance zones of raw milk produced from animals of susceptible species kept within the surveillance zone shall be authorised by the competent authorities;

(b) the authorisation shall include instructions on and designation of the transport route to the designated establishment;

(c) transport shall be carried out in vehicles which were cleaned and disinfected prior to the transport operation, which are constructed and maintained in such a way that there is no leakage of milk during transport and which are equipped to avoid aerosol dispersion during the loading and unloading of the milk;

(d) before leaving the holding from where milk of animals of susceptible species was collected, the connection pipes, tires, wheel cases, the lower parts of the vehicle and any spillage of milk are cleansed and disinfected and after the last disinfection and before leaving the surveillance zone the vehicle had no subsequent contact with holdings in the protection and surveillance zones keeping animals of susceptible species;

(e) the means of transport are strictly assigned to a defined geographical or administrative area, they are marked accordingly and may only be moved to another area after cleansing and disinfection under official supervision.

(9) The collection and transport of samples of raw milk of animals of susceptible species from holdings situated in the surveillance zone to a laboratory other than a veterinary diagnostic laboratory approved for diagnosis of foot-and-mouth disease and the processing of the milk in such laboratories shall be subject to official authorisation and measures to avoid any spread of possible foot-and-mouth disease virus.

Transport and distribution of dung and manure of animals of susceptible species produced in the surveillance zone

39. (1) The competent authority shall ensure that the transport and distribution of dung or manure from holdings and other premises such as those mentioned in rule 16 situated in the surveillance zone where animals of susceptible species are kept shall be prohibited within and outside that zone.

(2) By way of derogation from the prohibition provided for in sub-rule (1) the competent authorities may in exceptional circumstances authorise the transport of dung or manure in means of transport thoroughly cleansed and disinfected prior to and after use for distribution in designated areas within the surveillance zone and at sufficient distance to holdings where animals of susceptible species are kept under the following alternative conditions:

(a) either an examination by an official veterinarian of all the animals of susceptible species on the holding has ruled out the presence of animals suspected of being infected with the foot-and-mouth disease virus and the manure or dung is distributed close to the ground to avoid the generation of aerosols and immediately ploughed into the ground, or

(b) a clinical inspection by an official veterinarian of all the animals of susceptible species on the holding has been carried out with negative result and the manure is injected into ground, or;

(c) manure is subject to the provision of rule 27(2).

Measures in relation to other animal products produced in the surveillance zone

40. The competent authority shall ensure that the placing on the market of products of animal origin other than those referred to in rules 37 to 39 shall be subject to the conditions provided for in rules 26 and 28 to 30.

Additional measures applied by the competent authority in the surveillance zone

41. In addition to the measures provided for in rules 35 to 40, the competent authority may take additional national measures which are deemed necessary and proportionate to contain foot-and-mouth disease virus taking into account the particular epidemiological, animal husbandry, commercial and social conditions prevailing in the affected area. Where specific measures to restrict the movement of equidae are considered necessary, such measures shall take into account those provided for in Schedule VI.

Removal of measures in the surveillance zone

42. (1) The competent authority shall ensure that the measures applied in the surveillance zone are maintained until the following requirements have been met:

(a) at least 30 days have elapsed since the killing and safe disposal of all animals of susceptible species from the holding referred to in rule 10(1) and the completion of the preliminary cleansing and disinfection on that holding, carried out in accordance with rule11;

(b) the requirements provided for in rule 34 have been met in the protection zone;

(c) a survey has been concluded with negative results.

(2) The survey referred to in sub-rule (1)(c) shall be carried out to substantiate the absence of infection in the surveillance zone in compliance with the criteria of point 1 of Schedule III and shall include the measures provided for in point 2.4 of Schedule III based on the criteria of point 2.1 of Schedule III.

Regionalisation

43. (1) Without prejudice to European Union Council Directive 90/425/EC, and in particular Article 10 thereof, where the foot-and-mouth disease virus appears to be spreading despite the measures taken in accordance with these regulations and the epizootic becomes extensive and in any case when emergency vaccination is implemented, the competent authority shall ensure that Malta is regionalised into one or more restricted and free zones.

(2) The competent authority shall notify to the European Commission without delay the details of the measures implemented in the restricted zone and the European Commission shall review, where necessary amend, and endorse the measures in accordance with European Community legislation.

(3) Without prejudice to the obligation of the competent authority to regionalise referred to in sub-rule (1), regionalisation, and the measures to be applied within the restricted zone, may be decided in accordance with the procedure established in rule 78(2). This decision may extent its effects to neighbouring Member States not infected at the time the measures are taken.

(4) Prior to the delimitation of the restricted zone, a thorough epidemiological assessment of the situation shall be carried out, especially with respect to the possible time and probable location of introduction, the possible spread and the probable period of time necessary to eradicate the foot-and-mouth disease virus.

(5) The restricted zone shall as far as possible be delimited on the basis of administrative boundaries or geographical barriers. Regionalisation shall take as its starting point larger administrative units rather than regions. The restricted zone may be reduced in the light of the results of the epidemiological inquiry provided for in rule 13, to an area of the size not less than a sub-region, and where necessary the surrounding sub-regions. In the event of the foot-and-mouth disease virus spreading, the restricted zone shall be enlarged by including additional regions or sub-regions.

Measures applied in a restricted zone of Malta

44. (1) Where regionalisation is applied, the competent authority shall ensure that at least the following measures are taken:

(a) control within the restricted zone of transport and movement of animals of susceptible species, animal products and goods and of the movement of means of transport as potential carriers of foot-and-mouth disease virus;

(b) tracing and marking in accordance with European Community legislation of fresh meat and raw milk and as far as possible other products in stock not eligible for dispatch outside the restricted zone;

(c) specific certification of animals of susceptible species and products derived from such animals and health marking, in accordance with European Community legislation, of products for human consumption intended and eligible for dispatch outside the restricted zone.

(2) Where regionalisation is applied, the competent authority shall ensure that at least the animals of susceptible species dispatched from the restricted zone to other Member States during the time between the date of estimated introduction of the foot-

and-mouth disease virus until the date regionalisation is implemented shall be traced, and such animals shall be isolated under official veterinary control until possible infection or contamination is officially ruled out.

(3) The competent authority shall collaborate in tracing fresh meat and raw milk and raw milk products derived from animals of susceptible species produced in the restricted zone between the date of estimated introduction of the foot-and-mouth disease virus until the date regionalisation is implemented. Such fresh meat shall be treated in accordance with point 1 in Part A of Annex VII, and raw milk and milk products shall be treated in accordance with Part A or B of Schedule IX depending on the use, or detained until possible contamination with the foot-and-mouth disease virus is officially ruled out.

(4) Specific measures, in particular in relation to health marking of products derived from animals of susceptible species originating in the restricted zone and not intended for placing on the market outside the restricted zone may be adopted in accordance with Article 4(3) of European Union Council Directive 2002/99/EC.

Identification of animals of susceptible species

45. (1) Without prejudice to European Community legislation on identification of domestic bovine, ovine and caprine animals and swine, the competent authority shall ensure that in the event of an outbreak of foot-and-mouth disease on their territory animals of susceptible species shall only leave the holding on which they are kept, if they are identified in such a way as to enable the competent authorities to trace rapidly their movements and their holding of origin, or any holding from which they have come. However, for special cases referred to in rule 15(1) and rule 16(1), the competent authority may, in certain circumstances and having regard to the health situation, authorise other ways of rapidly tracing the movement of those animals and of their holding of origin, or of any holding from which they have come. The arrangements for

identifying such animals or for tracing their holdings of origin shall be determined by the competent authority and notified to the European Commission.

(2) The measures taken by the competent authority on additional, permanent and indelible marking of animals for the particular purpose of control of the foot-and-mouth disease, and in particular in case of vaccination carried out in accordance with rules 50 and 51, may be modified in accordance with rule 77(2).

Movement control in case of an outbreak of foot-and-mouth disease

46. (1) The competent authority shall ensure that, in the event of an outbreak of foot-and-mouth disease in Malta the following measures to control movement of animals of susceptible species are applied in the restricted zone established in accordance with rule 43:

(a) owners shall supply the competent authority, on request of that authority, with appropriate information concerning animals entering or leaving their holding. That information shall, in relation to all animals of susceptible species, include at least the details required by Article 14 of European Union Council Directive 64/432/EEC;

(b) persons engaged in the transport or marketing of animals of susceptible species shall supply the competent authority, on request of that authority, with appropriate information concerning the movements of such animals which they have transported or marketed. That information shall include at least the details required by Articles 12(2) and 13(1)(b) of European Union Council Directive 64/432/EEC.

(2) The competent authority may extend some or all the measures provided for in sub-rule (1) to a part or the entire free zone.

Use, manufacture, sales and controls of the vaccines

47. The competent authority shall ensure that:

(a) the use of foot-and-mouth disease vaccines and the administration of hyperimmune sera against foot-and-mouth disease are prohibited on their territory except as provided for in these rules;

(b) the production, storage, supply, distribution and sale of foot-and-mouth disease vaccines are carried out under official control;

(c) the marketing of foot-and-mouth disease vaccines is under the supervision of the competent authorities in accordance with European Community legislation;

(d) the use of foot-and-mouth disease vaccines for purposes other than to induce active immunity in animals of susceptible species, notably laboratory investigations, scientific research or testing of vaccines, is authorised by the competent authorities and carried out under appropriate bio-security conditions.

Decision on introducing emergency vaccination

48. (1) The competent authority may decide to introduce emergency vaccination where at least one of the following conditions applies:

(a) outbreaks of foot-and-mouth disease have been confirmed and threaten to become widespread in Malta where such outbreaks have been confirmed;

(b) other Member States are at risk due to the geographical situation of or the prevailing meteorological conditions in relation to reported outbreaks of foot-and-mouth disease in Malta;

(c) other Member States are at risk due to epidemiologically relevant contacts between holdings on their territories and holdings keeping animals of susceptible species in Malta where there are outbreaks of foot-and-mouth disease;

(d) the territory of Malta is at risk due to the geographical situation or the prevailing meteorological conditions in a neighbouring third country where there are outbreaks of foot-and-mouth disease.

(2) When deciding on the introduction of emergency vaccination, consideration shall be given to the measures provided for in rule 15 and to the criteria listed in Schedule X.

(3) The decision to introduce emergency vaccination shall be adopted in accordance with European Community legislation.

(4) The decision referred to in sub-rule (3) to introduce emergency vaccination on its own territory may be requested:

(a) either by the competent authority referred to in sub-rule (1)(a), or

(b) by a Member State referred to in sub-rule (1)(b), (c) or (d).

(5) By way of derogation from sub-rule (3), the decision to introduce emergency vaccination may be taken by the competent authority and implemented in accordance

with these rules, after a written notification to the European Commission which shall include the specifications provided for in rule 49.

(6) If the competent authority introduces emergency vaccination in accordance with sub-rule (5), that decision shall be immediately reviewed in the Standing Committee on the Food Chain and Animal Health and European Community measures shall be adopted in accordance with the procedure referred to in rule 78(2).

(7) By way of derogation from sub-rule (4), a decision to introduce emergency vaccination in Malta referred to in sub-rule (1)(a) may be adopted in concertation with the affected Member State in accordance with European Community legislation on the European Commission's own initiative, if the condition in sub-rule (1)(a) and sub-rule (1)(b) apply.

Conditions for emergency vaccination

49. (1) The decision to introduce emergency vaccination in accordance with rules 48(3) and (4) shall specify the conditions under which such vaccination shall be carried out and these conditions must specify at least:

(a) the delimitation in accordance with rule 43 of the geographical area in which emergency vaccination is to be carried out;

(b) the species and the age of the animals to be vaccinated;

(c) the duration of the vaccination campaign;

(d) a specific prohibition on movements of vaccinated and non-vaccinated animals of susceptible species and their products;

(e) the special additional and permanent identification and special registration of the vaccinated animals pursuant to rule 45(2);

(f) other matters appropriate to the emergency situation.

(2) The conditions for emergency vaccination as provided for in sub-rule (1), shall ensure that such vaccination is carried out in accordance with rule 50, irrespective of whether the vaccinated animals are subsequently slaughtered or stay alive.

(3) The competent authority shall ensure that an information programme shall be put in place to inform the public about the safety of meat, milk and dairy products from vaccinated animals for human consumption.

Protective vaccination

50. (1) Where the competent authority applies protective vaccination it shall ensure that:

(a) the vaccination zone shall be regionalised in accordance with rule 43, where necessary in close cooperation with neighbouring Member States;

(b) vaccination shall be carried out swiftly and in conformity with the rules of hygiene and bio-security so as to avoid the spread of foot-and-mouth disease virus;

(c) all measures applied in the vaccination zone shall be carried out without prejudice to the measures provided for in these rules;

(d) where the vaccination zone includes parts of or the entire protection or surveillance zone:

(i) the measures applicable for the protection zone or surveillance zone in accordance with these regulations shall be maintained within that part of the vaccination zone until such measures have been removed in accordance with rule 34 or rule 42;

(ii) after the measures applied in the protection zone and surveillance zone have been removed, the measures applicable for the vaccination zone, as provided for in rules 52 to 56, shall continue to apply.

(2) The competent authority applying protective vaccination shall ensure that the vaccination zone is surrounded by a surveillance area (surveillance zone as defined by OIE) of at least 10 kilometres width from the perimeters of the vaccination zone:

(a) in which vaccination is prohibited;

(b) in which intensified surveillance is carried out;

(c) in which the movement of animals of susceptible species is subject to controls by the competent authorities;

(d) which remains in place until the foot-and-mouth disease and infection free status is recovered in accordance with rule 59.

Suppressive vaccination

51. (1) The competent authority shall notify the European Commission if it decides in accordance with rule 48 and taking into account all relevant circumstances, to introduce suppressive vaccination and shall provide details of the control measures to be taken which shall include at least those provided for in rule 19.

(2) The competent authority shall ensure that suppressive vaccination is carried out:

(a) only within a protection zone;

(b) only on clearly identified holdings subject to the measures provided for in rule 10(1) and in particular paragraph (a) thereof:

Provided that, for logistical reasons and by way of derogation from rule 10(1)(a), the killing of all animals on such holdings may be delayed as long as necessary to comply with European Community legislation and the provisions of rule 10(1)(c) of these regulations.

