

Council Directive 2003/85/EC of 29 September 2003 on Community measures for the control of foot-and-mouth disease repealing Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC (Text with EEA relevance)

COUNCIL DIRECTIVE 2003/85/EC

of 29 September 2003

on Community measures for the control of foot-and-mouth disease repealing Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC

(Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 37(3) thereof,

Having regard to the proposal from the Commission<sup>(1)</sup>,

Having regard to the Opinion of the European Parliament<sup>(2)</sup>,

Having regard to the Opinion of the European Economic and Social Committee<sup>(3)</sup>,

Having regard to the Opinion of the Committee of the Regions<sup>(4)</sup>,

Whereas:

- (1) One of the Community's tasks in the veterinary field is to improve the state of health of livestock, thereby increasing the profitability of livestock farming and facilitating trade in animals and animal products. At the same time the Community is also a Community of values, and its policies to combat animal diseases must not be based purely on commercial interests but must also take genuine account of ethical principles.
- (2) Foot-and-mouth disease is a highly contagious viral disease of biungulates. Although foot-and-mouth disease has no public health importance, due to its exceptional economic importance, it is on the top of list A diseases of the Office International des Epizooties (OIE).
- (3) Foot-and-mouth disease is a compulsorily notifiable disease and outbreaks must be notified by the Member State affected to the Commission and other Member States, in accordance with Council Directive 82/894/EEC of 21 December 1982, on the notification of animal diseases within the Community<sup>(5)</sup>.
- (4) The Community measures for the control of foot-and-mouth disease are laid down in Council Directive 85/511/EEC of 18 November 1985 introducing Community measures for the control of foot-and-mouth disease<sup>(6)</sup>. That Directive has been significantly amended on many occasions. Now that new amendments are being made to the said

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Directive, it is desirable, in order to clarify matters, that the provisions in question should be recast.

- (5) Following the adoption of Council Directive 90/423/EEC of 26 June 1990 amending Directive 85/511/EEC, Directive 64/432/EEC on animal health problems affecting intra-Community trade in bovine animals and swine and Directive 72/462/EEC on health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat or meat products from third countries<sup>(7)</sup>, prophylactic vaccination against foot-and-mouth disease was prohibited throughout the Community as of 1 January 1992.
- (6) Preventive measures are necessary to avoid the incursion of foot-and-mouth disease into the Community and into Community livestock from neighbouring countries or through the introduction into the Community of live animals and products of animal origin. There is no indication that any of the outbreaks of foot-and-mouth disease reported since the prohibition of prophylactic vaccination can be attributed to imports in accordance with Community legislation and subject to veterinary checks at border inspection posts, established in accordance with Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organisation of veterinary checks on animals entering the Community from third countries<sup>(8)</sup>, and Council Directive 90/675/EEC of 10 December 1990 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries<sup>(9)</sup>.
- (7) Nevertheless, strict application of the Community rules on imports of animal products aimed at reducing risks should be strongly emphasised, if for no other reason than the increase in trade and movement of persons worldwide. The Member States should ensure that this legislation is implemented in its entirety and make enough personnel and resources available to provide strict controls on the external borders.
- (8) In addition, the European Parliament's Temporary Committee on Foot-and-Mouth Disease found that, in practice, border inspections are failing to prevent significant quantities of meat and meat products from entering the Community illegally.
- (9) Under the conditions of the single market and the overall satisfactory health status of livestock herds, the exchange of animals and animal products has increased substantially and certain regions of the Community have densely populated livestock areas.
- (10) The foot-and-mouth disease epidemic in certain Member States in 2001 demonstrated that due to intensive movement of and trade in animals susceptible to foot-and-mouth disease, an outbreak can quickly take on epizootic proportions, causing disturbances on a scale liable to reduce sharply the profitability of farming of animals of susceptible species and other parts of the rural economy and also requiring substantial financial resources to compensate farmers and the application of control measures.
- (11) During the 2001 foot-and-mouth disease crisis, the Commission reinforced the Community control measures for foot-and-mouth disease laid down in Directive 85/511/EEC by adopting protective measures in accordance with Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable

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- in intra-Community trade in certain live animals and products with a view to the completion of the internal market<sup>(10)</sup>, and Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market<sup>(11)</sup>.
- (12) In 2001, the Commission also adopted Decisions on the conditions for the use of emergency vaccination in accordance with Directive 85/511/EEC. Those conditions were laid down taking account of the recommendations contained in the report of the Scientific Committee on Animal Health and Animal Welfare on the strategy for emergency vaccination against foot-and-mouth disease of 1999.
  - (13) This Directive should take into account the report of expert groups from Member States on a review of Community legislation on foot-and-mouth disease of 1998, which reflects the experience gained by Member States during the classical swine fever epidemic in 1997, and the conclusions of the International Conference on the Prevention and Control of Foot-and-Mouth Disease held in Brussels in December 2001.
  - (14) The Resolution of 17 December 2002 of the European Parliament on the foot-and-mouth disease epidemic in 2001 in the European Union<sup>(12)</sup>, based on the conclusions of the Temporary Committee on Foot-and-Mouth Disease of the European Parliament should be taken into account in this Directive.
  - (15) The recommendations in the Report of the Thirtieth Session of the European Commission for the Control of Foot-and-Mouth Disease of the Food and Agriculture Organisation on minimum standards for laboratories working with foot-and-mouth virus in vitro and in vivo of 1993, should be taken into account.
  - (16) This Directive should also take into account the changes made in the Animal Health Code and the Manual of Standards for Diagnostic Tests and Vaccines of the OIE (OIE Manual).
  - (17) In order to ensure early detection of any possible outbreak of foot-and-mouth disease, legal provisions are necessary to oblige those in contact with animals of susceptible species to notify any suspect case to the competent authorities. Regular inspections should be introduced in the Member States to ensure that farmers are in fact familiar with and are applying the general rules on disease control and biosecurity.
  - (18) It is necessary that action be taken as soon as the presence of the foot-and-mouth disease is suspected so that immediate and effective control measures can be implemented once its presence is confirmed. Such measures should be modulated by the competent authorities depending on the epidemiological situation in the Member State concerned. However, the measures should also be reinforced by specific protection measures established in accordance with Community legislation.
  - (19) A rapid and detailed diagnosis of the disease and identification of the relevant virus should be carried out under the auspices of a network of national laboratories in the Member States. Where necessary, cooperation between the national laboratories should be ensured by a Community reference laboratory designated by the Commission in accordance with the procedure of the Standing Committee on the Food Chain and Animal Health established by Regulation (EC) No 178/2002 of the European

Parliament and the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety<sup>(13)</sup>.

- (20) With regard to the differential laboratory diagnosis for foot-and-mouth disease, account should be taken of Commission Decision 2000/428/EC of 4 July 2000 establishing diagnostic procedures, sampling methods and criteria for the evaluation of the results of laboratory tests for the confirmation and differential diagnosis of swine vesicular disease<sup>(14)</sup>.
- (21) Community measures for the control of foot-and-mouth disease should be based first of all on depopulation of the infected herd. The killing of infected and contaminated animals of susceptible species should be carried out without delay in accordance with Council Directive 93/119/EEC of 22 December 1993 on the protection of animals at the time of slaughter or killing<sup>(15)</sup>. Where possible the processing of the carcasses of dead or killed animals should be carried out in accordance with Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption<sup>(16)</sup>.
- (22) It is necessary to integrate public health and environment protection aspects in the event of a foot-and-mouth disease outbreak, in particular by establishing close cooperation between the veterinary health and environment competent authorities. Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control<sup>(17)</sup> requires an integrated environmental permit for installations for the disposal or recycling of animal carcasses and animal waste with a specified treatment capacity. Unnecessary risks from burning animal carcasses on pyres or burying them at mass burial sites should be avoided.
- (23) It is necessary to prevent any spread of the disease as soon as an outbreak occurs by carefully monitoring movements of animals and the use of products liable to be contaminated, and where appropriate, in particular in densely populated livestock areas, by emergency vaccination.
- (24) The action taken to control the foot-and-mouth disease epidemics which struck certain Member States in 2001 has shown that international and Community rules and the ensuing practices have not taken sufficient account of the possibility offered by the use of emergency vaccination and subsequent tests to detect infected animals in a vaccinated population. Too much importance was attached to the trade-policy aspects, with the result that protective vaccination was not carried out even when it had been authorised.
- (25) Various strategies are available for controlling foot-and-mouth disease. In the event of an epidemic, the choice of strategy to control the disease should likewise take account of which strategy causes the least possible economic damage for non-agricultural sectors of the economy.
- (26) By means of emergency vaccination without subsequent killing of the vaccinated animals the number of animals to be killed for disease control purposes may be reduced significantly. Appropriate testing should thereafter substantiate the absence of infection.

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- (27) Cleansing and disinfection should be an integral part of the Community control policy for foot-and-mouth disease. The use of disinfectants should be in compliance with Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market<sup>(18)</sup>.
- (28) Semen, ova and embryos collected from animals of susceptible species infected with the foot-and-mouth disease virus may contribute to the spread of the disease and should therefore be subject to restrictions in addition to those animal health conditions laid down for intra-Community trade in the following Directives:
- Council Directive 88/407/EEC of 14 June 1988 laying down the animal health requirements applicable to intra-Community trade in and imports of deep-frozen semen of domestic animals of the bovine species<sup>(19)</sup>;
  - Council Directive 89/556/EEC of 25 September 1989 on animal health conditions governing intra-Community trade in and importations from third countries of embryos of domestic animals of the bovine species<sup>(20)</sup>;
  - Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 90/425/EEC<sup>(21)</sup>.
- (29) In the event of an outbreak it may be necessary to apply control measures not only to infected animals of susceptible species, but also to contaminated animals of species not susceptible to the disease which may be mechanical vectors for the virus. During the 2001 foot-and-mouth disease epidemic, restrictions were also applied on the movement of equidae coming from holdings keeping animals of susceptible species or neighbouring such holdings and specific certification, in addition to the requirements of Council Directive 90/426/EEC of 26 June 1990 on animal health conditions governing the movement and import from third countries of equidae<sup>(22)</sup>, was required in order to control trade in equidae from Member States affected by foot-and-mouth disease.
- (30) With regard to animal health, the conditions governing placing on the market, trade and imports into the Community of animal products intended for human consumption are laid down in the following Directives:
- Council Directive 64/433/EEC of 26 June 1964 on health problems affecting intra-Community trade in fresh meat<sup>(23)</sup>;
  - Council Directive 77/99/EEC of 21 December 1976 on health problems affecting the intra-Community trade of meat products origin<sup>(24)</sup>;
  - Council Directive 80/215/EEC of 22 January 1980 on animal health problems affecting intra-Community trade in meat products<sup>(25)</sup>;
  - Council Directive 91/495/EEC of 27 November 1990 concerning public health and animal health problems affecting the production and placing on the market of rabbit meat and farmed game meat<sup>(26)</sup>;

