# ANNEX 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

# ANNEX II

## NOTIFICATION OF DISEASE AND FURTHER EPIDEMIOLOGICAL INFORMATION TO BE PROVIDED BY THE MEMBER STATE 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 Article 16, the Member State concerned must notify by means of the Animal Disease Notification System established in accordance with Article 5 of 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 Article 16, in addition to the data referred to in point 1, the Member State concerned 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 Article 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 Directive 82/894/EEC.

4. The Member State concerned shall ensure that the information to be provided in relation to any outbreak or case of 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 Article 18 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.

## ANNEX 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 Article 2(h) 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 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 Article 78, and

2.1.1.2. in support of tracing and the provision of evidence, taking also into account the definition in Annex 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 Annex.

2.1.3. Sampling of animals of susceptible species shall be carried out in accordance with the provisions of this Annex 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 Article 36 of the measures provided for in Articles 21 to 35, 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 Article 36(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 Article 44 of the measures provided for in Articles 37 to 43, 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 1 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 Article 21, 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.

## ANNEX IV

## PRINCIPLES AND PROCEDURES FOR CLEANSING AND DISINFECTION

1. General principles and procedures

1.1. Cleansing and disinfection operations as provided for in Article 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, re-contamination 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 this Directive 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 disinfectant 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 re-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 this Directive, 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.

## ANNEX 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 authorities 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 Annex 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 Annex 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 open-air holdings. Detailed provision on the use of sentinels may be laid down in accordance with the procedure referred to in Article 89(2).

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 Annex 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 Article 52 shall be carried out either in accordance with paragraphs 1 and 2 of this Annex or in accordance with Article 58(2) or (4)(a), (c) and (d).

3.2. The competent authorities may authorise the restocking of holdings situated outside the vaccination zone with vaccinated animals after the completion of the measures provided for in Article 61 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 Annex 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.

## ANNEX 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 Article 10, Member States 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 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 Article 7(3), transport of equidae from holdings under restrictions laid down in Articles 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 Directive 90/426/EEC.

2.2.2. Movement of equidae within the protection and surveillance zones established in accordance with Article 21 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 Articles 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.

# ANNEX 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 Directive 2002/99/EC.

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

3. Sheep wool, ruminant hair and pig bristles complying with the requirements in Article 20 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 Article 11 and in any case not before the end of the restrictions in the protection zone.

## ANNEX VIII

## PART A

### Treatment of fresh meat

1. De-boned fresh meat:

Meat as described in Article 2(a) of 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 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 Article 24(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 Article 24(2) within 24 hours of loading, and

(iii) samples taken in accordance with the statistical requirements provided for in point 2.2 of Annex 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 Directive 2002/99/EC and shall be subject to one of the treatments provided for in point 1 in Part A of Annex VII of this Directive.

3. Other products shall be subjected to the treatment provided for in Article 32.

# ANNEX 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 $F_0 3$;

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 Article 89(2), 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 $F_0 3$;

1.2. UHT [(3)] combined with another physical treatment referred to in either paragraph 1.4.1 or 1.4.2;

1.3. HTST [(4)] 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.

## ANNEX 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[(5)]

| **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 regionalisation after vaccination | Yes | No |

2. Additional criteria for the decision to introduce emergency vaccination

| Criteria | Decision | |
|---|---|---|
| | **For vaccination** | **Against vaccination** |
| Acceptance of regionalisation 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 |
| It is foreseeable that the 24/48 hours rule cannot be implemented effectively for two consecutive days[a] | 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 |

**a** 24/48 hours rule means:
(a) infected herds on holdings referred to in Article 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 safely carried out within 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 this Directive, and in particular the measures provided for in Article 52(2), Member States 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 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 Article 89(2).

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 $km^2$. The holding in question must be situated either in a sub-region as defined in Article 2(s) where there is a density of animals of susceptible species higher than 450 head per $km^2$ or at a distance of less than 20 km from such a sub-region.

# ANNEX XI

## PART A

## [F1National laboratories authorised to handle live foot-and-mouth disease virus

| **Member State where laboratory is situated** | | **Laboratory** | **Member States using the services of laboratory** |
|---|---|---|---|
| **ISO-code** | **Name** | | |
| AT | Austria | Österreichische Agentur für Gesundheit und Ernährungssicherheit Veterinärmedizinische Untersuchungen Mödling | Austria |
| BE | Belgium | Veterinary and Agrochemical Research Centre CODA-CERVA-VAR Uccle | Belgium<br>Luxembourg |
| CZ | Czech Republic | Statní veterinární ústav Praha, Praha | Czech Republic |
| DE | Germany | Friedrich-Loeffler-Institut Bundesforschungsinstitut für Tiergesundheit, Greifswald — Insel Riems | Germany<br>Slovakia |
| DK | Denmark | Danmarks Fødevareforskning, Afdeling for Virologi, Lindholm | Denmark<br>Finland<br>Sweden |
| ES | Spain | Laboratorio Central de Sanidad Animal, Madrid | Spain |
| FR | France | Agence française de sécurité sanitaire des aliments (AFSSA)<br>— Laboratoire d'études et de recherches en pathologie bovine et hygiène des | France |