Measures applicable in the vaccination zone during the period from the beginning of emergency vaccination until at least 30 days have elapsed following the completion of such vaccination (Phase 1)

52. (1) The competent authority shall ensure that the measures provided for in sub-rules (2) to (6) are applied in the vaccination zone during the period from the beginning of the emergency vaccination until at least 30 days have elapsed following the completion of such vaccination.

(2) Movement of live animals of susceptible species shall be prohibited between holdings within and out of the vaccination zone:

Provided that by way of derogation from such prohibition provided for herein, and after clinical inspection of such live animals and the herds of origin or dispatch of those animals, the competent authority may authorise their direct transport for immediate

slaughter in a slaughterhouse designated by the competent authority and situated within the vaccination zone or in exceptional cases close to that zone.

(3) Fresh meat produced from vaccinated animals slaughtered during the period referred to in sub-rule (1) shall:

(a) bear the mark provided for in European Union Council Directive 2002/99/EC and European Community legislation;

(b) be stored and transported separately from meat not bearing the mark referred to in paragraph (a), and shall subsequently be transported in sealed containers to an establishment designated by the competent authorities for treatment in accordance with point 1 in Part A of Schedule VII.

(4) Milk and milk products produced from vaccinated animals may be placed on the market within or outside the vaccination zone, provided that, depending on the final use for either human consumption or non-human consumption, it has undergone at least one of the treatments referred to in Parts A and B of Schedule IX. The treatment shall be carried out under the conditions set out in sub-rule (5) in establishments situated in the vaccination zone or, if there is no establishment in that zone, in establishments situated outside the vaccination zone to which the raw milk is transported under the conditions set down in sub-rule (7).

(5) Establishments referred to in sub-rule (4) shall comply with the following conditions:

(a) the establishment shall be operated under permanent and strict official control;

(b) all milk used in the establishment shall either comply with sub-rule (4) or the raw milk shall be obtained from animals outside the vaccination zone;

(c) during the whole production process the milk shall be clearly identified and transported and stored separately from raw milk and raw milk products which are not destined for dispatch outside the vaccination zone;

(d) transport of raw milk from holdings situated outside the vaccination zone to the establishments shall be carried out in vehicles which were cleaned and disinfected prior to the transport operation, and which have had no subsequent contact with holdings in a restricted zone keeping animals of susceptible species.

(6) Compliance with the conditions in sub-rule (5) shall be certified by the competent authority for milk intended for intra-European Community trade. The competent authority shall supervise the control of compliance undertaken by the Veterinary Services and in the case of intra-European Community trade communicate to other Member States and the European Commission, a list of those establishments which it has approved for the purpose of such certification.

(7) Transport of raw milk from holdings situated within the vaccination zone to establishments situated outside the vaccination zone and the processing of that milk shall be subject to the following conditions:

(a) processing in establishments situated outside the vaccination zone of raw milk produced from animals of susceptible species kept within the vaccination zone shall be authorised by the competent authorities;

(b) the authorisation shall include instructions on and designation of the transport route to the designated establishment;

(c) transport shall be carried out in vehicles which were cleaned and disinfected prior to the transport operation, which are constructed and maintained in such a way that there is no leakage of milk during transport and which are equipped to avoid aerosol dispersion during the loading and unloading of the milk;

(d) before leaving the holding from where milk of animals of susceptible species was collected, the connection pipes, tires, wheel cases, the lower parts of the vehicle and any spillage of milk are cleansed and disinfected and after the last disinfection and before leaving the vaccination zone the vehicle had no subsequent contact with holdings in the vaccination zone keeping animals of susceptible species;

(e) the means of transport are strictly assigned to a defined geographical or administrative area, they are marked accordingly and may only be moved to another area after cleansing and disinfection under official supervision.

(8) The collection and transport of samples of raw milk of animals of susceptible species from holdings situated in the vaccination zone to a laboratory other than a veterinary diagnostic laboratory approved for diagnosis of foot-and-mouth disease and the processing of the milk in such laboratories shall be forbidden.

(9) The collection of semen for artificial insemination from donor animals of susceptible species kept in semen collection centres situated within the vaccination zone shall be suspended. By way of derogation from the prohibition provided for herein, the competent authorities may authorise the collection of semen at semen collection centres within the vaccination zone for the production of frozen semen, subject to the following conditions:

(a) it is ensured that the semen collected during the period referred to in sub-rule (1) is stored separately for at least 30 days, and

(b) prior to dispatch of the semen:

(1) either the donor animal has not been vaccinated and the conditions of rule 26(3)(b) and (c) apply, or

(2) the donor animal has been vaccinated following a negative test for antibodies against foot-and-mouth disease virus carried out prior to vaccination; and

(i) a negative result has been achieved in a test for the detection of either virus or viral genome or an approved test for the detection of antibody against non-structural proteins, carried out at the end of the quarantine period for the semen on samples taken from all animals of susceptible species present at that time on the semen collection centre, and

(ii) the semen complies with the conditions of Article 4(3) of Chapter II of European Union Council Directive 88/407/EEC.

(10) Collection of ova and embryos from donor animals shall be prohibited.

(11) The placing on the market of products of animal origin other than those referred to in sub-rules (9) and (10) shall be subject to the conditions provided for in rules 28, 29, 30 and 39.

Measures applicable in the vaccination zone during the period from emergency vaccination until the survey and the classification of holdings are completed (Phase 2)

53. (1) The competent authority shall ensure that the measures provided for in sub-rules (2) to (5) are applied in the vaccination zone during a period starting not earlier than 30 days from the date of completion of emergency vaccination and terminating with the completion of the measures provided for in rules 54 and 55.

(2) Movement of animals of susceptible species between holdings within and out of the vaccination zone shall be prohibited.

(3) By way of derogation from the prohibition provided for in sub-rule (2), the competent authorities may authorise direct transport for immediate slaughter of animals of susceptible species from holdings referred to in rule 55(5) to a slaughterhouse situated within or out of the vaccination zone on the following conditions:

(a) during transport and in the slaughterhouse those animals shall not come into contact with other animals of susceptible species;

(b) the animals shall be accompanied by an official document certifying that all animals of susceptible species on the holding of origin or dispatch have undergone a survey provided for in rule 54(2);

(c) the transport vehicles shall be cleansed and disinfected before loading and after the animals have been delivered, with the date and time of the cleaning and disinfection being recorded in the logbook of the means of transport;

(d) the animals shall have passed the ante-mortem health inspection at the slaughterhouse during the 24 hours before slaughter and have in particular

undergone examination for mouth and feet disease and not shown signs of that disease.

(4) Fresh meat, excluding offal, produced from vaccinated large and small ruminants during the period referred to in sub-rule (1), may be placed on the market within and outside the vaccination zone under the following conditions:

(a) the establishment shall be operated under strict veterinary control;

(b) only fresh meat, excluding offal, which was subjected to the treatment described in points 1, 3 and 4 in Part A of Schedule VIII or fresh meat obtained from animals reared and slaughtered outside the vaccination zone shall be processed in the establishment;

(c) all such fresh meat shall bear the health mark in accordance with Chapter XI of Annex I to European Union Council Directive 64/433/EEC or, in the case of meat from other biungulates, the health mark provided for in Chapter III of Annex I of European Union Council Directive 91/495/EEC, or, in the case of minced meat and meat preparations, the health mark provided for in Chapter VI of Annex I of European Union Council Directive 94/65/EC;

(d) throughout the production process the fresh meat shall be clearly identified, and transported and stored separately from meat of different animal health status in accordance with these rules.

(5) Compliance with the conditions in sub-rule (4) shall be certified by the competent authority for fresh meat intended for intra-European Community trade. The competent authority shall supervise the control of compliance undertaken by the local veterinary authorities and, in the case of intra-European Community trade, communicate

to other Member States and the European Commission a list of those establishments which it has approved for the purpose of such certification.

(6) Fresh meat produced from vaccinated porcine animals slaughtered during the period referred to in sub-rule (1) shall bear the health mark provided for in European Union Council Directive 2002/99/EC and shall be stored and transported separately from meat not bearing that mark and subsequently be transported in sealed containers to an establishment designated by the competent authorities for treatment in accordance with point 1 in Part A of Schedule VII.

(7) Milk and milk products produced from vaccinated animals may be placed on the market within or outside the vaccination zone, provided that depending on the final use for either human consumption or non-human consumption it has undergone at least one of the treatments referred to in Parts A and B of Schedule IX. Such treatment shall have been undergone in an establishment located within or outside the vaccination zone in accordance with the provisions in rules 52(4) to (8).

(8) For the collection of semen, ova and embryos from animals of susceptible species, the measures provided for in rules 52(9) and (10) shall continue to apply.

(9) The placing on the market of products of animal origin other than those referred to in sub-rules (4), (6), (7) and (8) shall be subject to the conditions provided for in rules 28, 29, 30 and 39.

Clinical and serological survey in the vaccination zone (Phase 2-A)

54. (1) The competent authority shall ensure that the measures provided for in sub-rules (2) and (3) are applied in the vaccination zone during a period starting not earlier than 30 days from the date of completion of emergency vaccination and terminating with the completion of a clinical and serological survey.

(2) A survey shall be carried out with the aim to identify herds of animals of susceptible species that had contact with the foot-and-mouth disease virus without showing overt clinical signs of the foot-and-mouth disease. That survey shall include a clinical inspection of all animals of susceptible species in all herds in the vaccination zone, and laboratory testing in accordance with sub-rule 3.

(3) Laboratory testing shall be carried out by use of tests complying with the criteria for diagnostic tests as set out in Schedule XIII and approved in accordance with the procedure referred to in rule 77(1), and shall comply with one of the following conditions:

(a) testing for infection with the foot-and-mouth disease virus, either by an assay for antibodies against nonstructural proteins of the foot-and-mouth disease virus, or by another approved method, shall meet criteria for sampling on holdings set out in point 2.2 of Schedule III. Where the competent authority use in addition sentinel animals, the conditions for restocking of infected holdings in Schedule V shall be taken into account;

(b) testing for antibodies against non-structural proteins of the foot-and-mouth disease virus shall be carried out on samples taken from all vaccinated animals of susceptible species and their non-vaccinated offspring in all herds in the vaccination zone.

Classification of herds in the vaccination zone (Phase 2-B)

55. (1) The competent authority shall ensure that the holdings containing animals of susceptible species:

(a) are classified according to the outcome of the survey referred to in rule 54(2) and the criteria set out in Schedule I;

(b) comply with the measures set out in sub-rules (2) to (4).

(2) Holdings containing at least one animal suspected of being infected and where the presence of foot-and-mouth disease virus is confirmed in accordance with the criteria laid down in Schedule I shall be subject to the measures provided for in rules 10 and 19.

(3) Holdings containing at least one animal of susceptible species suspected of being infected through previous contact with the foot-and-mouth disease virus but where further testing including all animals of susceptible species present on the holding, confirmed the absence of circulating foot-and-mouth disease virus, shall be subject to at least the following measures:

(a) animals of susceptible species on the holding shall:

(1) either be killed and the carcasses processed, or

(2) the animals shall be classified and

(i) the animals positive to at least one of the approved tests referred to in rule 54(3) shall be killed and their carcasses processed, and

(ii) the remaining animals of susceptible species on the holding shall be slaughtered under conditions authorised by the competent authority;

(b) cleansing and disinfection of the holdings in accordance with rule 11;

(c) restocking of animals in accordance with Schedule V.

(4) The competent authority shall ensure that the following measures are applied to products derived from animals of susceptible species and produced during the period referred to in rule 54(1):

(a) fresh meat produced from the animals referred to in sub-rule (3)(a)(2)(ii) shall be subject to rule 53(4), for meat from ruminants, and in rule 53(6), for meat from porcine animals, respectively;

(b) milk and milk products produced from the animals referred to in sub-rule (3)(a)(2)(ii) shall undergo at least one of the treatments specified in Parts A and B of Schedule IX depending on the intended use and in compliance with the provisions in rule 52(4) to (8).

(5) Animals of susceptible species on holdings where the presence of previous or present infection with the foot-and-mouth disease virus has been officially ruled out in accordance with rule 54(3) may be subject to the measures provided for in rule 56.

Measures applicable in the vaccination zone after the completion of the survey and the classification of holdings until the foot-and-mouth disease and infection free status is recovered (Phase 3)

56. (1) The competent authority shall ensure that the measures provided for in sub-rules 2 to 6 are applied in the vaccination zone after the completion of the measures laid down in rule 55 and until the foot-and-mouth disease and infection-free status has been recovered in accordance with rule 57.

(2) The competent authority shall ensure that movement of animals of susceptible species between holdings situated in the vaccination zone is subject to authorisation.

(3) Movement of animals of susceptible species out of the vaccination zone shall be prohibited. By way of derogation from this prohibition, direct transport to a slaughterhouse for immediate slaughter of animals of susceptible species may be authorised under the conditions provided for in rule 53(3).

(4) By way of derogation from the prohibition in sub-rule (2), the competent authorities may authorise the transport of unvaccinated animals of susceptible species in accordance with the following provisions:

(a) within 24 hours of loading, all animals of susceptible species on the holding have been subjected to clinical examination and have not shown clinical signs of foot-and-mouth disease, and

(b) the animals have completed a standstill on the holding of origin of at least 30 days during which no animal of susceptible species has been introduced onto the holding, and

(c) the holding of origin is not situated in a protection or surveillance zone, and

(d) the animals intended for transport were either individually subjected with negative results to tests for the detection of antibodies against the foot-and-mouth disease virus at the end of the isolation period, or a serological survey was completed on that holding in accordance with point 2.2 of Schedule III irrespective of the species concerned;

(e) the animals were not exposed to any source of infection during their transportation from the holding of origin to the place of destination.

(5) Non-vaccinated offspring of vaccinated dams shall be prohibited from leaving the holding of origin unless being transported to:

(a) a holding within the vaccination zone of the same health status as the holding of origin;

(b) a slaughterhouse for immediate slaughter;

(c) a holding designated by the competent authority, from which the offspring are to be sent directly to the slaughterhouse;

(d) any holding, after having obtained a negative result in a serological test for the detection of antibody against the foot-and-mouth disease virus carried out on a sample of blood taken prior to dispatch from the holding of origin.