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- Council Directive 94/65/EC of 14 December 1994 laying down the requirements for the production and placing on the market of minced meat and meat preparations<sup>(27)</sup>,
  - Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption<sup>(28)</sup>.
- (31) Those Directives are now in the process of being replaced. In order to ease reference, the treatment of meat and meat products from animals of susceptible species, required to ensure the destruction of possible foot-and-mouth disease virus, is specified in the Annexes VII to IX of this Directive which are based on those Directives and comply with recommendations of the OIE.
- (32) The animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption are laid down in Council Directive 2002/99/EC of 16 December 2002<sup>(29)</sup>.
- (33) Council Directive 92/46/EEC of 16 June 1992 laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products<sup>(30)</sup> provides for the treatment of milk from animals kept within the perimeters of surveillance zones established in accordance with Community control measures for foot-and-mouth disease. The requirements of that Directive are not sufficient, as they do not provide for treatment of milk from protection zones and from vaccinated animals. In addition, the treatment for milk for human consumption provided for in that Directive exceeds the requirements of the code of the OIE on destruction of foot-and-mouth disease virus in milk and results in logistic problems in the disposal of substantial quantities of milk refused by dairy plants. More detailed provisions on the collection and transport of milk from animals of susceptible species in areas subject to control measures for foot-and-mouth disease should be included in this Directive. The treatment of milk and milk products specified in Annex IX of this Directive complies with recommendations of the OIE for the destruction of possible foot-and-mouth disease virus in milk and milk products. Directive 92/46/EEC should therefore be amended accordingly.
- (34) With regard to products of animal origin account should be taken of Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC<sup>(31)</sup>. Certain provisions of Directive 92/118/EEC have been included in Regulation (EC) No 1774/2002.
- (35) The application of the principle of regionalisation should allow the implementation of strict control measures, including emergency vaccination, in a defined part of the Community without endangering general Community interests. Dairy and meat products from vaccinated animals may be placed on the market in accordance with the relevant Community legislation and this Directive in particular.

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- (36) Directive 64/432/EEC provides for the definition of regions. Commission Decision 2000/807/EC of 11 December 2000 laying down the codified form and the codes for the notification of animal diseases pursuant to Council Directive 82/894/EEC<sup>(32)</sup> specifies administrative areas in Member States related to disease control measures and disease notification.
- (37) To guard against emergencies, the Community has, in accordance with Council Decision 91/666/EEC of 11 December 1991 establishing Community reserves of foot-and-mouth disease vaccines<sup>(33)</sup>, established reserves of inactivated foot-and-mouth disease virus antigen stored at designated premises, and the Community antigen and vaccine bank. Transparent and efficient procedures should be established to guarantee access to the antigen without undue delay. In addition, certain Member States have established and maintain national antigen and vaccine banks.
- (38) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products<sup>(34)</sup> requires that, with only minor exceptions, all veterinary medicinal products that are placed on the market within the Community hold a marketing authorisation. In addition, that Directive lays down the criteria for the granting of a marketing authorisation for veterinary medicinal products, including immunological veterinary medicinal products. That Directive authorises Member States to permit release onto their market of a product without a marketing authorisation in the event of a serious epidemic under certain conditions. Foot-and-mouth disease has the potential for a serious epidemic. Given the rapid variation of antigen required to produce an effective protection of animals of susceptible species in case of emergency, vaccines against foot-and-mouth disease qualify for the derogation provided for in that Directive.
- (39) The Community Reference Laboratory should advise the Commission and the Member States on the need for vaccines and antigens, in particular where virus strains are detected against which the vaccines produced on the basis of those antigens stored in the Community antigen and vaccine bank do not provide sufficient protection.
- (40) As a matter of precaution, in relation to the risks of a deliberate release of foot-and-mouth disease virus, it is appropriate to apply specific procedures to the procurement of antigens for the Community antigen and vaccine bank and to the publication of certain details relating to disease control measures.
- (41) The presence of an entirely non-immune population of susceptible livestock in Member States requires permanent disease-awareness and preparedness. The need for detailed contingency plans has been proven once more during the 2001 foot-and-mouth disease epidemic. At present, all Member States have contingency plans approved by Commission Decision 93/455/EEC of 23 July 1993 approving certain contingency plans for the control of foot-and-mouth-disease<sup>(35)</sup>. Such contingency plans should be reviewed regularly, among other things, in the light of the results of real-time alert exercises carried out in the Member States, the experience of the 2001 epidemic and in order to include measures to protect the environment. Member States should be encouraged to organise and carry out such exercises in close cooperation and across borders. The Commission should be encouraged, in cooperation with the Member

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States, to make provision for the setting-up of technical assistance which could be made available to Member States affected by an epidemic.

- (42) In order to protect Community livestock and based on risk assessment, provision should be made to assist neighbouring third countries infected by or at risk of foot-and-mouth disease, in particular as regards the emergency supply of antigen or vaccines. However, such provisions should apply without prejudice to agreements concluded between the third country concerned and the Community on access to the Community antigen and vaccine bank.
- (43) Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field<sup>(36)</sup>, applies in the event of the occurrence of foot-and-mouth disease and provides for Community aid to be granted to reference laboratories and antigen and vaccine banks. Any Community compensation paid to Member States for financial expenditures relating to control measures in the case of outbreaks of foot-and-mouth disease, should be subject to scrutiny regarding compliance with at least the minimum requirements laid down in this Directive.
- (44) In order to ensure close cooperation between the Member States and the Commission in controlling foot-and-mouth disease and taking into account the nature of the disease, the Commission should be empowered to modify and adapt certain technical aspects of the control measures. Where necessary, the Commission should base any such modifications or adaptations on the results of a veterinary inspection mission carried out in accordance with Commission Decision 98/139/EC of 4 February 1998 laying down certain detailed rules concerning on-the-spot checks carried out in the veterinary field by Commission experts in the Member States<sup>(37)</sup>.
- (45) The Member States should lay down rules on penalties applicable to infringements of the provisions of this Directive and ensure that they are implemented. Those penalties must be effective, proportionate and dissuasive.
- (46) In accordance with the principle of proportionality, it is necessary and appropriate for the achievement of the basic objective of maintaining and, in the event of an outbreak, of quick recovery of a foot-and-mouth disease and infection-free status of all Member States, to lay down rules on the measures to increase disease preparedness and to control outbreaks as quickly as possible, if necessary by emergency vaccination, and to limit the adverse effects on the production of and trade in livestock and products of animal origin. This Directive does not go beyond what is necessary in order to achieve the objectives pursued in accordance with the third paragraph of Article 5 of the Treaty.
- (47) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission<sup>(38)</sup>,

HAS ADOPTED THIS DIRECTIVE:



## CHAPTER I

**SUBJECT MATTER, SCOPE AND DEFINITIONS***Article 1***Subject matter and scope**

- 1 This Directive sets 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.
- 2 Member States shall remain free to take more stringent action in the field covered by this Directive.

*Article 2***Definitions**

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

- (a) ‘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 Article 1(2), Article 15 and Article 85(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.

- (b) ‘holding’ means any agricultural or other premises, including circuses, located in the national territory of a Member State where animals of susceptible species are being bred or kept on a permanent or temporary basis.

However, for the purpose of Article 10(1) this definition does not include living areas for humans on such premises, unless animals of susceptible species, including those referred to in Article 85(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 Article 10 inapplicable;

- (c) ‘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;
- (d) ‘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;
- (e) ‘competent authority’ means the authority of a Member State competent to carry out veterinary or zootechnical checks or any authority to which it has delegated that competence;

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- (f) ‘official veterinarian’ means the veterinarian designated by the competent authority of the Member State;
- (g) ‘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 the Member State concerned;
- (h) ‘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 this Directive, 14 days for bovine and porcine animals, and 21 days for ovine and caprine animals and any other animal of susceptible species;
- (i) ‘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;
- (j) ‘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;
- (k) ‘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 Annex 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 Annex XIII;
- (l) ‘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 Annex I;
- (m) ‘primary outbreak’ means the outbreak within the meaning of Article 2(d) of Directive 82/894/EEC;
- (n) ‘killing’ means the killing of animals within the meaning of Article 2(6) of Directive 93/119/EEC;
- (o) ‘emergency slaughter’ means the slaughter in emergency cases within the meaning of Article 2(7) of 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 foot-and mouth disease virus, including slaughter for reasons of animal welfare;
- (p) ‘processing’ means one of the treatments for high risk material laid down in 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;
- (q) ‘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 Article 45 in order to prevent the spread of foot-and-mouth disease into the free zone where no restrictions are applied in accordance with this Directive;
- (r) ‘region’ means an area as defined in Article 2(2) (p) of Directive 64/432/EEC;
- (s) ‘sub-region’ means an area specified in the Annex to Decision 2000/807/EC;

- (t) ‘Community antigen and vaccine bank’ means appropriate premises designated in accordance with this Directive 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 Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products<sup>(39)</sup>;
- (u) ‘emergency vaccination’ means vaccination in accordance with Article 50(1);
- (v) ‘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;
- (w) ‘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;
- (x) ‘wild animal’ means an animal of a susceptible species living outside holdings as defined in Article 2(b) or premises referred to in Articles 15 and 16;
- (y) ‘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 Article 85(3) or (4).

## CHAPTER II

### CONTROL OF OUTBREAKS OF FOOT-AND-MOUTH DISEASE

#### SECTION 1

#### NOTIFICATION

##### *Article 3*

##### **Foot-and-mouth disease notification**

- 1 Member States shall ensure that:
  - 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

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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 this Directive.

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

## SECTION 2

### MEASURES IN CASE OF SUSPICION OF AN OUTBREAK OF FOOT-AND-MOUTH DISEASE

#### *Article 4*

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

1 Member States shall ensure that the measures provided for in paragraphs 2 and 3 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 Annex I.