| | | | |
|---|---|---|---|
| | | — viandes, Lyon<br>— Laboratoire d'études et de recherches en pathologie animale et zoonoses, Maison-Alfort | |
| GB | United Kingdom | Institute for Animal Health, Pirbright | United Kingdom<br>Estonia<br>Finland<br>Ireland<br>Malta<br>Sweden |
| GR | Greece | Ινστιτούτο αφθώδους πυρετού, Αγία Παρασκευή Αττικής | Greece |
| HU | Hungary | Országos Állategészségügyi Intézet (OÁI), Budapest | Hungary |
| IT | Italy | Istituto zooprofilattico sperimentale della Lombardia e dell'Emilia Romagna, Brescia | Italy<br>Cyprus |
| LT | Lithuania | Nacionalinė veterinarijos laboratorija, Vilnius | Lithuania |
| LV | Latvia | Valsts veterinārmedicīnas diagnostikas centrs, Rīga | Latvia |
| NL | Netherlands | CIDC-Lelystad Central Institute for Animal Disease Control Lelystad | Netherlands |
| PL | Poland | Zakład Pryszczycy Państwowego Instytutu Weterynaryjnego – Państwowego | Poland |

| | | | |
|---|---|---|---|
| | | Instytutu Badawczego, Zduńska Wola | |
| SI | Slovenia | Nacionalni veterinarski inštitut, Lubljana | Slovenia**]** |

**Textual Amendments**

**F1** Substituted by Commission Decision of 16 August 2005 amending Annex XI to Council Directive 2003/85/EC with regard to national laboratories in certain Member States (notified under document number C(2005) 3121) (Text with EEA relevance) (2005/615/EC).

PART B

**Laboratories authorised to handle 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 |

ANNEX 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 Decision 98/139/EC.

## ANNEX XIII

## DIAGNOSTIC TESTS AND STANDARDS FOR FOOT-AND-MOUTH DISEASE AND FOR THE DIFFERENTIAL DIAGNOSIS OF OTHER VESICULAR VIRUS DISEASES

In the context of this Annex, 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 Article 89(2) 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 Article 89(2). 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 Annexe XIV of this Directive, 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 Article 89(2).

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 Annex 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 Annex 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 regulations 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 Article 89(2) 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 Article 89(2) 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 Article 89(2) 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 Article 89(2) 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 Article 89(2) after consultation of the Community Reference Laboratory.

The Commission may arrange that standardised reference sera 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.

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 Article 89(2).

Member States 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.

## ANNEX 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 non-structural 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 referred to in Article 81;

(b) production of a safe, sterile and efficient vaccine with a potency of at least 6 $PD_{50}$ 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 National 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 their State Veterinary Service, 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 Annex 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 Annex 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.

## ANNEX XVI

## FUNCTIONS AND DUTIES OF A COMMUNITY REFERENCE LABORATORY FOR FOOT-AND-MOUTH DISEASE

The functions and duties of the Community Reference Laboratory referred to in Article 69 for foot-and-mouth disease shall be as follows:

1. To ensure liaison between the national laboratories of the Member States and to provide optimal methods for the diagnosis of foot-and-mouth disease in livestock,

and differential diagnosis of other vesicular viral diseases, where necessary, for each Member State specifically by:

1.1. regularly receiving field samples from Member States and countries geographically or commercially linked to the European Union in terms of trade in animals of susceptible species or products derived from such animals with a view to monitoring the disease situation globally and regionally, to estimating and where possible predicting the risk evolving from emerging virus strains and particular epidemiological situations and determining the identity of the virus, where necessary in close collaboration with OIE designated regional reference laboratory and the WRL;

1.2. typing and full antigenic and genomic characterisation of vesicular viruses from the samples referred to in point 1.1 and communicating the results of such investigations without delay to the Commission, the Member State, and the National Laboratory concerned;

1.3. building up and maintaining an up-to-date collection of vesicular virus strains;

1.4. building up and maintaining an up-to-date collection of specific sera against vesicular virus strains;

1.5. advising the Commission on all aspects related to foot-and-mouth disease vaccine strain selection and use.