(6) Fresh meat produced from unvaccinated animals of susceptible species may be placed on the market inside and outside the vaccination zone under the following conditions:

(a) either the measures provided for in rule 55(3) have been completed in the entire vaccination zone or the animals are transported to the slaughterhouse under the conditions provided for in sub-rule (3) or (4)(d), and;

(b) the establishment shall be operated under strict veterinary control;

(c) only fresh meat produced from animals referred to in paragraph (a) or from animals reared and or slaughtered outside the vaccination zone or fresh meat referred to in sub-rule (8) shall be processed in the establishment;

(d) all such fresh meat shall bear the health mark in accordance with Chapter XI of Annex I to European Union Council Directive 64/433/EEC or in the case of meat from other biungulates, the health mark provided for in Chapter III of Annex I of European Union Council Directive 91/495/EEC, or in the case of minced meat

and meat preparations the health mark provided for in Chapter VI of Annex I of European Union Council Directive 94/65/EC;

(e) throughout the production process the fresh meat shall be clearly identified, and transported and stored separately from meat of different animal health status in accordance with these rules.

(7) Fresh meat produced from vaccinated animals of susceptible species or from non-vaccinated seropositive offspring of vaccinated dams slaughtered during the period referred to in sub-rule (1) shall bear the health mark provided for in European Council Directive 2002/99/EC and shall be stored and transported separately from meat not bearing that stamp and subsequently be transported in sealed containers to an establishment designated by the competent authorities for treatment in accordance with point 1 in Part A of Schedule VII.

(8) By way of derogation from sub-rule (7), fresh meat and trimmed offal produced from vaccinated large and small ruminants or their non-vaccinated seropositive offspring may be placed on the market within and outside the vaccination zone under the following conditions:

(a) the establishment shall be operated under strict veterinary control;

(b) only fresh meat excluding offal, which was subjected to the treatment described in point 1, 3 and 4 in Part A of Schedule VIII or fresh meat referred to in sub-rule (6) or produced from animals reared and, or slaughtered outside the vaccination zone, are processed in the establishment;

(c) all such fresh meat shall bear the health mark in accordance with Chapter XI of Annex I to European Directive 64/433/EEC or in the case of meat from other biungulates the health mark provided for in Chapter III of Annex I to European Directive 91/495/EEC, or in the case of minced meat and meat preparations the health mark provided for in Chapter VI of Annex I to European Directive 94/65/EC;

(d) throughout the production process the fresh meat shall be clearly identified, and transported and stored separately from meat which is of different animal health status in accordance with these rules.

(9) By way of derogation from sub-rule (7), fresh meat from vaccinated porcine animals and their non-vaccinated seropositive offspring, produced during the period from the beginning of the survey until the measures provided for in rule 55 have been completed in the entire vaccination zone and until at least three months have elapsed after the last outbreak recorded in that zone, may only be placed on the national market of Malta within and outside the vaccination zone under the following conditions:

(a) the establishment shall be operated under strict veterinary control;

(b) only fresh meat from animals originating in holdings complying with the conditions in rule 55(5) or fresh meat obtained from animals reared and slaughtered outside the vaccination zone are processed in the establishment;

(c) all such fresh meat shall bear a health mark to be decided in accordance with Article 4(3) of European Directive 2002/99/EC;

(d) throughout the production process the fresh meat shall be clearly identified, and transported and stored separately from meat of different animal health status in accordance with these rules.

(10) A Member State other than the territory of Malta may request a decision in accordance with European Community legislation to extend the marketing of the meat referred to in sub-rule (9) to its territory or part of its territory under conditions to be laid down under the same procedure.

(11) The rules for dispatch from the vaccination zone of fresh meat from vaccinated porcine animals produced after the period referred to in sub-rule (9) until free status has been regained in accordance with rule 59, shall be decided in accordance with the procedure provided for in rule 78(2)

(12) Compliance with the conditions provided for in sub-rule (6), sub-rule (8) and where applicable under the provisions of sub-rule (10), shall be certified by the competent authority. The competent authority shall supervise the control of compliance undertaken by the Veterinary Services and shall in the case of intra- European Community trade communicate to other Member States and the European Commission a list of those establishments which they have approved for such certification.

(13) By way of derogation from sub-rule (8) a special health mark which cannot be confused with the health mark referred to in sub-rules (8)(c) and (9)(c), may be decided in accordance with the procedure referred to in rule 78(2) for fresh meat of ruminants not subjected to the treatment in accordance with Part A of Schedule VIII, and minced meat and meat preparations produced from such meat, which are intended for placing on the market in a specific region of Malta.

(14) Milk and milk products produced from vaccinated animals may be placed on the market within and outside the vaccination zone, provided that depending on the final use for either human consumption or non-human consumption, it has undergone at least one of the treatments referred to in Parts A and B of Schedule IX. Such treatment shall have been undergone in an establishment located in the vaccination zone or in accordance with the provisions in rules 52(4) to (7).

(15) The collection and transport of samples of raw milk of animals of susceptible species, from holdings situated in the surveillance zone to a laboratory other than a veterinary diagnostic laboratory approved for diagnosis of foot-and-mouth disease, and the processing of the milk in such laboratories, shall be subject to official authorisation and to appropriate measures to avoid any possible spread of foot-and-mouth disease virus.

(16) The placing on the market of products of animal origin other than those referred to in sub-rules (6) to (11) and (13) to (15) shall be subject to the conditions provided for in rules 28, 29, 30 and 40.

Recovery of the foot-and-mouth disease and infection free status

57. The foot-and-mouth disease and infection free status of Malta or a region thereof shall be recovered in accordance with the procedure referred to in rule 78(2), taking into account the conditions referred to in rules 58 and 59.

Recovery of status following eradication of foot-and-mouth disease without emergency vaccination

58. (1) When Malta has been regionalised in accordance with rule 43 shall recover its previous foot-and-mouth disease and infection free status following the control and eradication of one or more outbreaks of foot-and-mouth disease without vaccination under the following conditions:

(a) all the measures provided for in rules 34 and 42 have been completed, and

(b) at least one of the following conditions applies:

(i) the relevant recommendations in the foot-and-mouth disease Chapter, as last amended, of the Animal Health Code of the OIE are met;

(ii) at least three months have elapsed after the last recorded outbreak of foot-and-mouth disease and clinical and laboratory surveillance carried out in accordance with Schedule III has confirmed the absence of infection with the foot-and-mouth disease virus in Malta or region concerned.

(2) Decisions on recovering a foot-and-mouth disease and infection-free status shall be adopted in accordance with the procedure referred to rule 78(2).

Recovery of status following eradication of foot-and-mouth disease with vaccination

59. (1) Malta, or any region thereof regionalised in accordance with rule 43, shall recover its previous foot-and-mouth disease and infection free status following the control and eradication of one or more outbreaks of foot-and-mouth disease with vaccination under the following conditions:

(a) all the measures provided for in rules 34, 42, 52, 53, 54 and 55 have been completed, and

(b) at least one of the following conditions applies:

(i) the relevant recommendations in the foot-and-mouth disease Chapter, as last amended, of the Animal Health Code of the OIE are met;

(ii) at least three months have elapsed since the slaughter of the last vaccinated animal and serological surveillance has been carried out in accordance with the guidelines established in accordance with rule 65(3);

(iii) at least six months have elapsed since the last outbreak of foot-and-mouth disease or the completion of emergency vaccination, what ever event occurred later, and in accordance with the guidelines established in accordance with rule 65(3), a serological survey based on the detection of antibodies against non-structural proteins of the foot-and-mouth disease virus has demonstrated the absence of infection in vaccinated animals.

(2) Decisions on recovering a foot-and-mouth and infection free status shall be adopted in accordance with the procedure referred to rule 78(2).

Modifications of measures to recover the foot-and-mouth disease and infection-free status

60. (1) By way of derogation from rule 58 it may be decided in accordance with the procedure referred to in rule 78(2), to withdraw the restrictions applied in accordance with these regulations after the requirements provided for in rules 34 and 42 have been met and the clinical and serological survey has been completed and confirmed the absence of foot-and-mouth disease virus infection.

(2) By way of derogation from rule 59 it may be decided in accordance with the procedure referred to in rule 78(2), to withdraw the restrictions applied in accordance with these rules after the clinical and serological survey provided for in rule 54 and the measures provided for in rule 55 have been completed and confirmed the absence of foot-and-mouth disease virus infection.

(3) Without prejudice to sub-rules (1) and (2) it may be decided in accordance with the procedure referred to in rule 78(2) that no animals of a susceptible species shall be removed from the territory or region of Malta where the outbreak of foot-and-mouth disease has occurred to another Member State until the foot-and-mouth disease and infection free status is recovered in accordance with the conditions of the Animal Health Code of the OIE, unless such animals:

(a) have not been vaccinated and are consigned directly to a slaughter house for immediate slaughter; or

(b) have been isolated for at least 30 days immediately prior to loading and have undergone a serological test for the detection of antibody against foot-and-mouth disease virus structural proteins, carried out with negative results on samples taken during the 10 days prior to loading.

(4) Without prejudice to sub-rule 2 it may be decided, in accordance with the procedure referred to in rule 78(2), that until the foot-and-mouth disease and infection

free status is recovered in accordance with the conditions of the Animal Health Code of the OIE the radius of the surveillance area around the vaccination zone referred to in rule 50(2) shall be reduced after the completion with satisfactory results of the measures provided for in rule 55.

Certification of animals of susceptible species and products derived from such animals for intra-Community trade

61. The competent authority shall ensure that additional certification for intra-Community trade in animals of susceptible species or products derived from such animals required in accordance with these rules shall be continued until the foot-and-mouth disease and infection free status of Malta or part of the territory, has been recovered in accordance with rules 58 and 59.

Movement of vaccinated animals of susceptible species after the recovery of the foot-and-mouth disease and infection-free status

62. (1) The dispatch from Malta to another Member State of animals of susceptible species vaccinated against foot-and-mouth disease, shall be prohibited.

(2) By way of derogation from the prohibition in sub-rule (1), the competent authority it may be decided in accordance with the procedure referred to in rule 78(1) to adopt specific measures with regard to vaccinated animals of susceptible species kept in zoos and included in a programme for wildlife conservation or kept on premises for farm animal resources, that have been listed by the competent authority as breeding nucleus of animals indispensable for the survival of the breed, subject to appropriate provisions in the Animal Health Code of the OIE.

CHAPTER III

PREVENTIVE MEASURES

Laboratories and establishments handling live foot-and-mouth disease virus

63. The competent authority shall ensure that:

(a) laboratories and establishments in which live foot-and-mouth disease virus, its genome, antigens or vaccines produced from such antigens are handled for research, diagnosis or manufacture are strictly controlled by the competent authorities;

(b) the handling of live foot-and-mouth disease virus for research and diagnosis is carried out only in approved laboratories listed in Part A of Schedule XI;

(c) the handling of live foot-and-mouth disease virus for the manufacturing of either inactivated antigens for the production of vaccines or vaccines and related research is carried out only in the approved establishments and laboratories listed in Part B of Schedule XI;

(d) the laboratories and establishments referred to in paragraphs (b) and (c) are operated at least according to the biosecurity standards set out in Schedule XII.

National Laboratories

64. (1) Member States shall ensure that:

(a) laboratory testing for foot-and-mouth disease is carried out in laboratories authorised for such testing by the competent authorities;

(b) laboratory testing to confirm the presence of foot-and-mouth disease virus or other vesicular disease viruses is carried out in accordance with rule 65 by one of the laboratories listed in Part A of Schedule XI;

(c) one of the laboratories listed in Part A of Schedule XI shall be designated as the national reference laboratory for Malta;

(d) the national reference laboratory carries out at least the functions and duties set out in Schedule XV;

(e) the national reference laboratory referred to in paragraph (c) liases with the Community Reference Laboratory according to European Community legislation and in particular ensures the sending of appropriate samples to the Community Reference Laboratory.

(2) The national reference laboratory referred to in sub-rule (1)(c) of one Member State may provide the services of a national reference laboratory to Malta. In this case, the cooperation shall be formalised in a mutual agreement between the competent authorities of Malta and of the Member States concerned, which shall be notified to the Commission. Such cooperation shall be listed in the special column in the table in Part A of Schedule XI.

(3) (a) The competent authority shall ensure that laboratory investigations provided for in these regulations are first of all carried out to confirm or rule out foot-and-mouth disease and to exclude other vesicular diseases.

(b) Where an outbreak of foot-and-mouth disease has been confirmed and the serotype of the virus was identified, that virus shall be antigenically characterised in relation to the reference vaccine strains, where necessary with the assistance of the Community Reference Laboratory.

(c) Samples from domestic livestock showing signs of vesicular disease which are negative for foot-and-mouth disease virus and, where relevant, Swine Vesicular Disease virus shall be sent to the Community Reference Laboratory for further investigation.

(4) The competent authority shall ensure that the national reference laboratory on their territory is adequately equipped and staffed with the appropriate numbers of trained personnel

to carry out the laboratory investigations required in accordance with this Directive.

Security standards and guidelines for surveillance, code of conduct for approved laboratories and establishments handling live foot-and-mouth disease virus

65. (1) An Operational Manual for Minimum Standards for Laboratories working with the foot-and-mouth disease virus in vitro and in vivo may be adopted in accordance with the procedure referred to in rule 78(1).

(2) Guidelines for the surveillance required to recover the foot-and-mouth disease and infection free status may be adopted in accordance with the procedure referred to in rule 78(1).

(3) A uniform code of good conduct for the security systems applied in the establishments and laboratories listed in Parts A and B of Schedule XI may be adopted in accordance with the procedure referred to in rule 78(1).

Standards and tests for the diagnosis of foot-and-mouth disease and for the differential diagnosis of other vesicular diseases

66. (1) The competent authority shall ensure that the national laboratories use the tests and standards for diagnosis set out in Schedule XIII.

(2) A decision regarding the suitable arrangements for the purchase, storage and supply to national laboratories of sufficient quantities of specific reagents or diagnostic tests in case of an emergency, in particular with regard to the measures provided for in rule 54(3) may be adopted in accordance with the procedure referred to in rule 78(1).

(3) An Operational Manual for the diagnosis of foot-and-mouth disease and the differential diagnosis of vesicular diseases other than swine vesicular disease, may be adopted in accordance with the procedure referred to in rule 78(1).

Contingency plans

67. (1) The competent authority shall draw up a contingency plan specifying the national measures required to maintain a high level of foot-and-mouth disease awareness and preparedness, and environmental protection and to be implemented in the event of an outbreak of foot-and-mouth disease.