3 The competent authority shall place the holding referred to in paragraph 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 point (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 Article 18, 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 Article 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 Annex III.

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### *Article 5*

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

1 Member States shall ensure that in addition to the measures provided for in Article 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 point (a) of paragraph 1, 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 points (b), (c) and (d) of paragraph 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.

### *Article 6*

#### **Extension of measures to other holdings**

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

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

### *Article 7*

#### **Temporary control zone**

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.

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2 At least the measures provided for in Article 4(2) and (3)(a), (b) and (d) and in Article 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 a Member State. 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.

#### *Article 8*

### **Preventive eradication programme**

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 Annex III.

3 The competent authority shall notify the Commission prior to the implementation of the measures provided for in this Article.

#### *Article 9*

### **Maintenance of measures**

Member States shall not withdraw the measures provided for in Articles 4 to 7 until the suspicion of foot-and-mouth disease has been officially ruled out.

## SECTION 3

### **MEASURES IN CASE OF CONFIRMATION**

#### *Article 10*

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

1 As soon as an outbreak of foot-and-mouth disease is confirmed, Member States shall ensure that, in addition to the measures provided for in Articles 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 Member State concerned shall notify the 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

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referred to in Article 13 have been taken in accordance with point 2.1.1.1 of Annex III, and in sufficient numbers.

The competent authority may decide that Article 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 Article, provided that appropriate and sufficient numbers of samples needed for the epidemiological inquiry referred to in Article 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 point (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 Article 72.
- d All products and substances referred to in Article 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 paragraph 1(d), Member States 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 Article 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 Annex V.

### *Article 11*

#### **Cleansing and disinfection**

1 Member States shall ensure that cleansing and disinfection operations, as integral parts of the measures provided for in this Directive, 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 Directive 98/8/EC, in order to ensure destruction of the foot-and-mouth disease virus.

2 Member States 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 Member States 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 Member States shall ensure that cleansing and disinfection operations are carried out in accordance with Annex IV.

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### *Article 12*

#### **Tracing and treatment of products and substances derived from or having been in contact with animals of an outbreak of foot-and-mouth disease**

Member States shall ensure that the products and substances referred to in Article 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.

### *Article 13*

#### **Epidemiological inquiry**

1 Member States 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 Article 72, 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 Article 4(3)(c) likely to have carried the foot-and-mouth disease virus to or from the holdings in question.

2 Member States shall inform and regularly update the Commission and the other Member States about the epidemiology and spread of the foot-and-mouth disease virus.

### *Article 14*

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

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.

However, the first subparagraph shall 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 Community legislation, so as to allow the control of their movement.



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2 The competent authority may apply the measures provided for in Article 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 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 Annex 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 Article 21.

4 The competent authority may apply the measures provided for in Articles 7 and 8.

#### SECTION 4

### MEASURES TO BE APPLIED IN SPECIAL CASES

#### *Article 15*

#### **Measures to be applied in case of an outbreak of foot-and-mouth disease in the vicinity or within certain specific premises keeping on a temporary or regular basis animals of susceptible species**

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 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 Member State concerned 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 paragraph 1, the Member State concerned may decide to derogate from Article 10(1)(a), provided that basic 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 paragraph 2 shall immediately be notified to the Commission. In the case of farm animal genetic resources, this notification shall include a reference to the list of premises established in accordance with Article 77(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.

#### *Article 16*

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

1 Where a case of foot-and-mouth disease is confirmed in a slaughterhouse, a border inspection post established in accordance with Directive 91/496/EEC or in a means of transport,

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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 Regulation (EC) 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 Article 11 and with the instructions laid down by the competent authority;
- f an epidemiological inquiry shall be carried out in accordance with Article 13.

2 Member States shall ensure that the measures provided for in Article 19 are applied in contact holdings.

3 Member States shall ensure that no animals are reintroduced for slaughter, inspection or transport in the premises or means of transport referred to in paragraph 1 until at least 24 hours after completion of the cleansing and disinfection operations referred to in paragraph 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 paragraph 1 must be suspected, Member States shall ensure that by way of derogation from Article 2(b), second sentence, an outbreak is declared on the premises or means of transport referred to in paragraph 1, and the measures provided for in Articles 10 and 21 are applied.

#### *Article 17*

#### **Review of measures**

The Commission shall review the situation regarding the special cases referred to in Article 15 in the Standing Committee on the Food Chain and Animal Health at the earliest possible opportunity. The necessary measures to prevent the spread of the foot-and-mouth disease virus, in particular in relation to regionalisation in accordance with Article 45, and to emergency vaccination in accordance with Article 52, shall be adopted in accordance with the procedure referred to in Article 89(3).

## SECTION 5

### **HOLDINGS CONSISTING OF DIFFERENT EPIDEMIOLOGICAL PRODUCTION UNITS AND CONTACT HOLDINGS**

#### *Article 18*

##### **Holdings consisting of different epidemiological production units**

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 Article 10(1)(a) as regards production units of such holdings not affected by foot-and-mouth disease.

2 The derogation provided for in paragraph 1 shall only be granted after the official veterinarian has confirmed at the time of the official investigation referred to in Article 4(2), that the following conditions to prevent the spread of foot-and-mouth disease virus between the production units referred to in paragraph 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 Article 10(1)(d) may be granted to a holding producing milk provided that:

- a such holding complies with the conditions set out in paragraph 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 Annex IX.

4 Where a derogation is granted in accordance with paragraph 1, Member States shall lay down in advance detailed rules for applying such derogation. The Member States shall notify the Commission of the derogation and provide details of the measures taken.

#### *Article 19*

##### **Contact holdings**

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 Articles 4(1) or 10(1) or from a holding referred to in Articles 4(1) or 10(1) to other holdings.

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

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virus on these contact holdings has been officially ruled out in accordance with the definition in Annex I and the survey requirements provided for in point 2.1.1.1 of Annex 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 concerned in Article 2(h). However, the competent authority may, by way of derogation from Article 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 Annex III.

4 Where the competent authority considers that the epidemiological situation permits, it may limit the recognition as a contact holding provided for in paragraph 1, to one identified epidemiological production unit of the holding and to the animals contained therein, provided that the epidemiological production unit complies with Article 18.

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

#### *Article 20*

### **Coordination of measures**

The Commission may review the situation regarding the holdings referred to in Articles 18 and 19 in the Standing Committee on the Food Chain and Animal Health with a view to the adoption, in accordance with the procedure referred to in Article 89(3), of the necessary measures to ensure coordination of the measures implemented by the Member States pursuant to Articles 18 and 19.

## SECTION 6

### **PROTECTION AND SURVEILLANCE ZONES**

#### *Article 21*

### **Establishment of protection and surveillance zones**

1 Member States shall ensure that, without prejudice to measures provided for in Article 7, at least the measures laid down in paragraphs 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 km and a surveillance zone based on a minimum radius of 10 km centred on the outbreak of foot-and-mouth disease referred to in paragraph 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.

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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 Articles 74 and 76 shall be established. For the purpose of carrying out the epidemiological inquiry as provided for in Article 13, those centres shall be assisted by an expert group as provided for in Article 78.

5 Member States 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 Commission about their results from tracing of animals.

6 Member States 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 paragraph 2 come into force. Such fresh meat, meat products, raw milk and raw milk products shall be treated in accordance with Articles 25, 26 and 27 respectively or detained until possible contamination with the foot-and-mouth disease virus is officially ruled out.

## *Article 22*

### **Measures to be applied to holdings in the protection zone**

1 Member States 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 subparagraph (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 Annex III or taking of samples from animals of susceptible species in accordance with point 2.1.1.1 of Annex III;
- c animals of susceptible species shall not be removed from the holding on which they are kept.

2 By way of derogation from paragraph 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.

The movement referred to in the first subparagraph shall only be authorised if the competent authority is satisfied on the basis of a clinical examination in accordance with point 1 of Annex 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 Article 25.

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### Article 23

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

Member States 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.

### Article 24

#### **Additional measures and derogations**

- 1 The competent authority may extend the prohibitions in Article 23 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 Article 33 to holdings keeping animals of susceptible species.
- 2 The competent authorities may authorise:
  - a the transit of animals of all species through the protection zone undertaken exclusively via major highways or mainline railways;
  - 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 Annex VI.

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- e the transport, under certain conditions, of goods referred to in Article 33 to holdings keeping animals of susceptible species.

#### *Article 25*

#### **Measures in relation to fresh meat produced in the protection zone**

1 Member States 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 Member States 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 Member States shall ensure that fresh meat, minced meat and meat preparations as referred to in paragraph 1, shall be marked in accordance with 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 Annex VII of this Directive.

4 By way of derogation, the prohibition provided for in paragraph 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 clear mark established in conformity with Community legislation.

5 By way of derogation, the prohibition provided for in paragraph 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 paragraph 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 Article 24(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 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 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 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 this Directive.

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

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7 Derogation from the prohibition provided for in paragraph 1 may be granted subject to specific conditions adopted in accordance with the procedure referred to in Article 89(3), 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.

#### *Article 26*

##### **Measures in relation to meat products produced in the protection zone**

1 Member States 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 paragraph 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 Annex VII or which have been produced from meats referred to in Article 25(4).

#### *Article 27*

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

1 Member States 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 Member States 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 paragraph 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 paragraph 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 Annex IX, depending on the use of the milk or milk products. The treatment shall be carried out under the conditions set out in paragraph 6 in establishments referred to in paragraph 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 paragraph 8.

5 By way of derogation, the prohibition provided for in paragraph 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 paragraph 6.

6 Establishments referred to in paragraphs 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 paragraphs 3 and 4 or the raw milk shall be obtained from animals outside the protection zone;



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- 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 paragraph 6 shall be certified by the competent authority for milk intended for intra-Community trade. The competent authority shall supervise the control of compliance undertaken by the local veterinary authority and, in the case of intra-Community trade, communicate to other Member States and the 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, 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 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.

### *Article 28*

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

1 Member States 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 paragraph 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.

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- 3 Frozen semen collected in accordance with Community legislation after the date of infection referred to in paragraph 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 Article 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 Annex 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.

#### *Article 29*

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

1 Member States shall ensure that the transport and distribution of dung or manure from holdings and premises or means of transport referred to in Article 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 paragraph 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 Regulation (EC) No 1774/2002 or for intermediate storage.