2. To support the functions of National Laboratories, in particular by:

2.1. storing and supplying National Laboratories with reagents and materials for use in diagnosis of foot-and-mouth disease such as virus and/or inactivated antigens, standardised sera, cell lines and other reference reagents;

2.2. retaining expertise on foot-and-mouth disease virus and other pertinent viruses to enable rapid differential diagnosis;

2.3. promoting harmonisation of diagnosis and ensuring proficiency of testing within the Community by organising and operating periodic comparative trials and external quality assurance exercises on foot-and-mouth disease diagnosis at Community level and the periodic transmission of the results of such trials to the Commission, the Member States, and National Laboratories;

2.4. carrying out research studies with the objective of developing improved methods of disease control in collaboration with National Laboratories and as agreed in the annual work plan of the Community Reference Laboratory.

3. To provide information and carry out further training, in particular by:

3.1. gathering data and information on the methods of diagnosis and differential diagnosis used in National Laboratories and the distribution of such information to the Commission and the Member States;

3.2. making and implementing the necessary arrangements for the further training of experts in laboratory diagnosis with a view to harmonising diagnostic techniques;

3.3. keeping abreast of developments in foot-and-mouth disease epidemiology;

3.4. organising an annual meeting where representatives of the National Laboratories may review diagnostic techniques and the progress of coordination.

4. To perform experiments and field trials in consultation with the Commission directed towards an improved control of foot-and-mouth disease.

5. To review at the annual meeting of National Reference Laboratories the contents of Annex XIII defining the tests and standards for foot-and-mouth disease diagnosis within the European Union.

6. To cooperate with the national reference laboratories of candidate countries in accordance with this Annex.

7. The Community Reference Laboratory shall operate according to recognised conditions of strict disease security as indicated 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, April 1985, as amended by Appendix 6 (ii) of the report to the 30th Session of the European Commission for the control of foot-and-mouth disease 1993, referred to in Annex XII to this Directive.

8. The Community Reference Laboratory shall provide assistance to the Commission as required on the disease security measures to be taken by the National Laboratories in matters of foot-and-mouth disease diagnosis.

## ANNEX XVII

## CRITERIA AND REQUIREMENTS FOR CONTINGENCY PLANS

Member States 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. Each Member State 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 a Member State 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. Member States 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, Member States with a limited population of animals of susceptible species 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 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. Member State 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.

## ANNEX XVIII

### 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 of a Member State shall immediately:

(a) notify the primary case in accordance with Annex 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) immediately place under official surveillance holdings keeping animals of susceptible species in the defined infected area and shall in particular order that:

  (i) an official census 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) appropriate means 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 Annex 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, Member States shall apply the measures laid down in Article 11(2) of Directive 92/45/EEC. Parts not intended for human consumption shall be processed under official supervision;

(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. If a case of foot-and-mouth disease has occurred in wild animals in an area of a Member State close to the territory of another Member State, the Member States concerned shall collaborate in the establishment of disease control measures.

3. By way of derogation to the provisions in point 1 specific measures may be adopted in accordance with the procedure referred to in Article 89(3), if a case of foot-and-mouth disease has occurred in wild animals in an area of a Member State 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, Member States shall submit to the 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 Commission shall examine the plan in order to determine whether it permits the desired objective to be attained. The plan, if necessary with amendments, shall be approved in accordance with the procedure referred to in Article 89(3). 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, Member States shall ensure that the Commission and the other Member States are informed of these amendments without delay.

If the amendments concern other provisions of the plan, Member States shall submit the amended plan to the Commission for examination and possible approval in accordance with the procedure referred to in Article 89(3).

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 the territory of the Member State concerned.

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 Annex 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, Member States shall apply the measures laid down in Article 11(2) of Directive 92/45/EEC. Parts not intended for human consumption shall be processed under official supervision;

(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 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 Article 89(3).

## ANNEX XIX

## DEADLINES FOR TRANSPOSITION INTO NATIONAL LAW

| **Directive** | **Deadline for transposition** |
|---|---|
| 85/511/EEC | 1 January 1987 |
| 90/423/EEC | 1 January 1992 |