(2) The contingency plan shall provide for the access to all facilities, equipment, personnel and other appropriate materials necessary for the rapid and efficient eradication of an outbreak of foot-and-mouth disease, it shall ensure coordination with neighbouring Member States and encourage cooperation with neighbouring third countries.

(3) The contingency plan shall provide for measures to be implemented in the event of a worst case scenario as referred to in point 12 of Schedule XVII and shall give indications of:

(a) the vaccine requirements considered necessary in the event of emergency vaccination, and

(b) the regions containing densely populated livestock areas, taking into account the criteria set down in Schedule X.

(4) The contingency plan shall ensure that all necessary arrangements are made to prevent any avoidable damage to the environment in the event of an outbreak, while ensuring at the same time the highest disease control level, and minimise any damage caused as a result of an outbreak, in particular if it is necessary to bury or burn the carcasses of dead or killed animals on site.

(5) The criteria and requirements for drawing up the contingency plan shall be those set out in Schedule XVI. Those criteria and requirements may be amended taking into account the specific nature of foot-and-mouth disease and progress made in the development of disease control and environmental protection measures in accordance with the procedure referred to in rule 78(1).

(6) The Commission shall examine the contingency plans in order to determine whether they permit the objective provided for in sub-rule (1) to be attained and shall suggest to the Member State concerned any amendments required, in particular to ensure that such plans are compatible with those of the other Member States.

(7) The contingency plans shall be approved in accordance with the procedure referred to in rule 78(1).

(8) The competent authority shall ensure that significant modifications in their approved contingency plans are notified to the European Commission without delay.

(9) The revised contingency plans may subsequently be approved in accordance with the procedure referred to in rule 78(1), to take into account developments in the situation.

(10) In any case, every five years the competent authority shall update its contingency plan in particular in the light of realtime alert exercises referred to in rule 68, and submit it to the Commission for approval in accordance with the procedure referred to in rule 78(1).

Real-time alert exercises

68. (1) The competent authority shall ensure that real-time alert exercises are carried out in accordance with their approved contingency plan and Schedule XVI.

(2) The competent authority shall ensure that, where possible and practical, real-time alert exercises are carried out in close collaboration with the competent authorities of neighbouring Member States or third countries.

(3) The competent authority shall inform the European Commission about the main results of real-time alert exercises. That information shall be submitted to the Commission as part of the information required in Article 8 of European Council Directive 64/432/EEC.

National/Central disease control centres— Functions and duties

69. (1) The competent authority shall ensure that a fully functional national/central disease control centre may be immediately established in the event of foot-and-mouth disease outbreaks.

(2) The national/central disease control centre shall first of all direct and monitor the operations of local disease control centres as provided for in rule 70. Certain functions originally attributed to the national/central disease control centre may subsequently be transferred to the local disease control centre operated at the administrative level provided for in Article 2(2)(p) of European Council Directive 64/432/EEC or higher provided that the tasks of the national disease control centre are not compromised.

(3) The national/central disease control centre shall be at least responsible for:

(a) designing the necessary control measures;

(b) ensuring the prompt and efficient implementation of those measures by the local disease control centres;

(c) deploying staff and other resources to local disease control centres;

(d) providing information to the European Commission, to the competent authorities of other Member States and other national authorities including

competent environmental authorities and bodies, as well as veterinary, agricultural and trading organisations and bodies;

(e) organising an emergency vaccination campaign and also the delimitation of vaccination zones;

(f) liasing with diagnostic laboratories;

(g) liasing with competent environmental authorities to coordinate the actions on veterinary and environmental safety;

(h) liasing with the media;

(i) liasing with the enforcement bodies to ensure adequate implementation of specific legal measures.

National/Central disease control centres — Technical requirements

70. (1) The competent authority shall ensure that the national/central disease control centres have all the necessary means including staff, facilities and equipment, to manage an efficient eradication campaign.

(2) The means referred to in sub-rule (1) shall include at least the following:

(a) a herd identifier and animal location system, preferably computerised;

(b) all suitable means of communication including telephones, fax and if possible facilities for communication with the media;

(c) a communication system allowing exchange of information with the local disease control centres, the laboratories and other relevant organisations, preferably computerised;

(d) maps and other sources of information that can be used in directing control measures;

(e) a shared daily journal which shall be maintained to record in chronological order all the events associated with an outbreak of foot-and-mouth disease and allowing different activities to be linked and coordinated;

(f) lists of national and international organisations and laboratories that are interested in an outbreak of foot-and-mouth and shall be contacted in such an event;

(g) lists of staff and other persons who may be called upon immediately to serve at local disease control centres or in expert groups provided for in rule 73 in the event of an outbreak of foot-and-mouth disease;

(h) lists of competent environmental protection authorities and bodies to contact in the event of an outbreak of foot-and-mouth disease;

(i) maps identifying appropriate processing site areas;

(j) lists of treatment and processing undertakings authorised to treat or process animal carcasses and animal waste that could be commissioned in the event of an outbreak of foot-and-mouth disease, in particular, indicating their capacity, address and other contact details;

(k) lists of measures to monitor and control disinfectant runoff as well as body tissue and fluid displacement into the surrounding environment as a result of carcass decomposition, particularly into surface waters and groundwaters.

Set-up, functions and duties of local disease control centres

71. (1) The competent authority shall ensure that fully functional local disease control centres may be established immediately in the event of outbreaks of foot-and-mouth disease.

(2) The competent authority shall ensure that within the framework of their contingency plans, provisions are made for likely locations of local disease control centres, their organisation, staff, accommodation, facilities and equipment, management systems, communication lines as well as information channels.

(3) The competent authority shall ensure the local disease control centres act in close coordination and cooperation with the national/central disease control centre, in particular in relation to the measures provided for in rule 68(3)(b).

(4) The competent authority shall ensure that local disease control centres have the necessary organisation to ensure the prompt implementation of the measures provided for in these rules to be applied in the event of an outbreak of foot-and-mouth disease.

Technical requirements of local disease control centres

72. (1) The competent authority shall ensure that the local disease control centres have staff, facilities and equipment as required, and a clear management structure and effective management to ensure the prompt implementation of the measures relating to the epidemiological inquiry, environmental protection, processing of carcasses from infected herds, official surveillance of the zones, tracing, welfare and emergency slaughter, cleansing and disinfection and others measures of sanitation, emergency vaccination, and all other policy decisions.

(2) The local disease control centres shall have at least:

(a) one telephone line reserved for communication with the national disease control centre accessible phone lines where farmers and other rural residents can obtain recent, accurate information about the measures taken;

(b) field staff equipped with necessary tools for communication and effective management of all necessary data;

(c) a record system, preferably computer-based, connected to the national disease control centre and to all necessary databases, laboratories and other organisations;

(d) a shared daily journal which shall be maintained to record in chronological order all the events associated with an outbreak of foot-and-mouth and allowing different activities to be linked and coordinated;

(e) up-to-date lists of persons, including private veterinarians, and local organisations in each region who shall be contacted and may be involved in the event of an outbreak of foot-and-mouth disease;

(f) up-to-date lists of holdings to which the provisions of rules 15 and 18 may be applied in the case of an outbreak of foot-and-mouth disease;

(g) up-to-date inventories of possible burning or burial places for animals killed in accordance with these rules and to be processed in accordance with Community and national legislation on the protection of the environment;

(h) up-to-date list of competent environmental authorities in each region, as well as other environmental bodies who must be contacted and are to be involved in the event of an outbreak of foot-and-mouth disease;

(i) maps identifying suitable disposal sites for burial of carcasses that will not present a risk of harm to the environment, in particular to surface waters or groundwaters;

(j) list of treatment and disposal undertakings authorised to treat or dispose of animal carcasses and animal waste;

(k) list of measures to monitor and control disinfectant runoff as well as body tissue and fluid displacement into the surrounding environment as a result of carcass decomposition, particularly into surface waters and groundwaters.

Expert group

73. (1) The competent authority shall create a permanently operational expert group, which is composed of epidemiologists, veterinary scientists and virologists in a balanced way, to maintain expertise in order to assist the competent authority in ensuring preparedness against an outbreak of foot-and-mouth disease:

Provided that by way of derogation hereof, the competent authority may arrange a formalised agreement with other Member States on mutual assistance in regard of the expert group. These arrangements shall be detailed in the contingency plans referred to in rule 66.

(2) In case of a suspicion of an outbreak of foot-and-mouth disease the expert group shall at least:

(a) evaluate the clinical picture and the epidemiological situation;

(b) give advice regarding the sampling and analyses needed for diagnosing the foot-and-mouth disease together with the additional actions and measures to be taken.

(3) In case of an outbreak of foot-and-mouth the expert group shall at least:

(a) conduct at least in the index case and if necessary on the spot, an evaluation of the clinical picture and an analysis of the epidemiological inquiry in order to collect the necessary data for determining:

(i) the origin of the infection;

(ii) the date of introduction of the infectious agent;

(iii) the possible spread of the disease;

(b) report to the Chief Veterinary Officer and the national disease control centre;

(c) give advice on screening, sampling, test procedures, control and the other measures to be applied and on the strategy to be implemented, including advice on biosecurity measures on holdings or on premises referred to in rule 16, and in relation to emergency vaccination;

(d) follow up and guide the epidemiological inquiry;

(e) supplement the epidemiological data with geographical, meteorological and other necessary information;

(f) analyse the epidemiological data and perform risk assessments at regular intervals;

(g) assist in ensuring that the processing of animal carcasses and animal waste is done with a minimum of detrimental effect on the environment.

National antigen and vaccine banks

74. (1) Malta may within the framework of the contingency plan establish or maintain national antigen and vaccine banks for the storage of reserves for emergency vaccination of antigens or vaccines authorised in accordance with European Council Directive 2001/82/EC.

(2) The competent authority may retain establishments for the packaging and storage of vaccines in the case of emergency vaccination.

(3) The competent authority shall ensure that the antigen and formulated vaccine in the national antigen and vaccine banks comply with the minimum standards laid down for the Community antigen and vaccines bank with respect to safety, sterility and content of non-structural proteins.

(4) In the event that Malta maintains a national antigen and vaccine bank, the competent authority shall inform the European Union Commission about the antigen and vaccine stocks kept. Such information shall be submitted to the European Commission every 12 months as part of the information required by Article 8 of European Council Directive 64/432/EEC. The information on quantities and subtypes of antigens or authorised vaccines stored in the national antigen and vaccine bank shall be treated as classified information and in particular shall not be published.

Additional measures to prevent and control foot-and-mouth disease

75. (1) Without prejudice to Regulation (EC) No 1774/2002, and any European Comunity legislation, the competent authority shall ensure that the prohibition on swill feeding in accordance with Community and national legislation is applicable to all animals irrespective of their use or the place inhabited by these animals. Detailed rules for the control measures to be applied by the competent authority may be adopted in accordance with the procedure referred to in rule 78(1).

(2) Detailed rules for the control of foot-and-mouth disease in animals referred to in the second sentence of the definition of 'animal of a susceptible species' in rule 2 hereof may be adopted in accordance with the procedure referred to in rule 78(1).

(3) Immediately after the competent authority has information that wild animals are suspected of being infected with foot-and-mouth disease, it shall take all appropriate measures to confirm or rule out the presence of the disease by investigations of all wild

animals of susceptible species shot or found dead, including laboratory testing. It shall inform owners of animals of susceptible species and hunters on the suspicion.

(4) As soon as the competent authority has confirmation of a primary case of foot-and-mouth disease in wild animals, it shall immediately apply the measures provided for in Part A of Schedule XVII in order to reduce the spread of disease, and shall draw up a plan for the eradication of foot-and-mouth disease in accordance with Part B of Schedule XVII. It shall inform owners of animals of susceptible species and hunters of the confirmed case.

CHAPTER IV

IMPLEMENTING MEASURES

Penalties

76. The competent authority shall lay down the rules on penalties applicable to infringements of these regulations and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The competent authority shall notify those provisions to the Commission and shall notify it without delay of any subsequent amendment affecting them.

Procedures for implementing specific articles, for the adoption of further detailed rules for the implementation of these rules and for amending the Schedules

77. (1) Detailed rules for the implementation of rules 69(2) and 77(2) may be adopted in accordance with the procedure referred to in rule 78(1).

(2) Further detailed rules for the implementation of these regulations may be adopted in accordance with the procedure referred to in rule 78(1).

(3) The Schedules to these regulations may be amended in accordance with the procedure referred to in rule 78(1) or, in the case of Schedule XI, in accordance with the procedure referred to in rule 78(2).

Committee procedure

78. (1) Where reference is made to this sub-rule, Articles 5 and 7 of European Council Decision 1999/468/EC shall apply. The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

(2) Where reference is made to this sub-rule, Articles 5 and 7 of Decision 1999/468/EC shall apply. The period laid down in Article 5(6) of that Decision shall be set at 15 days.

SCHEDULE I

DEFINITION OF OUTBREAK

An outbreak shall be declared where a holding meets one or more of the following criteria:

1. Foot-and-mouth disease virus has been isolated from an animal, any product derived from that animal, or its environment.

2. Clinical signs consistent with foot-and-mouth disease are observed in an animal of a susceptible species, and the viral antigen or viral ribonucleic acid (RNA) specific to one or more of the serotypes of foot-and-mouth disease virus has been detected and identified in samples collected from the animal or animals of the same epidemiological group.

3. Clinical signs consistent with foot-and-mouth disease are observed in an animal of a susceptible species and the animal or its cohorts are positive for antibody to foot-and-mouth disease virus structural or non-structural proteins, provided that previous vaccination, residual maternal antibodies or non-specific reactions can be excluded as possible causes of seropositivity.

4. Viral antigen or viral RNA specific to one or more of the serotypes of foot-and-mouth disease virus has been detected and identified in samples collected from animals of susceptible species and the animals are positive for antibody to foot-and-mouth disease virus structural or non-structural proteins, provided that in the case of antibodies to structural proteins previous vaccination, residual maternal antibodies or non-specific reactions can be excluded as possible causes of seropositivity.