3 By way of derogation from the prohibition in paragraph 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 Articles 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 point (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 Member states 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.

### *Article 30*

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

- 1 Member States 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 paragraph 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 Article 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 Annex VII.

### *Article 31*

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

- 1 Member States 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 paragraph 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 Article 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 Annex VII.

### *Article 32*

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

- 1 Member States shall ensure that the placing on the market of animal products derived from animals of susceptible species not referred to in Articles 25 to 31 shall be prohibited.
- 2 By way of derogation, the prohibitions provided for in paragraph 1 shall not apply to products referred to in paragraph 1 which:
  - a either have been produced at least 21 days before the estimated date of infection on the holding referred to in Article 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 Annex VII, or
  - c for specific products, comply with the appropriate requirements in points 5 to 9 in Part A of Annex 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 this Directive, or
  - e are packed products intended for use as in-vitro diagnostic or laboratory reagents.

### *Article 33*

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

- 1 Member State 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 paragraph 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 Article 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 paragraph 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 Annex VII.

### *Article 34*

#### **Granting of derogations and additional certification**

- 1 Any derogation from the prohibitions provided for in Articles 24 to 33 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 Articles 25 to 33 requires, in the case of intra-Community trade, additional certification by the competent authority.
- 3 Detailed rules for the implementation of the measures provided for in paragraph 2 may be adopted in accordance with the procedure referred to in Article 89(2).

### *Article 35*

#### **Additional measures applied by Member States in the protection zone**

In addition to the measures applicable in the protection zone in accordance with this Directive, Member States 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. Member States shall inform the Commission and the other Member States about such additional measures.

### *Article 36*

#### **Removal of measures in the protection zone**

- 1 Member States 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 Article 10(1) and the completion of the preliminary cleansing and disinfection on that holding, carried out in accordance with Article 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 Articles 37 to 42, shall continue to apply for at least 15 days until those measures are removed in accordance with Article 44.
- 3 The survey referred to in paragraph 1(b) shall be carried out to substantiate the absence of infection and at least in compliance with the criteria of point 1 of Annex III and shall include the measures provided for in point 2.3 of Annex III based on the criteria set out in points 2.1.1. and 2.1.3. of Annex III.

### *Article 37*

#### **Measures to be applied to holdings in the surveillance zone**

- 1 Member States shall ensure that the measures provided for in Article 22(1) are applied in the surveillance zone.
- 2 By way of derogation from the prohibition provided for in Article 22(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 Article 22(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 Annex 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 Article 39.

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### Article 38

#### **Movement of animals of susceptible species within the surveillance zone**

1 Member States 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 paragraph 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 Article 37(2);
- d for transporting them in accordance with Article 24(2)(a) and (b).

3 Movements of animals provided for in paragraph 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 Annex 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 paragraph 2(b) shall be authorised by the competent authority only after the measures provided for in Article 37(2)(a) and (b) have been completed with satisfactory results.

5 Member States 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.

### Article 39

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

1 Member States 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 Member States 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 paragraph 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

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dispatch outside the surveillance zone by means of clear mark established in conformity with Community legislation.

4 By way of derogation, the prohibition provided for in paragraph 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 Article 37(2)(a) to (e) under the condition that the meat is subject to the measures provided for in paragraph 5.

5 By way of derogation, the prohibition provided for in paragraph 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 paragraph 4 and subject to the additional conditions provided for in Part B of Annex VIII or obtained from animals reared and slaughtered outside the surveillance zone or obtained from animals transported in accordance with the provisions in Article 24(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 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 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 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 this Directive.

6 By way of derogation, the prohibition provided for in paragraph 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 Directive 2002/99/EC and transported under official supervision to a designated establishment for treatment in accordance with point 1 in Part A of Annex VII.

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

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

9 Derogation from the prohibition provided for in paragraph 1 may be granted subject to specific conditions adopted in accordance with the procedure referred to in Article 89(3), 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.

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#### Article 40

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

1 Member States 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 Member States 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 paragraph 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 paragraph 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 Annex IX depending on the use of the milk or milk products. The treatment shall be carried out under the condition set out in paragraph 6 in establishments referred to in paragraph 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 paragraph 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 paragraph 6.

6 Establishments referred to in paragraphs 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 paragraph 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 paragraph 6 shall be certified by the competent authority for milk intended for intra-Community trade. The competent authority shall supervise the control of compliance undertaken by the local veterinary authority and, in the case of intra-Community trade, communicate to other Member States and the 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.

#### *Article 41*

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

1 Member States shall ensure that the transport and distribution of dung or manure from holdings and other premises such as those mentioned in Article 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 paragraph 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 Article 29(2).

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#### *Article 42*

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

Member State shall ensure that the placing on the market of products of animal origin other than those referred to in Articles 39 to 41 shall be subject to the conditions provided for in Articles 28 and 30 to 32.

#### *Article 43*

### **Additional measures applied by Member States in the surveillance zone**

In addition to the measures provided for in Articles 37 to 42, Member States 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 Annex VI.

#### *Article 44*

### **Removal of measures in the surveillance zone**

1 Member states 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 Article 10(1) and the completion of the preliminary cleansing and disinfection on that holding, carried out in accordance with Article 11;
- b the requirements provided for in Article 36 have been met in the protection zone;
- c a survey has been concluded with negative results.

2 The survey referred to in paragraph 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 Annex III and shall include the measures provided for in point 2.4 of Annex III based on the criteria of point 2.1 of Annex III.

## SECTION 7

### **REGIONALISATION, MOVEMENT CONTROL AND IDENTIFICATION**

#### *Article 45*

### **Regionalisation**

1 Without prejudice to 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 this Directive and the epizootic becomes extensive and in any case when

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emergency vaccination is implemented, Member States shall ensure that their territory is regionalised into one or more restricted and free zones.

2 Member States shall notify to the Commission without delay the details of the measures implemented in the restricted zone and the Commission shall review, where necessary amend, and endorse the measures in accordance with the procedure referred to in Article 89(3).

3 Without prejudice to the obligation of Member States to regionalise referred to in paragraph 1, regionalisation, and the measures to be applied within the restricted zone, may be decided in accordance with the procedure referred to in Article 89(3). 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 Article 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.

#### *Article 46*

##### **Measures applied in a restricted zone of a member state**

1 Where regionalisation is applied, Member States 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 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 Community legislation, of products for human consumption intended and eligible for dispatch outside the restricted zone.

2 Where regionalisation is applied, Member States 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 Member States 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 Annex IX depending on the use, or detained until possible contamination with the foot-and-mouth disease virus is officially ruled out.

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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 Directive 2002/99/EC.

#### *Article 47*

### **Identification of animals of susceptible species**

1 Without prejudice to Community legislation on identification of domestic bovine, ovine and caprine animals and swine, Member States 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 Article 15(1) and Article 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 Commission.

2 The measures taken by Member States 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 Articles 52 and 53, may be modified in accordance with the procedure referred to in Article 89(3).

#### *Article 48*

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

1 Member States shall ensure that in the event of an outbreak of foot-and-mouth disease on their territory the following measures to control movement of animals of susceptible species are applied in the restricted zone established in accordance with Article 45:

- 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 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 Directive 64/432/EEC.

2 Member States may extend some or all the measures provided for in paragraph 1 to a part or the entire free zone.

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## SECTION 8

### VACCINATION

#### *Article 49*

#### **Use, manufacture, sales and controls of foot-and-mouth disease vaccines**

Member States 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 this Directive;
- (b) the production, storage, supply, distribution and sale of foot-and-mouth disease vaccines on their territory 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 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.

#### *Article 50*

#### **Decision on introducing emergency vaccination**

1 It may be decided 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 the Member State 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 a Member State;
- 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 a Member State where there are outbreaks of foot-and-mouth disease;
- d Member States are 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 Article 15 and to the criteria listed in Annex X.

3 The decision to introduce emergency vaccination shall be adopted in accordance with the procedure referred to in Article 89(3).

4 The decision referred to in paragraph 3 to introduce emergency vaccination on its own territory may be requested:

- a either by the Member State referred to in paragraph 1(a), or
- b by a Member State referred to in paragraph 1(b), (c) or (d).

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5 By way of derogation from paragraph 3, the decision to introduce emergency vaccination may be taken by the Member State concerned and implemented in accordance with this Directive, after a written notification to the Commission which shall include the specifications provided for in Article 51.

6 If a Member State introduces emergency vaccination in accordance with paragraph 5, that decision shall be immediately reviewed in the Standing Committee on the Food Chain and Animal Health and Community measures shall be adopted in accordance with the procedure referred to in Article 89(3).

7 By way of derogation from paragraph 4, a decision to introduce emergency vaccination in a Member State referred to in paragraph (1)(a) may be adopted in concertation with the affected Member State in accordance with the procedure referred to in Article 89(3) on the Commission's own initiative, if the condition in paragraph (1)(a) and paragraph (1)(b) apply.

#### *Article 51*

### **Conditions for emergency vaccination**

1 The decision to introduce emergency vaccination in accordance with Article 50(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 Article 45 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 Article 47(2);
- f other matters appropriate to the emergency situation.

2 The conditions for emergency vaccination as provided for in paragraph 1, shall ensure that such vaccination is carried out in accordance with Article 52, irrespective of whether the vaccinated animals are subsequently slaughtered or stay alive.

3 Member States 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.

#### *Article 52*

### **Protective vaccination**

- 1 Member States applying protective vaccination shall ensure that:
- a the vaccination zone shall be regionalised in accordance with Article 45, 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 Section 7;

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- 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 this Directive shall be maintained within that part of the vaccination zone until such measures have been removed in accordance with Article 36 or Article 44;
    - (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 Articles 54 to 58 shall continue to apply.
- 2 Member States 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 km 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 Article 61.

#### *Article 53*

### **Suppressive vaccination**

- 1 Member States shall notify the Commission if they decide in accordance with Article 50 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 Article 21.
- 2 Member States 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 Article 10(1) and in particular subparagraph (a) thereof.

However, for logistical reasons and by way of derogation from Article 10(1)(a), the killing of all animals on such holdings may be delayed as long as necessary to comply with Directive 93/119/EEC and the provisions of Article 10(1)(c) of this Directive.