## ANNEX XX

## CORRELATION TABLE

| **This Directive** | **Directive 85/511/EEC** |
|---|---|
| Article 1, paragraph 1 (a) | Article 1 |
| Article 1, paragraph 1 (b) | — |
| Article 1, paragraph 2 | — |
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| Article 2 (b) to (h) and (l) to (y) | — |
| Article 2 (i) | Article 2 (d) |
| Article 2 (j) | Article 2 (e) |
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| Article 4 (1) | — |
| Article 4 (2) | Article 4 (1), first subparagraph |
| Article 4 (3) first sentence | Article 4 (1) second subparagraph |
| Article 4 (3) (a) | Article 4 (1) second subparagraph first indent, first part of sentence |

| | |
|---|---|
| Article 4 (3) (b) | Article 4 (1) second subparagraph first indent, second part of sentence |
| Article 4 (3) (c) | — |
| Article 4 (3) (d) | Article 4 (1) second subparagraph second and third indent |
| Article 4 (3) (e) | Article 4 (1) second subparagraph ninth indent |
| Article 4 (3) (f) | Article 4 (1) second subparagraph tenth indent |
| Article 4 (3) (g) | — |
| Article 5 (1) (a) | Article 4 (1) second subparagraph fifth indent |
| Article 5 (1) (b) | Article 4 (1) second subparagraph fourth indent |
| Article 5 (1) (c) | Article 4 (1) second subparagraph seventh indent |
| Article 5 (1) (d) | Article 4 (1) second subparagraph eighth indent |
| Article 5 (2) | Article 4 (1) second subparagraph sixth indent |
| Article 5 (3) | — |
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| Article 7 | — |
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| Article 9 | Article 4 (3) |
| Article 10 (1) (a) first sentence | Article 5 (2) first indent |
| Article 10 (1) (a) second sentence | — |
| Article 10 (1) (b) first subparagraph | Article 5 (1) |
| Article 10 (1) (b) second subparagraph | Article 5 (3) |
| Article 10 (1) (c) first sentence | Article 5 (2) second and fourth indent |
| Article 10 (1) (c) second and third sentences | — |
| Article 10 (1) (d) | Article 5 (2) fifth and sixth indent |
| Article 10 (2) (a) | Article 5 (2) seventh indent |
| Article 10 (2) (b) | — |
| Article 10 (2) (c) | Article 5 (2) eighth indent |
| Article 11 (1) | Article 10 |

| | |
|---|---|
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| Article 11 (3) | — |
| Article 11 (4) | — |
| Article 12 (relating to meat) | Article 5 (2) third indent |
| Article 12 (relating to other substances) | — |
| Article 13 (1) | Article 5 (2) ninth indent and Article 7 |
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| Article 17 | — |
| Article 18 (1) | Article 6 |
| Article 18 (2) | Decision 88/397/EEC |
| Article 18 (3) | Article 6 (1) second subparagraph |
| Article 18 (4) | — |
| Article 19 (1) to (4) | Article 8 |
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| Article 20 | Article 6 (3) |
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| Article 22 (1) (c) | Article 9 (2) (a) third indent first part of sentence |
| Article 22 (2) | Article 9 (2) (a) third indent second part of sentence |
| Article 23 (a) | Article 9 (2) (a) fifth to sixth indent |
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|---|---|
| Article 24 (2) (a) | Article 9 (2) (a) seventh indent last part of sentence |
| Article 24 (2) (b) | — |
| Article 24 (2) (c) | Article 9 (2) (a) fourth indent |
| Article 24 (2) (d) | — |
| Article 25 | — |
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| Article 35 | — |
| Article 36 (1) (a) | Article 9 (2) (b) first sentence |
| Article 36 (1) (b) | — |
| Article 36 (2) | Article 9 (2) (b) second sentence |
| Article 36 (3) | — |
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| Article 37 (2) | Article 9 (3) (a) |
| Article 38 (1) | Article 9 (3) (a) second indent first part |
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| Article 47 (1) | Article 12, first indent |
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| Article 48 | Article 12, second and third indent |
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| Article 50 (3) | Article 13 (3) second subparagraph |
| Article 50 (4) and (5) | Article 13 (3) third subparagraph |
| Article 50 (6) | — |
| Article 51 (1) | Article 13 (3) first subparagraph first to sixth indent |
| Article 51 (2) | — |
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| Article 63 | — |
| Article 64 | — |
| Article 65 (a), (b) and (c) | Article 13 (1) second indent |
| Article 65 (d) | Article 13 (1) fourth indent |

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|---|---|
| Article 66 | Article 13 (2) first and second subparagraph |
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| Article 68(1) (a) and (b) | Article 11 (1) first indent |
| Article 68 (1) (c) and (e) | Article 11 (1) second and third indent |
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| Article 69 | Council Decision 89/531/EEC |
| Article 70 (1) | — |
| Article 70 (2) | Article 13 (2) third subparagraph |
| Article 71 | — |
| Article 72 | Article 5 of Directive 90/423/EEC |
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| Article 92 (1) | Article 6 of Directive 90/423/EEC |
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|---|---|---|---|
| (**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. |
| (**3**) | UHT | = | Ultra High Temperature treatment at 132 °C for at least one second. |
| (**4**) | 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. |

(**5**) in accordance with the report of the Scientific Committee on Animal Health 1999