5. An epidemiological link has been established to a confirmed foot-and-mouth disease outbreak and at least one of the following conditions applies:

(a) one or more animals are positive for antibody to foot-and-mouth disease virus structural or non-structural proteins, provided that previous vaccination, residual maternal antibodies or non-specific reactions can be excluded as possible causes of seropositivity;

(b) viral antigen or viral RNA specific to one or more of the serotypes of foot-and-mouth disease virus has been detected and identified in samples collected from one or more animals of susceptible species;

(c) serological evidence of active infection with foot-and-mouth disease by detection of seroconversion from negative to positive for antibody to foot-and-mouth disease virus structural or non-structural proteins has been established in one or more animals of susceptible species, and previous vaccination, residual maternal antibodies or non-specific reactions can be excluded as possible causes of seropositivity.

Where a previously seronegative status cannot be reasonably expected, this detection of seroconversion is to be carried out in paired samples collected from the same animals on two or more occasions at least 5 days apart, in the case of structural proteins, and at least 21 days apart, in the case of non-structural proteins.

(d) Clinical signs consistent with foot-and-mouth disease are observed in an animal of a susceptible species

SCHEDULE II

NOTIFICATION OF DISEASE AND FURTHER EPIDEMIOLOGICAL INFORMATION TO BE PROVIDED BY THE COMPETENT AUTHORITY WHERE FOOT-AND-MOUTH DISEASE HAS BEEN CONFIRMED

1. Within 24 hours from the confirmation of each primary outbreak or case in premises or means of transport referred to in regulation 16, the competent authority must notify by means of the Animal Disease Notification System established in accordance with Article 5 of European Council Directive 82/894/EEC:

   (a) date of dispatch;
   (b) time of dispatch;
   (c) country of origin;
   (d) name of disease and type of virus, where appropriate;
   (e) serial number of outbreak;
   (f) type of outbreak;
   (g) reference number of outbreak linked to this outbreak;
   (h) region and geographical location of the holding;
   (i) other region affected by restrictions;
   (j) date of confirmation and method used for confirmation;
   (k) date of suspicion;
   (l) date of estimation of first infection;
   (m) origin of disease, as far as can be indicated;
   (n) disease control measures taken.

2. In case of primary outbreaks or cases in premises or means of transport referred to in regulation 16, in addition to the data referred to in point 1, the competent authority must also forward the following information:

   (a) the number of animals of each susceptible species in the outbreak, or premises and means of transport referred to in rule 16;
   (b) for each species and type (breeding, fattening, slaughter, etc.), the number of dead animals of susceptible species on the holding, slaughterhouse or means of transport;

(c) for each type (breeding, fattening, slaughter, etc.), the morbidity of the disease and the number of animals of susceptible species in which foot-and-mouth disease has been confirmed;

(d) the number of animals of susceptible species killed in the outbreak, slaughterhouse or means of transport;

(e) the number of carcasses processed and disposed of;

(f) the distance of the outbreak from the nearest holding on which animals of susceptible species are kept;

(g) if foot-and-mouth disease was confirmed in a slaughterhouse or means of transport, the location of the holding or holdings of origin of the infected animals or carcasses.

3. In case of secondary outbreaks, the information referred to in points 1 and 2 must be forwarded within the time limit laid down in Article 4 of European Union Council Directive 82/894/EEC.

4. The competent authority shall ensure that the information to be provided in relation to any outbreak or case of foot-and-mouth disease in a holding, slaughterhouse or means of transport in accordance with points 1, 2 and 3 is followed as soon as possible by a written report to the Commission and the other Member States including at least:

(a) the date on which the animals of susceptible species on the holding, slaughterhouse or means of transport were killed and their carcasses processed;

(b) the results of the tests carried out on samples taken when animals of susceptible species were killed;

(c) where the derogation provided for in rule 17 has been applied, the number of animals of susceptible animals killed and processed and where applicable the number of animals of susceptible species which are to be slaughtered at a later date and the time limit laid down for their slaughter;

(d) any information relating to the possible origin of the disease or the origin of the disease if this has been ascertained;

(e) in the case of a primary outbreak or a case of foot-and-mouth disease in a slaughterhouse or means of transport, the genetic type of virus responsible for the outbreak or the case;

(f) in cases where animals of susceptible species have been killed in contact holdings or in holdings containing animals of susceptible species suspected of being infected with foot-and-mouth disease virus, information on:

(i) the date of killing and the number of animals of susceptible species of each category killed in each holding and in cases where animals of susceptible species in contact holdings were not killed, information must be provided on the reasons for this decision,

(ii) the epidemiological link between the outbreak or case of foot-and-mouth disease and each contact holding or the reasons that have induced suspicion of foot-and-mouth disease in each suspected holding,

(iii) the results of the laboratory tests carried out on the samples taken from the animals of susceptible species in the holdings and when they were killed.

5. Where the Animal Disease Notification System is for whatever reason temporarily not operational, other means of communication shall be employed.

SCHEDULE III

SURVEY

1. **Clinical examination**

1.1. Holdings must undergo clinical examinations of all animals of susceptible species for signs or symptoms of foot-and-mouth disease.

1.2. Special emphasis must be laid on animals which may have been exposed to foot-and-mouth disease virus with a high probability, notably transport from holdings at risk or close contact to persons or equipment that had close contact to holdings at risk.

1.3. The clinical examination must take into account the transmission of foot-and-mouth disease, including the incubation period referred to in the definition "incubation period" in rule 2 of these rules, and the way in which animals of susceptible species are kept.

1.4. Relevant records kept on the holding must be examined in detail with particular regard to data required for animal health purposes by European Community legislation and, where available, on morbidity, mortality and abortion, clinical observations, changes in productivity and feed intake, purchase or sale of animals, visits of persons likely to be contaminated and other anamnestically important information.

2. **Procedures for sampling**

2.1. *General provisions*

2.1.1. Serological sampling shall be carried out:

2.1.1.1. according to the recommendations of the epidemiological team established within the expert group referred to in rule 73, and

2.1.1.2. in support of tracing and the provision of evidence, taking also into account the definition in Schedule I, for the absence of previous infection.

2.1.2. Where sampling is carried out in the framework of disease surveillance after an outbreak, actions shall not commence before at least 21 days have elapsed since the elimination of susceptible

animals on the infected holding(s) and the carrying out of preliminary cleansing and disinfection, unless otherwise provided for in this Schedule.

2.1.3. Sampling of animals of susceptible species shall be carried out in accordance with the provisions of this Schedule in each case where sheep and goats or other susceptible animals not displaying clear clinical signs are involved in the outbreak, and in particular where such animals have been isolated from bovine and porcine animals.

2.2. *Sampling on holdings*

In holdings where the presence of foot-and-mouth disease is suspected but in the absence of clinical signs, sheep and goats, and on recommendation of the epidemiological team other susceptible species, should be examined pursuant to a sampling protocol suitable to detect 5 % prevalence with at least 95 % level of confidence.

2.3. *Sampling in protection zones*

In order to seek the repeal in accordance with regulation 34 of the measures provided for in rules 19 to 33, all holdings within the perimeters of the protection zone where sheep and goats have not been in direct and close contact with bovine animals during a period of at least 21 days prior to taking the samples shall be examined pursuant to a sampling protocol suitable to detect 5 % prevalence of disease with at least 95 % level of confidence.

However, the competent authorities may decide where epidemiological circumstances allow and in particular in application of the measures provided for in rule 34(1)(b), that samples are taken not earlier than 14 days after the elimination of susceptible animals on the infected holding(s) and the carrying out of preliminary cleansing and disinfection, under the condition that the sampling is carried out in accordance with point 2.3 using statistical parameters suitable to detect 2 % prevalence of disease within the herd with at least 95 % level of confidence.

2.4. *Sampling in surveillance zones*

In order to seek the repeal in accordance with rule 42 of the measures provided for in rules 35 to 41, holdings within the perimeters of the surveillance zone where the presence of foot-and-mouth disease in the absence of clinical signs must be suspected, notably where sheep and goats are

kept, shall be examined. For the purpose of this survey the model of a multistage sampling shall be sufficient, provided that samples are taken:

2.4.1. from holdings in all administrative units within the perimeter of the zone where sheep and goats have not been in direct and close contact with bovine animals during a period of at least 30 days prior to taking the samples, and

2.4.2. from as many holdings referred to above as necessary to detect with at least 95 % level of confidence at least one infected holding if the estimated prevalence of the disease was 2 % equally distributed throughout the zone, and

2.4.3. from as many sheep and goats per holding as necessary to detect 5 % prevalence of disease within the herd with at least 95 % level of confidence, and from all sheep and goats if there are less than 15 sheep and goats on the holding.

2.5. *Sampling for monitoring*

2.5.1. For monitoring the areas outside the zones established in accordance with the provisions of rule 19, and in particular to substantiate the absence of infection in the sheep and goat population which is not in close and direct contact with non-vaccinated bovine or porcine animals, a sampling protocol recommended for monitoring purposes by the OIE or a sampling protocol as provided for in paragraph 2.4 shall be applied with the difference compared to paragraph 2.4.2 that the estimated herd prevalence shall be set at 1 %.

3. The number of samples calculated in accordance with requirements in paragraphs 2.2, 2.3 and 2.4.3 shall be increased in order to take into account the established diagnostic sensitivity of the test employed.

SCHEDULE IV

PRINCIPLES AND PROCEDURES FOR CLEANSING AND DISINFECTION

1. **General principles and procedures**

1.1. Cleansing and disinfection operations as provided for in rule 11 shall be carried out under official supervision and in accordance with the instructions given by the official veterinarian.

1.2. The disinfectants to be used and their concentrations shall be officially recognised by the competent authority to ensure destruction of foot-and-mouth virus.

1.3. The activity of disinfectants must not be impaired by prolonged storage.

1.4. The choice of disinfectants and of procedures for disinfection should be made taking into account the nature of the premises, vehicles and objects which are to be treated.

1.5. The conditions under which degreasing agents and disinfectants are used must ensure that their efficacy is not impaired. In particular technical parameters provided by the manufacturer, such as pressure, minimum temperature and required contact time must be observed. The activity of the disinfectant must not be compromised by interaction with other substances, such as degreasing agents.

1.6. *Independently of the disinfectant used, the following general rules shall apply:*

1.6.1. thorough soaking of bedding and litter as well as faecal matter with the disinfectant,

1.6.2. washing and cleaning by careful brushing and scrubbing of all surfaces possibly contaminated and in particular of the ground, floors, ramps and walls after the removal or dismantling, where possible, of equipment or installations otherwise impairing the effective cleansing and disinfection procedures,

1.6.3. then further application of disinfectant for a minimum contact time as stipulated in the manufacturers recommendations;

1.6.4. the water used for cleaning operations is to be disposed of in such a way as to avoid any risk of spreading the foot-and-mouth disease virus and in accordance with the instructions of the official veterinarian.

1.7. Where washing is carried out with liquids applied under pressure and following the disinfection, recontamination of the previously cleansed or disinfected parts must be avoided.

1.8. Washing, disinfecting or destroying of equipment, installations, articles or compartments likely to be contaminated should be included.

1.9. Cleansing and disinfection operations required in the framework of these regulations must be documented in the holding register or, in the case of vehicles, in the log-book and where official approval is required be certified by the supervising official veterinarian.

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

2.1. *Preliminary cleansing and disinfection*

2.1.1. During the killing of the animals all necessary measures shall be taken to avoid or minimise the dispersion of foot-and-mouth virus. This shall include among other things the installation of temporary disinfection equipment, supply of protective clothing, showers, decontamination of used equipment, instruments and facilities and the interruption of power supply to the ventilation.

2.1.2. Carcasses of killed animals must be sprayed with disinfectant and removed from the holding in covered and leak-proof containers for processing and disposal.

2.1.3. As soon as the carcasses of the animals of susceptible species have been removed for processing and disposal, those parts of the holding in which these animals were housed and any parts of other buildings, yards, etc. contaminated during killing, slaughter or post-mortem examination should be sprayed with disinfectants approved for this purpose.

2.1.4. Any tissue or blood which may have been spilled during slaughter or post-mortem examination and any gross contamination of buildings, yards, utensils, etc. should be carefully collected and disposed of with the carcasses.

2.1.5. The used disinfectant shall remain on the surface for at least 24 hours.

2.2. *Final cleansing and disinfection*

2.2.1. Grease and dirt should be removed from all surfaces by the application of a degreasing agent and washed with cold water.

2.2.2. After washing with cold water further spraying with disinfectant should be applied.

2.2.3. After seven days the premises should be treated again with a degreasing agent, rinsed with cold water, sprayed with dis infectant and rinsed again with cold water.

3. **Disinfection of contaminated bedding, manure and slurry**

3.1. The solid phase of manure and used bedding should be stacked to heat, preferably by adding 100 kg granulated quick lime on 1 m^3 manure, ensuring a temperature of at least 70 °C throughout the stack, sprayed with disinfectant and left for at least 42 days, during which the stack should be either covered or regulation stacked to ensure thermic treatment of all layers.

3.2. The liquid phase of manure and slurry should be stored for at least 42 days after the last addition of infective material. This period may be extended if the slurry has been heavily contaminated or during adverse weather conditions. This period may be shortened if disinfectant has been added so as to alter the pH sufficiently throughout the substance to destroy the foot-and-mouth disease virus.

4. **Special cases**

4.1. Where for technical or security reasons the cleansing and disinfection procedures cannot be completed in accordance with these regulations, the buildings or premises must be cleansed and disinfected as much as possible to avoid spread of the foot-and-mouth disease virus and must remain unoccupied by animals of susceptible species for at least 1 year.

4.2. By way of derogation from points 2.1 and 2.2, in case of open-air holdings, the competent authority may establish specific procedures for cleaning and disinfection, taking into account the type of holding and the climatic conditions.

4.3. By way of derogation from point 3, the competent authority may establish specific procedures for the disinfection of dung and manure in accordance with scientific evidence that the procedure ensure effective destruction of the foot-and-mouth disease virus.

SCHEDULE V

RESTOCKING OF HOLDINGS

1. **General principles**

1.1. Restocking should not commence until 21 days after completion of the final disinfection of the holding.

1.2. *Animals for restocking can only be introduced under the following conditions:*

1.2.1. the animals shall not come from areas subject to animal health restrictions in relation to foot-and-mouth disease;

1.2.2. the competent authority must be satisfied that any possible residual foot-and-mouth disease virus can be detected in the animals intended for restocking either on the base of clinical signs, in the case of bovine or porcine animals, or though laboratory investigations in the case of other species susceptible to foot-and-mouth disease, carried out at the end of the observation period specified in paragraph 1.3;

1.2.3. in order to ensure an adequate immune response referred to in paragraph 1.2.2 in the animals intend for restocking, the animals must:

1.2.3.1. either originate in and come from a holding situated in an area of at least 10 km radius centred on that holding where there was no outbreak of foot-and-mouth disease for at least 30 days, or

1.2.3.2. the animals have been tested with negative results in an assay as described in Schedule XIII for the detection of antibodies against the foot-and-mouth disease virus carried out on samples taken prior to introduction onto the holding.