#### *Article 54*

### **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)**

- 1 Member States shall ensure that the measures provided for in paragraphs 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.

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By way of derogation from the prohibition provided for in the first subparagraph, and after clinical inspection of such live animals and the herds of origin or dispatch of those animals, the competent authorities 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 paragraph 1 shall:

- a bear the mark provided for in Directive 2002/99/EC;
- b be stored and transported separately from meat not bearing the mark referred to in point (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 Annex 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 Annex IX. The treatment shall be carried out under the conditions set out in paragraph 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 paragraph 7.

5 Establishments referred to in paragraphs 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 paragraph 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 paragraph 5 shall be certified by the competent authority for milk intended for intra-Community trade. The competent authority shall supervise the control of compliance undertaken by the local veterinary authority and in the case of intra-Community trade communicate to other Member States and the 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 in the first subparagraph, 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 paragraph 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 Article 28(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 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 paragraphs 9 and 10 shall be subject to the conditions provided for in Articles 30, 31, 32 and 41.

#### *Article 55*

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

1 Member States shall ensure that the measures provided for in paragraphs 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 Articles 56 and 57.

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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 paragraph 2, the competent authorities may authorise direct transport for immediate slaughter of animals of susceptible species from holdings referred to in Article 57(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 Article 56(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 paragraph 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 Annex 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 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 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 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 this Directive.

5 Compliance with the conditions in paragraph 4 shall be certified by the competent authority for fresh meat intended for intra-Community trade. The competent authority shall supervise the control of compliance undertaken by the local veterinary authorities and, in the case of intra-Community trade, communicate to other Member States and the 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 paragraph 1 shall bear the health mark provided for in 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 Annex 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 Annex IX. Such treatment shall have been undergone in an establishment located within or outside the vaccination zone in accordance with the provisions in Article 54(4) to (8).

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8 For the collection of semen, ova and embryos from animals of susceptible species, the measures provided for in Article 54(9) and (10) shall continue to apply.

9 The placing on the market of products of animal origin other than those referred to in paragraphs 4, 6, 7 and 8 shall be subject to the conditions provided for in Articles 30, 31, 32 and 41.

#### *Article 56*

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

1 Member States shall ensure that the measures provided for in paragraphs 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 paragraph 3.

3 Laboratory testing shall be carried out by use of tests complying with the criteria for diagnostic tests as set out in Annex XIII and approved in accordance with the procedure referred to in Article 89(2), 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 non-structural 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 Annex III. Where the competent authorities use in addition sentinel animals, the conditions for restocking of infected holdings in Annex 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.

#### *Article 57*

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

1 Member States shall ensure that the holdings containing animals of susceptible species:

- a are classified according to the outcome of the survey referred to in Article 56(2) and the criteria set out in Annex I;
- b comply with the measures set out in paragraphs 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 Annex I shall be subject to the measures provided for in Articles 10 and 21.

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:

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- (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 Article 56(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 authorities;
  - b cleansing and disinfection of the holdings in accordance with Article 11;
  - c restocking of animals in accordance with Annex V.
- 4 Member States shall ensure that the following measures are applied to products derived from animals of susceptible species and produced during the period referred to in Article 56(1):
- a fresh meat produced from the animals referred to in paragraph 3(2)(ii) shall be subject to Article 55(4), for meat from ruminants, and (6), for meat from porcine animals, respectively;
  - b milk and milk products produced from the animals referred to in paragraph 3(2)(ii) shall undergo at least one of the treatments specified in Parts A and B of Annex IX depending on the intended use and in compliance with the provisions in Article 54(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 Article 56(3) may be subject to the measures provided for in Article 58.

#### *Article 58*

##### **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)**

- 1 Member States shall ensure that the measures provided for in paragraphs 2 to 6 are applied in the vaccination zone after the completion of the measures laid down in Article 57 and until the foot-and-mouth disease and infection-free status has been recovered in accordance with Article 59.
- 2 Member States 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 Article 55(3).
- 4 By way of derogation from the prohibition in paragraph 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 Annex 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 Article 57(3) have been completed in the entire vaccination zone or the animals are transported to the slaughterhouse under the conditions provided for in paragraph 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 point (a) or from animals reared and/or slaughtered outside the vaccination zone or fresh meat referred to in paragraph 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 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 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 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 this Directive.
- 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 paragraph 1 shall bear the health mark provided for in 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 Annex VII.
- 8 By way of derogation from paragraph 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 Annex VIII or fresh meat referred to in paragraph 6 or produced

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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 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 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 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 this Directive.

9 By way of derogation from paragraph 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 Article 57 have been completed in the entire vaccination zone and until at least 3 months have elapsed after the last outbreak recorded in that zone, may only be placed on the national market of the Member State of origin 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 Article 57(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 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 this Directive.

10 A Member State other than the Member State referred to in paragraph 9 may request a decision in accordance with the procedure provided for in Article 89(3) to extend the marketing of the meat referred to in paragraph 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 paragraph 9 until free status has been regained in accordance with Article 61, shall be decided in accordance with the procedure provided for in Article 89(3).

12 Compliance with the conditions provided for in paragraph 6, paragraph 8 and where applicable under the provisions of paragraph 10, shall be certified by the competent authority for fresh meat intended for intra-Community trade. The competent authority shall supervise the control of compliance undertaken by the local veterinary authorities and shall in the case of intra-Community trade communicate to other Member States and the Commission a list of those establishments which they have approved for such certification.

13 By way of derogation from paragraph 8 a special health mark which cannot be confused with the health mark referred to in paragraphs 8(c) and 9(c), may be decided in accordance with the procedure referred to in Article 89(3) for fresh meat of ruminants not subjected to the treatment in accordance with Part A of Annex VIII, and minced meat and meat preparations produced from such meat, which are intended for placing on the market in the a specific region of the Member State of origin.

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 Annex IX. Such treatment shall have been undergone in an establishment located in the vaccination zone or in accordance with the provisions in Article 54(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 paragraphs 6 to 11 and 13 to 15 shall be subject to the conditions provided for in Articles 30, 31, 32 and 42.

## SECTION 9

### **RECOVERY OF THE FOOT-AND-MOUTH DISEASE AND INFECTION FREE STATUS**

#### *Article 59*

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

The foot-and-mouth disease and infection free status of a Member State or a region thereof shall be recovered in accordance with the procedure referred to in Article 89(3), taking into account the conditions referred to in Articles 60 and 61.

#### *Article 60*

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

1 A Member State or region of a Member State regionalised in accordance with Article 45 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 Articles 36 and 44 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 Annex III has confirmed the absence of infection with the foot-and-mouth disease virus in the Member State 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 Article 89(3).

### Article 61

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

1 A Member State or region of a Member State regionalised in accordance with Article 45 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 Articles 36, 44, 54, 55, 56 and 57 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 Article 70(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 Article 70(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 Article 89(3).

### Article 62

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

1 By way of derogation from Article 60 it may be decided in accordance with the procedure referred to in Article 89(3), to withdraw the restrictions applied in accordance with this Directive after the requirements provided for in Articles 36 and 44 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 Article 61 it may be decided in accordance with the procedure referred to in Article 89(3), to withdraw the restrictions applied in accordance with this Directive after the clinical and serological survey provided for in Article 56 and the measures provided for in Article 57 have been completed and confirmed the absence of foot-and-mouth disease virus infection.

3 Without prejudice to paragraphs 1 and 2 it may be decided in accordance with the procedure referred to in Article 89(3) that no animals of a susceptible species shall be removed from the territory or region of the Member State 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:



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- 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 paragraph 2 it may be decided in accordance with the procedure referred to in Article 89(3) 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 Article 52(2) shall be reduced after the completion with satisfactory results of the measures provided for in Article 57.

#### *Article 63*

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

Member States shall ensure that additional certification for intra-Community trade in animals of susceptible species or products derived from such animals required in accordance with this Directive shall be continued until the foot-and-mouth disease and infection free status of the Member State or part of the territory of a Member State has been recovered in accordance with Articles 60 and 61.

#### *Article 64*

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

1 The dispatch from one Member State 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 paragraph 1, it may be decided in accordance with the procedure referred to in Article 89(2) 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 authorities 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

### PREVENTATIVE MEASURES

#### SECTION 10

#### LABORATORIES AND ESTABLISHMENTS HANDLING FOOT-AND-MOUTH DISEASE VIRUS

##### *Article 65*

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

Member States 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 Annex 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 Annex XI;
- (d) the laboratories and establishments referred to in points (b) and (c) are operated at least according to the bio-security standards set out in Annex XII.

##### *Article 66*

##### **Checks of laboratories and establishments handling live foot-and-mouth disease virus**

Veterinary experts from the Commission, in collaboration with the competent authorities of the Member States, shall carry out spot-checks to ascertain whether the security systems applied in the establishments and laboratories referred to in Parts A and B of Annex XI comply with the bio-security standards set out in Annex XII.

##### *Article 67*

##### **Modification of the list of approved laboratories and establishments handling live foot-and-mouth disease virus**

1 The list of establishments and laboratories in Part A and B of Annex XI may be amended in accordance with the procedure referred to in Article 89(3), in the light of the spot-checks provided for in Article 66.

2 The list of establishments and laboratories in Part A and B of Annex XI shall be regularly updated based on written information submitted by the Member States, in accordance with the procedure referred to in Article 89(2).

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## Article 68

### National Laboratories

- 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 Article 71 by one of the laboratories listed in Part A of Annex XI;
  - c one of the laboratories listed in Part A of Annex XI shall be designated as the national reference laboratory for the Member State on whose territory it is situated, and it shall be responsible for coordinating standards and methods of diagnosis in that Member State;
  - d the national reference laboratory carries out at least the functions and duties set out in Annex XV;
  - e the national reference laboratory referred to in point (c) liaises with the Community Reference Laboratory provided for in Article 69 and in particular ensures the sending of appropriate samples to the Community Reference Laboratory.

2 The national reference laboratory referred to in paragraph 1(c) of one Member State may provide the services of a national reference laboratory to one or more other Member States. Member States which have no national reference laboratory situated on their territory may use the services of the national reference laboratory in one or more other Member States.

That cooperation shall be formalised in a mutual agreement between the competent authorities 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 Annex XI.

3 Member States shall ensure that laboratory investigations provided for in this Directive are first of all carried out to confirm or rule out foot-and-mouth disease and to exclude other vesicular diseases.