1.3. *Irrespective of the type of farming practised on the holding, re-introduction must conform with the following procedures:*

1.3.1. animals must be introduced in all units and buildings of the holding involved;

1.3.2. in the case of a holding consisting of more than one unit or building, re-introduction is not necessary for every unit or building at the same time;

However no animals of species susceptible to foot-and-mouth disease may leave the holding until all the re-introduced animals in all units and buildings have fulfilled all restocking procedures.

1.3.3. animals must be subjected to clinical inspection every three days for the first 14 days following the introduction;

1.3.4. during the period from 15 to 28 days after re-introduction, animals are to be subjected to clinical inspection once every week;

1.3.5. not earlier than 28 days after the last re-introduction, all animals must be clinically examined and samples for testing for the presence of antibody against foot-and-mouth disease virus shall be taken in accordance with the requirements of point 2.2 of Schedule III;

1.4. The restocking procedure shall be considered completed when the measures provided for in point 1.3.5 have been completed with negative results.

2. **Extension of measures and derogations**

2.1. *The competent authority may impose:*

2.1.1. the use of sentinel animals, in particular in holdings difficult to clean and disinfect and notably openair holdings. Detailed provision on the use of sentinels may be laid down in accordance with the procedure referred to in rule 78(1).

2.1.2. Additional safeguard and control measures within the framework of restocking.

2.2. The competent authorities may derogate from the measures provided for in points 1.3.2 to 1.3.4 of this Schedule where restocking is carried out after 3 months have elapsed following the last outbreak in an area of 10 km radius centred on the holding subject to the restocking operation.

3. **Restocking in connection with emergency vaccination**

3.1. Restocking in a vaccination zone established in accordance with rule 50 shall be carried out either in accordance with paragraphs 1 and 2 of this Schedule or in accordance with rules 56(2) or (4)(a), (c) and (d).

3.2. *The competent authority may authorise the restocking of holdings situated outside the vaccination zone with vaccinated animals after the completion of the measures provided for in regulation 59 and under the following conditions:*

3.2.1. the proportion of vaccinated animals used for restocking exceeds 75 % in which case, not earlier than 28 days after the last re-introduction of animals of susceptible species, the vaccinated animals are tested for the detection of antibodies against non-structural proteins, randomly, the sampling using the statistical parameters provided for in point 2.2 of Schedule III and for the non-vaccinated animals the provisions of paragraph 1 shall apply, or

3.2.2. The proportion of vaccinated animals does not exceed 75 % in which case the non-vaccinated animals shall be considered sentinels and provisions of paragraph 1 shall apply.

SCHEDULE VI

RESTRICTIONS ON THE MOVEMENT OF EQUIDAE

1. **Minimum measures**

Where at least one outbreak of foot-and-mouth disease has been confirmed in accordance with rule 10, the competent authority shall ensure that equidae are not dispatched to other Member States, unless accompanied in addition to the identification document provided for in Decisions 93/623/EEC or 2000/68/EC by an animal health certificate provided for in Annex C of European Council Directive 90/426/EEC.

2. **Recommended additional measures**

2.1. *Measures during the stand-still*

In the case where the competent authorities apply a complete stand-still as provided for in rule 7(3), transport of equidae from holdings under restrictions laid down in rules 4 and 10 may be authorised for equidae which need special veterinary treatment in premises without animals of susceptible species, if the following conditions are met:

2.1.1. the emergency must be documented by the veterinary surgeon on call 24 hours per day, 7 days per week;

2.1.2. the agreement of the clinic of destination must be producible;

2.1.3. the transport operation must be authorised by the competent authorities who must be reachable 24 hours per day, 7 days per week;

2.1.4. equidae must be accompanied during the transport by an identification document in accordance with Decisions 93/623/EEC or 2000/68/EC;

2.1.5. the on-call official veterinarian must be informed about the route prior to departure;

2.1.6. equidae must be groomed and treated with an effective disinfectant;

2.1.7. equidae must travel in dedicated equine transport which is recognisable as such and cleansed and disinfected prior to and after use.

2.2. *Controls on equidae in relation to protection and surveillance zones*

2.2.1. Movement of equidae outside the protection and surveillance zones is not subject to conditions in excess of those resulting from European Council Directive 90/426/EEC.

2.2.2. Movement of equidae within the protection and surveillance zones established in accordance with regulation 19 is subject to the following conditions:

2.2.2.1. the use of equidae kept on holdings in the protection and surveillance zone not keeping animals of susceptible animals may be authorised in the protection zone, subject to appropriate cleansing and disinfection measures, and may not be restricted on premises situated in the surveillance zone;

2.2.2.2. equidae may be transported without restrictions in dedicated equine transport to a holding not keeping animals of susceptible species;

2.2.2.3. the competent authorities may in exceptional cases authorise the transport of equidae in dedicated or registered equine transport from a holding not keeping animals of susceptible species to another holding keeping animals of susceptible species situated in the protection zone, subject to cleansing and disinfection of the transport prior to loading of the animals and before leaving the holding of destination;

2.2.2.4. movement of equidae may be allowed on public roads, on pastures belonging to holdings not keeping animals of susceptible species and exercise premises.

2.2.3. The collection of equine semen, ova and embryos from donor animals on holdings not keeping animals of susceptible species in the protection and surveillance zone and the transport of equine semen, ova and embryos to recipient equine animals on holdings not keeping animals of susceptible species shall not be restricted.

2.2.4. Visits from owners of equidae, the veterinary surgeon, the inseminator and the farrier on holdings keeping animals of susceptible species in the surveillance zones but not subject to the restrictions provided for in regulations 4 and 10 shall be subject to the following conditions:

2.2.4.1. equidae are kept separated from animals of susceptible species and access of the persons referred to above to animals of susceptible species is effectively prevented;

2.2.4.2. all visitors must be registered;

2.2.4.3. cleansing and disinfecting of means of transportation and of the boots of visitors.

SCHEDULE VII

TREATMENT OF PRODUCTS TO ENSURE THE DESTRUCTION OF FOOT-AND-MOUTH DISEASE VIRUS

PART A

Products of animal origin

1. Meat products that have undergone at least one of the treatments provided for in the first column in Table 1 of Annex III of European Council Directive 2002/99/EC.

2. Hides and skins complying with the requirements in Article 20 of European Council Directive 2003/85/EC and points A(2)(c) or (d) of Chapter VI of Annex VIII to European Council Regulation (EC) No 1774/2002.

3. Sheep wool, ruminant hair and pig bristles complying with the requirements in Article 20 of European Council Directive 2003/85/EC and point A(1) of Chapter VI of Annex VIII to Regulation (EC) No 1774/2002.

4. Products derived from animals of susceptible species which have undergone:

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

   (b) a heat treatment in which the centre temperature is raised to at least 70 °C for at least 60 minutes.

5. Blood and blood products of animals of susceptible species used for technical purposes, including pharmaceuticals, in vitro diagnostics and laboratory reagents which have undergone at least one of the treatments referred to in point B(3) (e) (ii) of Chapter IV of Annex VIII to Regulation (EC) No 1774/2002.

6. Lard and rendered fats which have undergone the heat treatment referred to in point B(2) (d) (iv) of Chapter IV of Annex VII to Regulation (EC) No 1774/2002.

7. Petfood and dogchews which comply with the requirements of points B(2), (3) or (4) of Chapter II of Annex VIII to Regulation (EC) No 1774/2002.

8. Game trophies of ungulates which comply with the requirements of points A(1), (3) or (4) of Chapter VII of Annex VIII to Regulation (EC) No 1774/2002.

9. Animal casings which in accordance with Chapter 2 of Annex I to Directive 92/118/EEC have been cleaned, scraped and either salted with sodium-chloride for 30 days or bleached or dried after scraping and were protected from re-contamination after treatment.

PART B

Products not of animal origin

1. Straw and forage which

(a) either has undergone the action of

(i) steam in a closed chamber for at least 10 minutes and at a minimum temperature of 80 °C, or

(ii) formalin fumes (formaldehyde gas) produced in a chamber kept closed for at least 8 hours and at a minimum temperature of 19 °C, using commercial-type solutions at 35-40 % concentration, or

(b) has been stored in package or bales under shelter at premises situated not closer than 2 km to the nearest outbreak of foot-and-mouth disease and is not released from the premises before at least three months have elapsed following the completion of cleansing and disinfection measures provided for in rule 11 and in any case not before the end of the restrictions in the protection zone.

SCHEDULE VIII

PART A

Treatment of fresh meat

1. *De-boned fresh meat:*

Meat as described in Article 2(a) of European Union Council Directive 64/433/EEC together with diaphragms but excluding offal, from which the bone and the main accessible lymphatic glands have been removed.

2. *Trimmed offal:*

— heart from which lymphatic glands, connective tissue and adhering fat have been completely removed;

— liver from which lymphatic glands, adhering connective tissue and fat have been completely removed;

— whole masseter muscles, incised in accordance with paragraph 41(a) of Chapter VIII of Annex I to European Union Council Directive 64/433/EEC, from which lymphatic glands, connective tissue and adhering fat have been completely removed;

— tongues with epithelium and without bone, cartilage and tonsils;

— lungs from which the trachea and main bronchi and the mediastinal and bronchial lymphatic glands have been removed;

— other offal without bone or cartilage from which lymphatic glands, connective tissue, adhering fat and mucous membrane have been completely removed.

3. *Maturation:*

— maturation of carcasses at a temperature of more than + 2 °C for at least 24 hours;

— pH value in the middle of Longissimus dorsi muscle recorded as less than 6,0.

4. *Effective measures must be applied to avoid cross-contamination.*

PART B

Additional measures applicable to the production of fresh meat from animals of susceptible species originating in the surveillance zone

1. Fresh meat, excluding heads, viscera and offals, intended for placing on the market outside the protection and surveillance zone shall be produced according to at least one of the following additional conditions:

(a) *in the case of ruminants:*

(i) the animals have been subjected to the controls provided for in Article 24(2), and

(ii) the meat is subject to the treatment provided for in points 1, 3 and 4 of Part A;

(b) *in the case of all animals of susceptible species:*

(i) the animals have been resident on the holding for at least 21 days and are identified so as to allow the tracing of the holding of origin, and

(ii) the animals have been subjected to the controls provided for in rule 22(2), and

(iii) the meat is clearly identified and detained under official supervision for at least 7 days and is not released until any suspicion of infection with the foot-and-mouth disease virus on the holding of origin has been officially ruled out at the end of the detention period;

(c) *in the case of all animals of susceptible species:*

(i) the animals have completed a 21-day standstill on the holding of origin during which no animal of a species susceptible to foot-and-mouth disease has been introduced onto the holding, and

(ii) the animals have been subjected to the controls provided for in rule 22(2) within 24 hours of loading, and

(iii) samples taken in accordance with the statistical requirements provided for in point 2.2 of Schedule III within 48 hours of loading have been tested with negative result in an assay for the detection of antibodies against the foot-and-mouth disease virus, and

(iv) the meat is detained under official control for 24 hours and not released before a repeat inspection of the animals in the holding of origin has ruled out on clinical inspection the presence of infected or suspected of being infected animals.

2. Trimmed offal shall be marked with the health mark provided for in European Union Council Directive 2002/99/EC and shall be subject to one of the treatments provided for in point 1 in Part A of Schedule VII of these regulations.

3. Other products shall be subjected to the treatment provided for in rule 30.

SCHEDULE IX

TREATMENT OF MILK TO ENSURE DESTRUCTION OF FOOT-AND-MOUTH VIRUS

PART A

Milk and milk products intended for human consumption

The following treatments are recognised to provide sufficient guaranties with regard to the destruction of the foot-and-mouth disease virus in milk and milk products for human consumption. Necessary precautions must be taken to avoid contact of the milk or milk products with any potential source of foot-and-mouth virus after processing.

1. Milk intended for human consumption must be subject to at least one of the following treatments:

1.1. sterilisation at a level of at least F03;

1.2. UHT ([1]) treatment;

1.3. HTST ([2]) treatment applied twice to milk with a pH equal to or above 7,0;

1.4. HTST treatment of milk with a pH below 7,0;

1.5. HTST combined with another physical treatment by:

1.5.1. either lowering the pH below 6 for at least one hour, or

1.5.2. additional heating to 72 °C or more, combined with desiccation.

2. Milk products must either undergo one of the above treatments or be produced from milk treated in accordance with paragraph 1.

3. Any other treatment shall be decided in accordance with the procedure referred to in rule 78(1), in particular in relation to raw milk products undergoing an extended period of ripening including a lowering of the pH below 6.

PART B

Milk and milk products not intended for human consumption and milk and milk products for animal consumption

The following treatments are recognised to provide sufficient guaranties with regard to the destruction of the foot-and-mouth disease virus in milk and milk products not intended for human consumption or intended for animal consumption. Necessary precautions must be taken to avoid contact of the milk or milk products with any potential source of foot-and-mouth virus after processing.

1. Milk not intended for human consumption and milk intended for animal consumption must be subject to at least one of the following treatments:

1.1. sterilisation at a level of at least F03;

1.2. UHT ([1]) combined with another physical treatment referred to in either paragraph 1.4.1 or 1.4.2;

1.3. HTST ([2]) applied twice;

1.4. HTST combined with another physical treatment by:

1.4.1. either lowering the pH below 6 for at least one hour, or

1.4.2. additional heating to 72 °C or more, combined with desiccation.

2. Milk products must either undergo one of the above treatments or be produced from milk treated in accordance with paragraph 1.

3. Whey to be fed to animals of susceptible species and produced from milk treated as described in paragraph 1 must be collected at least 16 hours after milk clotting and its pH must be recorded as <6.0 before transport to pig holdings.

([1]) UHT = Ultra High Temperature treatment at 132 °C for at least one second.

([2]) HTST = High Temperature Short Time pasteurisation at 72 °C for at least 15 seconds or equivalent pasteurisation effect achieving a negative reaction to a phosphatase test.

SCHEDULE X

CRITERIA FOR THE DECISION TO APPLY PROTECTIVE VACCINATION AND GUIDELINES FOR THE EMERGENCY VACCINATION PROGRAMMES

1. Criteria for the decision to apply protective vaccination

Criteria	**Decision**	
	For vaccination	**Against vaccination**
Population density of susceptible animals	High	Low
Predominant species clinically affected	Pigs	Ruminants
Movement of potentially infected animals or products out of the protection zone	Evidence	No evidence
Predicted airborne spread of virus from infected holdings	High	Low or absent
Suitable vaccine	Available	Not available
Origin of outbreaks (traceability)	Unknown	Known
Incidence slope of outbreaks	Rising rapidly	Shallow or slow rise
Distribution of outbreaks	Widespread	Restricted
Public reaction to total stamping out policy	Strong	Weak
Acceptance of regionalization after vaccination	Yes	No

1. Additional citeria for the decision to introduce emergency vaccination

Criteria	**Decision**	
	For vaccination	**Against vaccination**
Acceptance of regionalization by third countries	known	unknown
Economic assessment of competing control strategies	If it is foreseeable that a control strategy without emergency vaccination would lead to significantly higher economic losses in the agricultural and non agricultural sectors	If it is foreseeable that a control strategy with emergency vaccination would lead to significantly higher economic losses in the agricultural and non agricultural sectors

Criteria	Decision	
	For vaccination	**Against vaccination**
It is foreseeable that the 24/48 hours rule cannot be implemented effectively for two consecutive days ([1])	Yes	No
Significant social and psychological impact of total stamping out policy	Yes	No
Existence of large holdings of intensive livestock production in a non-densely populated livestock area	Yes	No

([1]) 24/48 hours rule means:
(a) infected herds on holdings referred to in rule 10 cannot be stamped out within 24 hours after the confirmation of the disease, and
(b) the pre-emptive killing of animals likely to be infected or contaminated cannot be carried out with less than 48 hours.

3. **Definition of Densely Populated Livestock Areas (DPLAs)**

3.1. When deciding about the measures to be taken in application of these regulations, and in particular the measures provided for in rule 50(2),the competent authority shall in addition to a thorough epidemiological assessment consider the definitions of DPLAs as provided for in point 3.2. or where applicable as provided for in Article 2(u) of European Council Directive 2001/89/EC and use the definition which is the more stringent.

The definition may be modified in the light of new scientific evidence in accordance with the procedure referred to in rule 78(1).

3.2. *Animals of susceptible species*

In the case of animals of susceptible species a DPLA shall be a geographical area, with a radius of 10 km around a holding containing animals of susceptible species suspected of or infected with foot-and-mouth disease, where there is a density of animals of susceptible species higher than 1 000 head per km2. The holding in question must be situated either in a sub-region where there is a density of animals of susceptible species higher than 450 head per km2 or at a distance of less than 20 km from such a subregion.

SCHEDULE XI

PART A

National laboratories authorised to handle live foot-and-mouth disease virus

Member State where Laboratory is situated	Laboratory	Member States using the services of laboratory
Belgium	Veterinary and Agrochemical Research Centre CODA-CERVA-VAR, Uccle	**Belgium** **Luxembourg**
Denmark	Danish Veterinary Institute, Department of Virology, Lindholm	**Denmark** **Finland** **Sweden**
Germany	Bundesforschungsanstalt der Tiere für Viruskrankheiten, — Anstalsteil Tübingen — Anstaltsteil Friedrich-Loeffler-Institut, Insel Riems	**Germany**
Greece	**Ινστιτούτο Αφθώδους Πυρετού, Αγία Παρασκευή** Αττικής	**Greece**
Spain	Laboratorio Central de Veterinaria Algete, Madrid	**Spain**
France	Agence française de sécurité sanitaire des aliments (AFSSA) — Laboratoire d'études et de recherches en pathologie bovine et hygiène des viandes, Lyon — Laboratoire d'études et de recherches en pathologie animale et zoonoses, Maison-Alfort	**France**
Italy	Istituto zooprofilattico sperimentale della Lombardia e dell'Emilia Romagna, Brescia	**Italy**
Netherland	CIDC-Lelystad, Central Institute for Animal Disease Control, Lelystad	**Netherlands**
Austria	Austria Österreichische Agentur für Gesundheit und Ernährungssicherheit Veterinärmedizinische Untersuchungen Mödling	**Austria**
United Kingdom	Institute for Animal Health, Pirbright	**United Kingdom** **Ireland** **Sweden** **Finland**

PART B

Laboratorios authorised to andel live foot-and-mouth virus for vaccine production

Member State	Manufacturer
Germany	Bayer AG, Köln
France	Merial, S.A.S., Laboratoire IFFA, Lyon
Netherlands	CIDC-Lelystad, Central Institute for Animal Disease Control, Lelystad
United Kingdom	Merial, S.A.S., Pirbright Laboratory, Pirbright

SCHEDULE XII

BIOSECURITY STANDARDS FOR LABORATORIES AND ESTABLISHMENTS HANDLING LIVE FOOT-AND-MOUTH DISEASE VIRUS

1. The laboratories and establishments handling live foot-and-mouth disease virus must meet or exceed the minimum requirements laid down in the 'Minimum standards for Laboratories working with foot-and-mouth virus in vitro and in vivo' established by the European Commission for the control of foot-and-mouth disease, 26th session, Rome, April 1985, as modified in 1993.

2. The laboratories and establishments handling live foot-and-mouth disease virus must be subject to at least two inspections within five years, with one of the inspections being carried out unannounced.

3. The inspection team shall comprise at least of

   — one expert from the Commission,

   — one expert in foot-and-mouth disease,

   — one independent expert for questions of bio-security in laboratories working with microbiological hazards.

4. The inspection team shall submit a report to the Commission and the Member States in accordance with European Union Council Decision 98/139/EC.

SCHEDULE XIII

DIAGNOSTIC TESTS AND STANDARDS FOR FOOT-AND-MOUTH DISEASE AND FOR THE DIFFERENTIAL DIAGNOSIS OF OTHER VES ICULAR VIRUS DISEASES

In the context of this Schedule, a 'test' refers to a laboratory diagnostic procedure and a 'standard' to a reference reagent that has become an internationally accepted standard following a procedure of comparative testing carried out in several different laboratories.

PART A

Diagnostic tests

1. *Recommended procedures*

Diagnostic tests described in the OIE Manual, hereinafter the 'OIE Manual', as the 'Prescribed Tests' for international trade, constitute the reference tests for vesicular disease diagnosis within the Community. National Laboratories must adopt standards and tests at least as stringent as those defined in the OIE Manual.

The Commission may, in accordance with the procedure referred to in rule 78(1) decide to adopt more stringent testing procedures than those defined in the OIE Manual.

2. *Alternative procedures*

The use of tests defined in the OIE Manual as 'Alternative Tests', or other tests not included in the OIE Manual, is permitted provided that the performance of the test has been shown to match or exceed the sensitivity and specificity parameters laid down in the OIE Manual or in the annexes to Community legislation, whichever is the more stringent.

National Laboratories generating results for the purposes of national, intra-Community or international trade must generate and store the necessary records demonstrating compliance of their testing procedures with the relevant OIE or Community requirements.

3. *Standards and quality control*

National Laboratories shall participate in periodic standardisation and external quality assurance exercises organised by the Community Reference Laboratory.

In the framework of such exercises, the Community Reference Laboratory may take account of the results achieved by a National Laboratory which has within a reasonable timespan participated in a quality assurance exercise organised by one of the international organisations responsible for external quality assurance of vesicular virus disease diagnosis, such as OIE, the Food and Agriculture Organisation (FAO) of the United Nations or the International Atomic Energy Agency.

National Laboratories shall operate internal quality assurance programmes. The specification of such programmes may be laid down in accordance with the procedure referred to in rule 78(1). Pending the adoption of detailed provisions, the specifications in the OIE Guidelines for Laboratory Quality Evaluation shall apply (OIE Standards Commission, September 1995).

As part of quality assurance, National Laboratories shall demonstrate compliance of the tests in routine use with the requirements for sensitivity and specificity defined in the OIE Manual, or in Schedule XIV of these rules, whichever is more stringent.

4. *Procedures for adoption and review of tests and standards for vesicular virus disease diagnosis.*

Tests and standards for vesicular virus disease diagnosis shall be adopted in accordance with the procedure referred to in rule 78(1).

The Commission may consider the scientific advice produced by the meetings of the National Laboratories to be organised by the Community Reference Laboratory.

5. *Compliance procedure*

Data from standardisation and external quality assurance exercises organised by the Community Reference Laboratory shall be assessed at the annual meetings of the National Laboratories and communicated to the Commission for review of the list of National Laboratories as laid down in Part A of Schedule XI.

Those laboratories whose tests do not meet the prescribed requirements for sensitivity and specificity shall be required by the Commission to adapt their procedures within an appropriate period of time to ensure that these requirements are met. Failure to demonstrate the required level of

proficiency within the time limit required shall result in loss of recognition within the Community of all testing performed after that deadline.

6. *Selection and transportation of samples*

An aliquot of field material should be sent to one of the laboratories listed in Part A of Schedule XI. However, where such samples are not available or not suitable for transport, animal passage material, obtained from the same host species, or low passage cell culture material is acceptable.

The history of animal or cell passage material should be provided.

Samples for vesicular virus diagnosis can be transported at 4 °C if the anticipated transport time to the recipient laboratory is less than 24 hours.

For oesophageal-pharyngeal (probang) samples, transportation above solid carbon dioxide or liquid nitrogen is recommended, especially if delays at airports cannot be excluded.

Special precautions are required for the safe packaging of material from suspect cases of foot-and-mouth disease both within and between countries. These rules are mainly designed to prevent breakage or leakage of containers and the risk of contamination, but are also important to ensure that specimens arrive in a satisfactory state. Ice-packs are preferred to wet ice to prevent the possibility of escape of water from the package.

Prior notice of arrival, and agreement for receipt, must be arranged with the receiving laboratory before despatch of samples.

Compliance with the import and export regulations of the Member States involved must be ensured.

PART B

Standards

The protocols specified in the OIE Manual provide reference procedures for virus isolation, antigen detection and antibody detection for vesicular diseases.

1. *Foot-and-mouth disease*

1.1. Antigen detection

The standards for detecting foot-and-mouth disease virus antigen shall be established in accordance with the procedure referred to in rule 78(1) after consultation of the Community Reference Laboratory.

Standardised, inactivated antigens of all seven serotypes are available from the OIE/FAO World Reference Laboratory for foot-and-mouth disease (WRL).

National Laboratories should ensure that their antigen detection system complies with these minimum standards. They shall where necessary receive advice from the Community Reference Laboratory on the dilutions of these antigens to be used as strong and weak positive controls.

1.2. Virus isolation

The standards for foot-and-mouth disease virus detection shall be established in accordance with the procedure referred to in rule 78(1) after consultation of the Community Reference Laboratory.

Isolates of foot-and-mouth disease virus are available from the WRL.

National Laboratories shall ensure that the tissue culture systems in use for foot-and-mouth virus isolation are sensitive to the full range of serotypes and strains for which the laboratory maintains a diagnostic capacity.

1.3. Nucleic acid detection methods

The standards for the detection of foot-and-mouth disease viral RNA shall be established in accordance with the procedure referred to in rule 78(1) after consultation of the Community Reference Laboratory.

The Commission may arrange that for future standardisation, comparative testing of the sensitivity of RNA detection methods is carried out between National Laboratories.

The Commission may arrange that, taking into account the practical difficulties of storing nucleic acids for prolonged periods of time, standardised quality assurance reagents for the detection of foot-and-mouth viral RNA will become available from the Community Reference Laboratory.

1.4. Antibody detection (structural proteins)

The standards for the detection of antibody to foot-and-mouth disease virus shall be established in accordance with the procedure referred to in rule 78(1) after consultation of the Community Reference Laboratory.

Standardised antisera for foot-and-mouth disease virus types O1-Manisa, A22-Iraq and C-Noville have been defined by the 'FAO Phase XV Standardisation Exercise in foot-and-mouth disease antibody detection' in 1998.

The Commission may arrange that standardised reference sera for all the main antigenic variants of foot-and-mouth disease virus are adopted as a result of standardisation exercises between the Community Reference Laboratory and the National Laboratories. These reference sera will be adopted as the standards for use by National Laboratories within the Community.

1.5. Antibody detection (non-structural proteins)

The standards for the detection of antibody to foot-and-mouth disease virus shall be established in accordance with the procedure referred to in rule 78(1) after consultation of the Community Reference Laboratory.

The Commission may arrange that standardised reference sera are adopted as a result of standardization exercises between the Community Reference Laboratory and the National Laboratories. These reference sera will be adopted as the standards for use by National Laboratories within the Community.

2. *Swine vesicular disease (SVD)*

Diagnosis of SVD must be carried out in accordance with Decision 2000/428/EC.

3. *Other vesicular diseases*

Where necessary, the Commission may arrange that standards for the laboratory diagnosis of vesicular stomatitis or vesicular exanthema of swine are established in accordance with the procedure referred to in rule 78(1).

The competent authority may maintain the laboratory capacity to diagnose the vesicular virus diseases other than foot-and-mouth disease and SVD, i.e. vesicular stomatitis and vesicular exanthema of swine.

National Laboratories wishing to maintain a diagnostic capacity for these viruses can obtain reference reagents from the WRL, Pirbright or from the relevant OIE Reference Laboratory.

SCHEDULE XIV

COMMUNITY ANTIGEN AND VACCINE BANK

1. Conditions for the supply and storage of the concentrated inactivated antigen supplied to the Community antigen and vaccine bank:

(a) each antigen consists of a single homogeneous batch;

(b) each batch is split in order to permit it to be stored at two separate geographical sites under the responsibility of the designated premises of the Community antigen and vaccine bank;

(c) the antigen meets at least the requirements of the European Pharmacopoeia and the relevant provisions of the OIE Manual;

(d) the principles of Good Manufacturing Practise are maintained throughout the production process and this shall include the storage and finishing of the vaccine reconstituted from the antigens in store;

(e) if not otherwise specified in the texts referred to in point (c), the antigen is purified to remove nonstructural proteins of the foot-and-mouth disease virus. The purification shall at least ensure that the residual content of non-structural proteins in vaccines reconstituted from such antigen does not induce detectable levels of antibody against non-structural proteins in animals which had received one initial and one subsequent booster vaccination.