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.

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 Member States 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.

## Article 69

### Community Reference Laboratory

1 The Community Reference Laboratory shall be designated in agreement with the laboratory concerned and in accordance with the procedure referred to in Article 89(2), for a period to be determined under that procedure.

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2 When designating a Community Reference Laboratory, the technical and scientific competence of the laboratory as well as the expertise and excellence of the scientific and technical staff employed shall firstly be taken into account.

3 The Commission shall review the designation of the Community Reference Laboratory by the end of the designated period of operation or earlier in the light of its compliance with the functions and duties of the Community Reference Laboratory specified in Annex XVI.

#### *Article 70*

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

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 Article 89(2).

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 Article 89(2).

3 A uniform code of good conduct for the security systems applied in the establishments and laboratories listed in Parts A and B of Annex XI may be adopted in accordance with the procedure referred to in Article 89(2).

## SECTION 11

### **DIAGNOSIS OF FOOT-AND-MOUTH DISEASE**

#### *Article 71*

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

1 Member States shall ensure that the national laboratories use the tests and standards for diagnosis set out in Annex 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 Article 56(3) may be adopted in accordance with the procedure referred to in Article 89(2).

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 Article 89(2).

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## SECTION 12

### CONTINGENCY PLANS AND REAL TIME ALERT EXERCISES

#### *Article 72*

#### **Contingency plans**

1 Member States 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 Annex 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 Annex 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 Annex XVII. 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 Article 89(2).

6 The Commission shall examine the contingency plans in order to determine whether they permit the objective provided for in paragraph 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 Article 89(2).

8 Member States shall ensure that significant modifications in their approved contingency plans are notified to the Commission without delay.

9 The revised contingency plans may subsequently be approved in accordance with the procedure referred to in Article 89(2), to take into account developments in the situation.

10 In any case, every five years each Member State shall update its contingency plan in particular in the light of real-time alert exercises referred to in Article 73, and submit it to the Commission for approval in accordance with the procedure referred to in Article 89(2).

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### Article 73

#### Real-time alert exercises

- 1 Member States shall ensure that real-time alert exercises are carried out in accordance with their approved contingency plan and Annex XVII.
- 2 Member States 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 Member States shall inform the 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 Directive 64/432/EEC.

## SECTION 13

### CONTROL CENTRES AND EXPERT GROUPS

#### Article 74

##### National/Central disease control centres — Functions and duties

- 1 Member States 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 Article 76. 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 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 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 liaising with diagnostic laboratories;
  - g liaising with competent environmental authorities to coordinate the actions on veterinary and environmental safety;
  - h liaising with the media;
  - i liaising with the enforcement bodies to ensure adequate implementation of specific legal measures.

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## Article 75

### **National/Central disease control centres — Technical requirements**

- 1 Member States 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 paragraph 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 Article 78 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 run-off as well as body tissue and fluid displacement into the surrounding environment as a result of carcass decomposition, particularly into surface waters and groundwaters.

## Article 76

### **Local disease control centres — set-up, functions and duties**

- 1 Member States shall ensure that fully functional local disease control centres may be established immediately in the event of outbreaks of foot-and-mouth disease.
- 2 Member States 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 Member States 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 Article 74(3)(b).

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4 Member States shall ensure that local disease control centres have the necessary organisation to ensure the prompt implementation of the measures provided for in this Directive to be applied in the event of an outbreak of foot-and-mouth disease.

#### *Article 77*

#### **Local disease control centres — Technical requirements**

1 Member States 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 Article 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 this Directive 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 run-off as well as body tissue and fluid displacement into the surrounding environment as a result of carcass decomposition, particularly into surface waters and groundwaters.



## Article 78

### Expert Group

1 Member States 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.

By way of derogation from the first subparagraph, Member States with a limited number of animals of susceptible species 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 Article 72.

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 bio-security measures on holdings or on premises referred to in Article 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.

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## SECTION 14

### ANTIGEN AND VACCINE BANKS

#### *Article 79*

##### **National antigen and vaccine banks**

1 Member States 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 Directive 2001/82/EC.

2 Member States may retain establishments for the packaging and storage of vaccines in the case of emergency vaccination.

3 Member States 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 Member States maintaining a national antigen and vaccine bank shall inform the Commission about the antigen and vaccine stocks kept. Such information shall be submitted to the Commission every 12 months as part of the information required by Article 8 of 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.

#### *Article 80*

##### **Community antigen and vaccine bank**

1 A Community antigen and vaccine bank shall be established in accordance with the procedure referred to in Article 89(2).

2 The Commission shall ensure that Community reserves of concentrated inactivated antigens for the production of foot-and-mouth disease vaccines are maintained on the premises of the Community antigen and vaccine bank. For that purpose, the number of doses and the diversity of strains and subtypes of antigen of foot-and-mouth disease virus and, if necessary, of authorised in accordance with Directive 2001/82/EC vaccines stored in the Community antigen and vaccine bank shall be decided in accordance with the procedure referred to in Article 89(2), taking into account the needs as estimated in the context of the contingency plans provided for in Article 72 and the epidemiological situation, where appropriate after consultation with the Community Reference Laboratory.

3 The information on quantities and subtypes of antigens or authorised vaccines stored in the Community antigen and vaccine bank shall be treated as classified information and in particular shall not be published.

4 The conditions for the establishment and maintenance of Community reserves of antigen and authorised vaccines at the premises of preferably at least two manufacturing establishments shall be laid down in contracts concluded between the Commission and the manufacturing establishments. Such contracts shall include at least:

- a conditions for supply of quantities and subtypes of concentrated inactivated antigen;
- b conditions for secure storage of antigen and authorised vaccines;

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- c guarantees and conditions of rapid formulation, production, bottling, labelling and distribution of vaccines.

5 The conditions and guarantees referred to in paragraph 4(a) to (c) may be amended in accordance with the procedure referred to in Article 89(3).

#### *Article 81*

### **Supply and storage of concentrated inactivated antigen**

The Commission shall ensure that the contracted manufacturer of the concentrated inactivated antigen supplied to the Community antigen and vaccine bank, guarantees conditions for the supply and storage of concentrated inactivated antigen of the foot-and-mouth disease virus at least equivalent to those laid down in point 1 of Annex XIV.

#### *Article 82*

### **Formulation, production, bottling, labelling and distribution of vaccine**

1 The Commission shall ensure that the contracted manufacturer of the concentrated inactivated antigen supplied to the Community antigen and vaccine bank guarantees conditions for the formulation, finishing, bottling, labelling and delivery of vaccines reconstituted from antigens referred to in Article 81 at least equivalent to those laid down in point 2 of Annex XIV.

2 In case of emergency and with due regard to the epidemiological situation, the Commission shall be authorised to arrange for the immediate production, bottling, labelling, temporary storage and distribution of necessary quantities of vaccines reconstituted from any suitable antigen.

#### *Article 83*

### **Access to the Community antigen and vaccine bank**

1 Member States shall have access to the Community antigen and vaccine bank following a request to the Commission.

The Commission shall, within the limits of the Community reserves of antigens and vaccines, immediately arrange for the formulation, production, bottling, labelling and distribution of the required quantities and subtypes of vaccines, in particular in application of Article 51.

2 Member States that maintain a national antigen and vaccine bank or Member States that are associated to an international antigen and vaccine bank shall have the same rights and obligations to the Community antigen and vaccine bank as other Member States without such reserves.

3 Where it is in the interest of the Community, the Commission may supply or lend to third countries antigens from the Community reserves or vaccines reconstituted from such antigens.

Without prejudice to agreements concluded between the Community and third countries, access of third countries to the Community antigen and vaccine bank shall be authorised in accordance with the procedure referred to in Article 89(2), subject to

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detailed arrangements between the Commission and the third country concerned on the financial and technical cooperation to be adopted under that procedure.

4 Following the use of the antigen or formulated vaccine from the Community reserves, the Commission shall ensure that the used antigen or vaccine is replaced as soon as possible and according to the epidemiological situation.

#### *Article 84*

### **Testing of foot-and-mouth disease vaccines**

1 The Commission shall be responsible for arranging independent testing for potency and innocuity of vaccines reconstituted from antigen stored in the Community antigen and vaccine bank, and of vaccines reconstituted from other antigens and intended for use within the framework of Community assistance to control measures against foot-and-mouth disease in third countries in accordance with Articles 82(2) and 83(3).

2 For the purpose of the testing referred to in paragraph 1 the Commission may employ the services of an independent Community Coordinating Institute.

If necessary, the Community Coordinating Institute shall be designated, and detailed rules on its functions, responsibilities and Community financial contributions shall be adopted, in accordance with the procedure referred to in Article 89(2).

3 Without prejudice to the standards for potency, safety and production procedures provided for in Community legislation, vaccines reconstituted from antigen stored within the Community antigen and vaccine bank shall meet at least the minimum standards for potency, safety and production procedures laid down in the European Pharmacopoeia and the relevant provisions of the OIE Manual.

## SECTION 15

### **FOOT-AND-MOUTH DISEASE IN OTHER SPECIES**

#### *Article 85*

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

1 Without prejudice to Regulation (EC) No 1774/2002, and any implementing legislation, Member States 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 Member States may be adopted in accordance with the procedure referred to in Article 89(2).

2 Detailed rules for the control of foot-and-mouth disease in animals referred to in Article 2(a) second sentence may be adopted in accordance with the procedure referred to in Article 89(2).

3 Immediately after the competent authority of a Member State 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 of a Member State 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 Annex XVIII 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 Annex XVIII. It shall inform owners of animals of susceptible species and hunters of the confirmed case.

## CHAPTER IV

### IMPLEMENTING MEASURES

#### *Article 86*

##### **Penalties**

The Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission by the date specified in Article 93(1) at the latest and shall notify it without delay of any subsequent amendment affecting them.

#### *Article 87*

##### **Procedures for implementing specific articles, for the adoption of further detailed rules for the implementation of this Directive and for amending the Annexes**

1 Detailed rules for the implementation of Articles 75(2) and 77(2) may be adopted in accordance with the procedure referred to in Article 89(2).

2 Further detailed rules for the implementation of this Directive may be adopted in accordance with the procedure referred to in Article 89(2).