2. Conditions for the formulation, finishing, bottling, labelling and delivery of vaccines reconstituted from concentrated inactivated antigen supplied to the Community antigen and vaccine bank:

(a) rapid formulation into vaccine of the antigen;

(b) production of a safe, sterile and efficient vaccine with a potency of at least 6 PD50 in accordance with the tests prescribed by the European Pharmacopoeia, and suitable for use in case of emergency vaccination of ruminants and pigs;

(c) a capacity to formulate from concentrated inactivated antigen in stock:

(i) up to one million doses of vaccine within four days of instruction from the Commission;

(ii) additionally, up to four million doses of vaccine within 10 days of instruction from the Commission;

(d) rapid bottling, labelling and distribution of the vaccine according to the specific needs of the area where vaccination is to be carried out.

ANNEX XV

FUNCTIONS AND DUTIES OF NATIONAL LABORATORIES

The functions and duties of National Laboratories referred to in Article 68 for foot-and-mouth and other vesicular diseases shall be as follows:

1. All National Laboratories handling live foot-and-mouth disease virus must operate under high security conditions laid down in 'Minimum Standards for Laboratories working with foot-and-mouth disease virus in vitro and in vivo', European Commission for the Control of Foot-and-Mouth Disease — 26th Session, Rome, 1985, as amended by Appendix 6 (ii) of the Report of the 30th Session, Rome, 1993.

2. National Laboratories must provide an uninterrupted service for diagnosing vesicular viral diseases and must be equipped and skilled for providing a rapid initial diagnosis.

3. National Laboratories must keep inactivated reference strains of all serotypes of foot-and-mouth disease virus, and immune sera against the viruses, as well as all other reagents necessary for a rapid diagnosis. Appropriate cell cultures should be in constant readiness for confirming a negative diagnosis.

4. National Laboratories must be equipped and skilled for large-scale serological surveillance.

5. In all suspected primary outbreaks appropriate samples must be collected and quickly transported, according to a set protocol, to a National Laboratory. In anticipation of a suspicion of foot-and-mouth disease, the competent authority shall ensure that the necessary equipment and materials for sample collection and transportation to a National Laboratory are stored in readiness at local sites.

6. Antigenic typing and genomic characterisation must be carried out on all viruses responsible for new incursions into the Community. This can be performed by the National Laboratory, if facilities exist. Otherwise, at the earliest possible occasion, the National Laboratory must send a sample of virus from the primary case to the Community Reference Laboratory for confirmation and further characterisation, including advice on the antigenic relationship of the field strain to vaccine strains in the Community antigen and vaccine banks. The same procedure should be followed for viruses

received by National Laboratories from third countries in situations where characterisation of the virus is likely to be of benefit to the Community.

7. National Laboratories should provide disease data to the competent authority, which shall provide these data to the Community Reference Laboratory.

8. National Laboratories should collaborate with the Community Reference Laboratory in ensuring that members of the field section of State Veterinary Services have the opportunity of seeing clinical cases of foot-and-mouth disease in National Laboratories as part of their training.

9. National Laboratories shall collaborate with the Community Reference Laboratory and other National Laboratories to develop improved diagnostic methods and exchange relevant materials and information.

10. National Laboratories shall participate in external quality assurance and standardisation exercises organised by the Community Reference Laboratory.

11. National Laboratories shall use tests and standards that meet or exceed the criteria laid down in Schedule XIII. National Laboratories shall provide the Commission on request with data proving that the tests in use meet or exceed the requirements.

12. National Laboratories should have the competence to identify all vesicular disease viruses and encephalomyocarditis virus in order to avoid delays in diagnosis and consequently in implementing control measures by the competent authorities.

13. National Laboratories shall cooperate with other laboratories designated by the competent authorities for performing tests, for example serological tests, that do not involve handling of live foot-and-mouth disease virus. These laboratories shall not carry out virus detection in samples taken from suspect cases of vesicular diseases. Such laboratories need not comply with the bio-security standards referred to in Schedule XII, point 1, but must have established procedures which ensure that the possible spread of foot-and-mouth disease virus is effectively prevented.

Samples giving inconclusive results in tests must be transmitted to the National Reference Laboratory for carrying out confirmatory tests.

SCHEDULE XVI

CRITERIA AND REQUIREMENTS FOR CONTINGENCY PLANS

The competent authority shall ensure that contingency plans meet at least the following requirements:

1. Provision shall be made to ensure the legal powers necessary for the implementation of contingency plans and allow for a rapid and successful eradication campaign.

2. Provision must be made to ensure access to emergency funds, budgetary means and financial resources in order to cover all aspects of the fight against a foot-and-mouth disease epizootic.

3. A chain of command shall be established guaranteeing a rapid and effective decision-making process for dealing with foot-and-mouth disease epizootics. A central decision-making unit shall be in charge of the overall direction of control strategies and the chief veterinary officer shall be a member of this unit.

4. The competent authority must be prepared to immediately establish a functional national disease control centre in the event of an outbreak, which shall coordinate the implementation of all decisions taken in the central decision-making unit. A permanently operational coordinator shall be appointed to guarantee the prompt establishment of the centre.

5. Detailed plans shall be available to enable the competent authority to be prepared for the immediate establishment of local disease control centres in the event of foot-and-mouth disease outbreaks in order to implement disease control and environment protection measures at a local level.

6. The competent authority shall ensure the cooperation between the national disease control centre, the local disease control centres and environmental competent authorities and bodies in order to ensure that actions on veterinary and environmental safety issues are appropriately coordinated.

7. A permanently operational expert group shall be created, where necessary in collaboration with other Member States, to maintain expertise and assist the relevant authority in qualitative disease preparedness.

8. Provision must be made for adequate resources to ensure a rapid and effective campaign, including personnel, equipment and laboratory capacity.

9. An up-to-date operations manual shall be available. It shall describe in detail and in a comprehensive and practical way all the actions procedures, instructions and control measures to be employed in handling an outbreak of foot-and-mouth disease.

10. Detailed plans shall be available for emergency vaccination.

11. Staff shall be regularly involved in:

11.1. training in clinical signs, epidemiological enquiry and control of epizootic diseases;

11.2. real-time alert exercises, conducted as follows:

11.2.1. two times within a five years period, the first of which should not have started later than 3 years after the approval of the plan, or

11.2.2. during the five years period after an outbreak of a major epizootic disease has been effectively controlled and eradicated, or

11.2.3. one of the two exercises referred to in paragraph 11.2.1 is replaced by a real-time exercise required within the framework of contingency plans for other major epidemic diseases affecting terrestrial animals, or

11.2.4. by way of derogation from paragraph 11.2.1 and subject to appropriate provisions in the contingency plan, Malta may arrange for the participation in and contribution to real-time exercises carried out in a neighbouring Member States and alarm-drills are carried out as provided for in paragraph (g) (ii) of Annex VII of European Union Council Directive 2001/89/EC in relation to all animals of species susceptible to foot-and-mouth disease.

11.3. Training in communication skills to provide ongoing disease awareness campaigns for authorities, farmers and veterinarians.

12. Contingency Plans shall be prepared taking into account the resources needed to control a large number of outbreaks occurring within a short time and caused by several antigenically distinct

serotypes or strains as it may be necessary amongst others in the case of deliberate release of foot-and-mouth disease virus.

13. Without prejudice to veterinary requirements, contingency plans shall be prepared with a view to ensuring that in the event of an outbreak of foot-and-mouth disease, any mass disposal of animal carcasses and animal waste is done without endangering human health and without using processes or methods which prevent any avoidable damage to the environment and in particular:

(i) with a minimum risk to soil, air, surface and groundwater, to plants and animals,

(ii) with a minimum nuisance through noise or odours,

(iii) with a minimum adverse effect to the countryside or places of special interest.

14. Such plans shall include the identification of appropriate sites and undertakings for the treatment or disposal of animal carcasses and animal waste in the event of an outbreak.

15. The competent authority shall ensure that farmers, the rural populace and the population in general are kept informed. Direct and accessible contact shall be provided for the inhabitants of affected areas (inter alia via helplines), as well as information through the national and regional media.

SCHEDULE XVII

PART A

Measures in case of confirmation of the presence of foot-and-mouth disease in wild animals

1. As soon as confirmation of a primary case of foot-and-mouth disease in wild animals of susceptible species has taken place, in order to reduce the spread of disease, the competent authority shall immediately:

(a) notify the primary case in accordance with Schedule II;

(b) epidemiologists. The expert group shall assist the competent authority in:

(i) studying the epidemiological situation and defining an infected area, in accordance with the provisions laid down in point 4(b) of Part B,

(ii) establishing appropriate measures to be applied in the infected area in addition to the ones referred to in points (c) and (d); these measures may include suspension of hunting and a ban in feeding wild animals,

(iii) drawing up the eradication plan to be submitted to the Commission in accordance with Part B,

(iv) carrying out audits to verify the effectiveness of the measures adopted to eradicate foot-and-mouth disease from the infected area;

(c) place under official surveillance holdings keeping animals of susceptible species in the defined infected area and shall in particular order that:

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

(ii) all animals of susceptible species on the holdings situated in the infected area be kept in their living quarters or some other place where they can be isolated from wild animals. Wild animals must not have access to any material which may subsequently come in contact with animals of susceptible species on the holdings,

(iii) no animal of a susceptible species enter or leave the holding save where authorised by the competent authority having regard to the epidemiological situation,

(iv) appropriatemeans of disinfection be used at the entrance and exits of buildings housing animals of susceptible species and of the holding itself,

(v) appropriate hygiene measures be applied by all persons coming in contact with wild animals, to reduce the risk of spread of foot-and-mouth disease virus, which may include a temporary ban on persons having been in contact with wild animals from entering a holding keeping animals of susceptible species,

(vi) all dead or diseased animals of susceptible species with foot-and-mouth disease symptoms on a holding be tested for the presence of foot-and-mouth disease,

(vii) no part of any wild animals, whether shot or found dead, as well as any material or equipment which could be contaminated with foot-and-mouth disease virus shall be brought into a holding keeping animals of susceptible species,

(viii) animals of susceptible species, their semen, embryos or ova shall not be moved from the infected area for the purpose of intra-Community trade;

(d) arrange that all wild animals shot or found dead in the defined infected area are inspected by an official veterinarian and examined for foot-and-mouth disease to officially rule out or confirm foot-and-mouth disease in accordance with the definition for an outbreak in Schedule I. Carcasses of all wild animals found positive as regards foot-and-mouth disease shall be processed under official supervision. Where such testing proves negative as regards foot-and-mouth disease, the competent authority shall apply the measures laid down in Article 11(2) of European Union Council Directive 92/45/EEC. Parts not intended for human consumption shall be processed under official supervision;

(e) ensure that the foot-and-mouth disease virus isolate is subject to the laboratory procedure required to identify the genetic type of virus and its antigenic characteristic in relation to existing vaccines strains.

2. By way of derogation to the provisions in point 1 specific measures may be adopted in accordance with the procedure referred to in rule 78(2), if a case of foot-and-mouth disease has occurred in wild animals in an area of Malta where extensive keeping of domestic animals of susceptible species makes certain provisions in paragraph 1 inapplicable.

PART B

Plans for the eradication of foot-and-mouth disease in wild animals

1. Without prejudice to the measures laid down in Part A, the competent authority shall submit to the European Commission within 90 days from the confirmation of the primary case of foot-and-mouth disease in wild animals a written plan of the measures taken to eradicate the disease in the area defined as infected and of the measures applied on the holdings in that area.

2. The European Commission shall examine the plan in order to determine whether it permits the desired objective to be attained. The plan, if necessary with amendments, shall be approved in accordance with the procedure referred to in rule 78(2). The plan may subsequently be amended or supplemented to take account of developments in the situation.

If these amendments concern the redefinition of the infected area, the competent authority shall ensure that the Commission and the other Member States are informed of these amendments without delay.

If the amendments concern other provisions of the plan, the competent authority shall submit the amended plan to the European Commission for examination and possible approval in accordance with the procedure referred to in rule 78(2).

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

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

(a) the results of the epidemiological investigations and controls carried out in accordance with Part A and the geographical distribution of the disease;

(b) a defined infected area within Malta.

When defining the infected area, the competent authority shall take into account:

(i) the results of the epidemiological investigations carried out and the geographical distribution of the disease,

(ii) the wild animal population in the area,

(iii) the existence of major natural or artificial obstacles to movements of wild animals;

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

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

(e) specific efforts made to determine the number and location of groups of wild animals with limited contacts to other groups of wild animals in and around the infected area;

(f) the approximate number of groups of wild animals referred to in paragraph (e) and their size in and around the infected area;

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

(h) the measures adopted to reduce spread of disease due to movements of wild animals and/or contact between groups of wild animals; these measures may include a prohibition of hunting;

i) the measures adopted to reduce the population of wild animals and in particular young animals of susceptible species in the wild animal population;

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

(k) the method of removal of wild animals found dead or shot, which shall be based on:

(i) processing under official supervision, or

(ii) inspection by an official veterinarian and laboratory tests as provided for in Schedule XIII. Carcasses of all wild animals found positive as regards foot-and-mouth disease shall be processed under official supervision. Where such testing proves negative as regards foot-and-mouth disease, the competent authority shall apply the measures laid down in Article 11(2) of European Council Directive 92/45/EEC. Parts not intended for human consumption shall be processed under official supervision;

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

(i) the geographical area where the animal was found dead or shot,

(ii) the date on which the animal was found dead or shot,

(iii) the person who found or shot the animal,

(iv) the age and sex of the animal,

(v) if shot: symptoms before shooting,

(vi) if found dead: the state of the carcass,

(vii) laboratory findings;

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

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

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

(p) the system established in order that the expert group appointed in accordance with point 1(b) in Part A can review on a regular basis the results of the eradication plan;

(q) the disease monitoring measures that shall be enforced after a period of at least 12 months has elapsed from the last confirmed case of foot-and-mouth disease in wild animals in the defined infected area; these monitoring measures shall stay in place for at least 12 months and shall at least include the measures already enforced in accordance with points (g), (k) and (l).

5. A report concerning the epidemiological situation in the defined area and the results of the eradication plan shall be transmitted to the European Commission and to the other Member States every 6 months.

6. More detailed rules relating to the establishment of plans for the eradication of foot-and-mouth disease in wild animals may be adopted in accordance with the procedure referred to in rule 78(2).