3 The Annexes to this Directive may be amended in accordance with the procedure referred to in Article 89(2) or, in the case of Annex XI, in accordance with the procedure referred to in Article 89(3).

#### *Article 88*

##### **Procedure for the adoption of ad hoc epidemiological measures**

Where, in implementing the measures provided for by this Directive, a Member State determines that a measure is not adapted to the epidemiological situation, or where the foot-and-mouth disease virus appears to be spreading despite the measures taken in accordance with this Directive, a Decision may be adopted on an ad hoc basis in accordance with the procedure referred to in Article 89(3) to authorise that Member State to implement alternative measures with equivalent epidemiological effect for a limited period of time appropriate to the epidemiological situation.

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### *Article 89*

#### **Committee procedure**

1 The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health established by Regulation (EC) No 178/2002.

2 Where reference is made to this paragraph, Articles 5 and 7 of 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.

3 Where reference is made to this paragraph, 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.

4 The Committee shall adopt its Rules of Procedure.

## CHAPTER V

### **TRANSITIONAL AND FINAL PROVISIONS**

#### *Article 90*

##### **Amendment to Directive 92/46/EEC**

In point 4(b) of Chapter I of Annex A to Council Directive 92/46/EEC, the second subparagraph is deleted.

#### *Article 91*

##### **Repeals**

1 Directive 85/511/EEC, without prejudice to the obligations of the Member States concerning the time-limits for transposition and application set out in Annex XIX, and Decisions 89/531/EEC of 25 September 1989 designating a reference laboratory for the identification of foot-and-mouth disease virus and determining the functions of that laboratory<sup>(40)</sup> and 91/665/EEC of 11 December 1991 designating a Community Coordinating Institute for foot-and-mouth disease vaccines and laying down its functions<sup>(41)</sup>, adopted in implementation thereof, are hereby repealed as from the date referred to in Article 93.

2 References made to the repealed Directive 85/511/EEC shall be construed as being made to this Directive and should be read in accordance with the correlation table in Annex XX.

## Article 92

### **Transitional provisions**

1 Transitional provisions may be adopted in accordance with the procedure referred to in Article 89(2) for a period of five years from the date of entry into force of this Directive.

2 Within six months after the date referred to in Article 94, Member States shall submit to the Commission amended contingency plans to take into account the provisions of Article 72.

The Commission shall examine those contingency plans against the objectives of this Directive and shall suggest to the Member States concerned any amendments it deems necessary, in particular to ensure that the plans are compatible with those of the other Member States.

Those amended contingency plans shall be approved in accordance with the procedure referred to in Article 89(2).

## Article 93

### **Transposition**

1 Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 30 June 2004 at the latest. They shall forthwith inform the Commission thereof.

They shall apply these provisions as from 1 July 2004.

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

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

## Article 94

### **Entry into force**

This Directive shall enter into force on the day of its publication in the Official Journal of the European Union.

## Article 95

### **Addressees**

This Directive is addressed to the Member States.

## 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;

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- (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 anamnesticly 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

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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.

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- 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<sup>3</sup> 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 through 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 intended 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.

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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.

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## 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

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- (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.*

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## 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<sub>03</sub>;
  - 1.2. UHT<sup>(42)</sup> treatment;
  - 1.3. HTST<sup>(43)</sup> 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<sub>03</sub>;
  - 1.2. UHT<sup>(42)</sup> combined with another physical treatment referred to in either paragraph 1.4.1 or 1.4.2;

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- 1.3. HTST<sup>(43)</sup> 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<sup>(44)</sup>

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

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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 <sup>a</sup>	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<sup>2</sup>. 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<sup>2</sup> or at a distance of less than 20 km from such a sub-region.

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## [<sup>F1</sup>ANNEX XI

### Textual Amendments

- F1** Substituted by [Commission Implementing Decision \(EU\) 2018/1099](#) of 1 August 2018 amending Annex XI to Council Directive 2003/85/EC as regards the list of laboratories authorised to handle live foot-and-mouth disease virus and amending [Commission Implementing Decision \(EU\) 2018/136](#) as regards the denomination of the designated European Union reference laboratory for foot-and-mouth disease (notified under document C(2018) 4987) (Text with EEA relevance).

## PART A

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

Member State where laboratory is located		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	Laboratory for Exotic Viruses and Particular Diseases of the federal research centre Sciensano, Uccle	Belgium Luxembourg
CZ	Czech Republic	Státní veterinární ústav Praha, Praha	Czech Republic
DE	Germany	Friedrich-Loeffler-Institut Bundesforschungsinstitut für Tiergesundheit, Greifswald — Insel Riems	Germany Slovakia
DK	Denmark	Danmarks Tekniske Universitet, Veterinærinstituttet, Afdeling for Virologi, Lindholm Danish Technical University, Veterinary Institute, Department	Denmark Finland Sweden

**a** Use of services in accordance with Article 68(2) until 29 March 2019.



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		of Virology, Lindholm	
EL	Greece	Διεύθυνση Κτηνιατρικού Κέντρου Αθηνών, Τμήμα Μοριακής Διαγνωστικής, Αφθώδους Πυρετού, Ιολογικών, Ρικετσιακών και Εξωτικών Νοσημάτων, Αγία Παρασκευή Αττικής	Greece
ES	Spain	— Laboratorio Central de Sanidad Animal, Algete, Madrid — Centro de Investigación en Sanidad Animal (CISA), Valdeolmos, Madrid	Spain
FR	France	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES), Laboratoire de santé animale de Maisons- Alfort	France
HU	Hungary	Nemzeti Élelmiszerlánc- biztonsági Hivatal, Állategészségügyi Diagnosztikai Igazgatóság (NÉBIH- ADI), Budapest	Hungary
IT	Italy	Istituto zooprofilattico sperimentale della Lombardia e dell'Emilia-Romagna, Brescia	Italy Cyprus

**a** Use of services in accordance with Article 68(2) until 29 March 2019.

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NL	Netherlands	Wageningen Bioveterinary Research (WBVR), Lelystad	Netherlands
PL	Poland	Zakład Pryszczycy Państwowego Instytutu Weterynaryjnego — Państwowego Instytutu Badawczego, Zduńska Wola	Poland
RO	Romania	Institutul de Diagnostic și Sănătate Animală, București	Romania
UK	United Kingdom	The Pirbright Institute	United Kingdom Bulgaria <sup>a</sup> Croatia <sup>a</sup> Estonia <sup>a</sup> Finland <sup>a</sup> Ireland <sup>a</sup> Latvia <sup>a</sup> Lithuania <sup>a</sup> Malta <sup>a</sup> Portugal <sup>a</sup> Slovenia <sup>a</sup> Sweden <sup>a</sup>

<sup>a</sup> Use of services in accordance with Article 68(2) until 29 March 2019.

## PART B

### Laboratories authorised to handle live foot-and-mouth disease virus for vaccine production

Member State where laboratory is located		Laboratory
ISO code	Name	
DE	Germany	Intervet International GmbH/MSD Animal Health, Köln
NL	Netherlands	Boehringer-Ingelheim Animal Health Netherlands BV, Lelystad
UK	United Kingdom	Merial, S.A.S., Pirbright Laboratory, Pirbright <sup>a</sup>

<sup>a</sup> Applicable until 29 March 2019]

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## [<sup>F2</sup>ANNEX XII

### **BIO-SECURITY STANDARDS FOR LABORATORIES AND ESTABLISHMENTS HANDLING LIVE FOOT-AND-MOUTH DISEASE VIRUS**

#### **Textual Amendments**

**F2** Substituted by [Commission Implementing Decision \(EU\) 2015/1358](#) of 4 August 2015 amending Annexes XI, XII and XV to Council Directive 2003/85/EC as regards the list of laboratories authorised to handle live foot-and-mouth disease virus and minimum bio-security standards applicable to them (notified under document C(2015) 5341) (Text with EEA relevance).

1. The laboratories and establishments handling live foot-and-mouth disease virus must operate at least in accordance with Section I of the ‘Minimum biorisk management standards for laboratories working with foot-and-mouth disease virus in vitro and in vivo’ in Appendix 7 to the Report adopted by the 40th General Session of the European Commission for the control of foot-and-mouth disease (EuFMD) on 2224 April 2013 in Rome (bio-security standards)<sup>(45)</sup>.
2. The laboratories and establishments handling live foot-and-mouth disease virus shall be subject to regular and risk-based inspections, including those carried out by and on behalf of the European Commission.
3. The inspection team shall have at its disposition expertise from the Commission or a Member State in foot-and-mouth disease and bio-security in laboratories working with microbiological hazards.
4. Inspection teams deployed by the European Commission 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.

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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 Annex 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

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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.

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### 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<sub>50</sub> 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:

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1. [<sup>F3</sup>All national laboratories handling live foot-and-mouth disease virus must operate at least according to the bio-security standards referred to in point 1 of Annex XII.]
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. [<sup>F2</sup>National Laboratories, designated as the National Reference Laboratories in accordance with Article 68(1)(c), 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. [<sup>F2</sup>National Laboratories shall cooperate with other laboratories designated by the competent authorities, and listed in the contingency plans for foot-and-mouth disease



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as referred to in Article 72, 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 isolation (by infection of cells or animals) from samples taken from suspect cases of vesicular diseases. Such laboratories must have established procedures which ensure that the possible spread of foot-and-mouth disease virus is effectively prevented, taking into account the recommendations in Section II of the ‘Minimum biorisk management standards for laboratories working with foot-and-mouth disease virus in vitro and in vivo’ in Appendix 7 to the report adopted by the 40th General Session of the European Commission for the control of foot-and-mouth disease (EuFMD) on 2224 April 2013 in Rome (bio-security standards)<sup>(46)</sup>.

Samples giving inconclusive results in tests must be transmitted to the National Reference Laboratory for carrying out confirmatory tests.]

#### Textual Amendments

- F3** Substituted by [Commission Decision of 27 November 2009 amending Annexes XI, XII, XV and XVI to Council Directive 2003/85/EC as regards the list of and minimum security standards applicable to laboratories authorised to handle live foot-and-mouth disease virus \(notified under document C\(2009\) 9094\) \(Text with EEA relevance\) \(2009/869/EC\)](#).

## 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;

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- 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.
- [<sup>F37</sup>7. The Community Reference Laboratory must operate at least according to the bio-security standards referred to in point 1 of Annex XII.]
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

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- 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:

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- (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

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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:

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- (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,

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- (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

<b>Directive</b>	<b>Deadline for transposition</b>
85/511/EEC	1 January 1987
90/423/EEC	1 January 1992

## ANNEX XX

### CORRELATION TABLE

<b>This Directive</b>	<b>Directive 85/511/EEC</b>
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Article 1, paragraph 1 (a)	Article 1
Article 1, paragraph 1 (b)	—
Article 1, paragraph 2	—
Article 2 (a)	Article 2 (a)
Article 2 (b) to (h) and (l) to (y)	—
Article 2 (i)	Article 2 (d)
Article 2 (j)	Article 2 (e)
Article 2 (k)	Article 2 (c)
Article 3 (1) (a)	Article 3
Article 3 (1) (b) and (c)	—
Article 3 (2)	—
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)	—
Article 6 (1)	Article 4 (2)

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Article 6 (2)	—
Article 7	—
Article 8	—
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
Article 11 (2)	—
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
Article 13 (2)	—
Article 14	—
Article 15	—
Article 16	—
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
Article 19 (5)	—
Article 20	Article 6 (3)
Article 21 (1)	—

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Article 21 (2)	Article 9 (1)
Article 21 (3)	—
Article 21 (4) to (6)	—
Article 22 (1) (a)	Article 9 (2) (a) first indent
Article 22 (1) (b)	Article 9 (2) (a) second indent
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
Article 23 (b)	—
Article 23 (c)	—
Article 23 (d)	—
Article 24 (1) (a)	—
Article 24 (1) (b) to (f)	—
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	—
Article 26	—
Article 27	—
Article 28	—
Article 29	—
Article 30	—
Article 31	—
Article 32	—
Article 33	—
Article 34	—
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 (1)	—
Article 37 (2)	Article 9 (3) (a)
Article 38 (1)	Article 9 (3) (a) second indent first part
Article 38 (2) (a)	Article 9 (3) (a) second indent last part
Article 38 (2) (b) to (d)	—
Article 38 (3)	—
Article 38 (4)	—
Article 38 (5)	—
Article 39	—
Article 40	—
Article 41	—
Article 42	—
Article 43	—
Article 44 (1) (a)	Article 9 (3) (b)
Article 44 (1) (b) and (c)	—
Article 44 (2)	—
Article 45	—
Article 46	—
Article 47 (1)	Article 12, first indent
Article 47 (2)	—
Article 48	Article 12, second and third indent
Article 49 (a)	Article 13 (1) first indent
Article 49 (b)	Article 13 (1) third indent
Article 49 (c) and (d)	—
Article 50 (1) (a)	Article 13 (3) first subparagraph first sentence
Article 50 (1) (b), (c) and (d)	—
Article 50 (2)	—
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)	—
Article 52	—

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Article 53	—
Article 54	—
Article 55	—
Article 56	—
Article 57	—
Article 58	—
Article 59	—
Article 60	—
Article 61	—
Article 62	—
Article 63	—
Article 64	—
Article 65 (a), (b) and (c)	Article 13 (1) second indent
Article 65 (d)	Article 13 (1) fourth indent
Article 66	Article 13 (2) first and second subparagraph
Article 67	Article 13 (2) second subparagraph
Article 68(1) (a) and (b)	Article 11 (1) first indent
Article 68 (1) (c) and (e)	Article 11 (1) second and third indent
Article 68 (1) (d)	—
Article 68 (2), (3) and (4)	—
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
Article 73	—
Article 74	—
Article 75	—
Article 76	—
Article 77	—
Article 78	—
Article 79 (1)	Article 14 (1) first subparagraph second half sentence
Article 79 (2)	Article 14 (1) third subparagraph second half sentence

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Article 79 (3)	—
Article 79 (4)	—
Article 80	Decision 91/666/EEC
Article 81	—
Article 82	—
Article 83	—
Article 84	Decision 91/665/EEC
Article 85	—
Article 86	—
Article 87	—
Article 88	—
Article 89	Articles 16 and 17
Article 90	—
Article 91	—
Article 92 (1)	Article 6 of Directive 90/423/EEC
Article 92 (2) first subparagraph	—
Article 92 (2) second and third subparagraphs	Article 5(4) of Directive 90/423/EEC
Article 93	Article 19
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Annex XI Part A	Annex B
Annex XI Part B	Annex A

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Annex XII	—
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Annex XIV	Decision 91/666/EEC
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Annex XVI	Decision 89/531/EEC
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Financial Statement	—

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- (1) Proposal of 18 December 2002.
- (2) Opinion delivered on 15 May 2003 (not yet published in the Official Journal).
- (3) Opinion delivered on 14 May 2003 (not yet published in the Official Journal).
- (4) Opinion delivered on 2 July 2003 (not yet published in the Official Journal).
- (5) [OJ L 378, 31.12.1982, p. 58](#). Directive as last amended by Commission Decision 2000/556/EC ([OJ L 235, 19.9.2000, p. 27](#)).
- (6) [OJ L 315, 26.11.1985, p. 11](#). Directive as last amended by the 2003 Act of Accession.
- (7) [OJ L 224, 18.8.1990, p. 13](#).
- (8) [OJ L 268, 24.9.1991, p. 56](#). Directive as last amended by Directive 96/43/EC ([OJ L 162, 1.7.1996, p. 1](#)).
- (9) [OJ L 373, 31.12.1990, p. 1](#). Directive as last amended by Directive 96/43/EC ([OJ L 162, 1.7.1996, p. 1](#)).
- (10) [OJ L 224, 18.8.1990, p. 29](#). Directive as last amended by Directive 2002/33/EC of the European Parliament and of the Council ([OJ L 315, 19.11.2002, p. 149](#)).
- (11) [OJ L 395, 30.12.1989, p. 13](#). Directive as last amended by Directive 92/118/EEC ([OJ L 62, 15.3.1993, p. 49](#)).
- (12) [OJ C 21 E, 24.1.2002, p. 339](#).
- (13) [OJ L 31, 1.2.2002, p. 1](#).
- (14) [OJ L 167, 7.7.2000, p. 22](#).
- (15) [OJ L 340, 31.12.1993, p. 21](#).
- (16) [OJ L 273, 10.10.2002, p. 1](#). Regulation as last amended by Commission Regulation (EC) No 808/2003 ([OJ L 117, 13.5.2003, p. 1](#)).
- (17) [OJ L 257, 10.10.1996, p. 26](#).
- (18) [OJ L 123, 24.4.1998, p. 1](#).
- (19) [OJ L 194, 22.7.1988, p. 10](#). Directive as last amended by the 2003 Act of Accession.
- (20) [OJ L 302, 19.10.1989, p. 1](#). Directive as last amended by Commission Decision 94/113/EC ([OJ L 53, 24.2.1994, p. 23](#)).
- (21) [OJ L 268, 14.9.1992, p. 54](#). Directive as last amended by Commission Regulation (EC) No 1282/2002 ([OJ L 187, 16.7.2002, p. 13](#)).
- (22) [OJ L 224, 18.8.1990, p. 42](#). Directive as last amended by Commission Decision 2002/160/EC ([OJ L 53, 23.2.2002, p. 37](#)).
- (23) [OJ 121, 29.7.1964, p. 2012/64](#). Directive as last amended by Directive 95/23/EC ([OJ L 243, 11.10.1995, p. 7](#)).
- (24) [OJ L 26, 31.1.1977, p. 85](#). Directive as last amended by Directive 97/76/EC ([OJ L 10, 16.1.1998, p. 25](#)).
- (25) [OJ L 47, 21.2.1980, p. 4](#). Directive as last amended by the 2003 Act of Accession.
- (26) [OJ L 268, 24.9.1991, p. 41](#). Directive as last amended by Directive 94/65/EC ([OJ L 368, 31.12.1994, p. 10](#)).
- (27) [OJ L 368, 31.12.1994, p. 10](#).
- (28) [OJ L 18, 23.1.2003, p. 11](#). Directive as last amended by the 2003 Act of Accession.
- (29) [OJ L 18, 23.1.2003, p. 11](#).
- (30) [OJ L 268, 14.9.1992, p. 1](#). Directive as last amended by Directive 94/71/EC ([OJ L 368, 31.12.1994, p. 33](#)).
- (31) [OJ L 62, 15.3.1993, p. 49](#). Directive as last amended by Commission Decision 2003/42/EC ([OJ L 13, 18.1.2003, p. 24](#)).



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- (32) [OJ L 326, 22.12.2000, p. 80](#). Decision as last amended by Decision 2002/807/EC ([OJ L 279, 17.10.2002, p. 50](#)).
- (33) [OJ L 368, 21.12.1991, p. 21](#). Decision as last amended by Decision 2001/181/EC ([OJ L 66, 8.3.2001, p. 39](#)).
- (34) [OJ L 311, 28.11.2001, p. 1](#).
- (35) [OJ L 213, 24.8.1993, p. 20](#). Decision as last amended by Decision 2001/96/EC ([OJ L 35, 6.2.2001, p. 52](#)).
- (36) [OJ L 224, 18.8.1990, p. 19](#). Decision as last amended by Decision 2001/572/EC ([OJ L 203, 28.7.2001, p. 16](#)).
- (37) [OJ L 38, 12.2.1998, p. 10](#).
- (38) [OJ L 184, 17.7.1999, p. 23](#).
- (39) [OJ L 311, 28.11.2001, p. 1](#).
- (40) [OJ L 279, 28.9.1989, p. 32](#).
- (41) [OJ L 368, 31.12.1991, p. 19](#).
- (42) UHT = Ultra-High Temperature treatment at 132 °C for at least one second.
- (43) 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.
- (44) in accordance with the report of the Scientific Committee on Animal Health 1999
- (45) [<sup>F2</sup>[http://www.fao.org/fileadmin/user\\_upload/eufmd/Lab\\_guidelines/FMD\\_Minimumstandards\\_2013\\_Final\\_version.pdf](http://www.fao.org/fileadmin/user_upload/eufmd/Lab_guidelines/FMD_Minimumstandards_2013_Final_version.pdf).]
- (46) [<sup>F2</sup>[http://www.fao.org/fileadmin/user\\_upload/eufmd/Lab\\_guidelines/FMD\\_Minimumstandards\\_2013\\_Final\\_version.pdf](http://www.fao.org/fileadmin/user_upload/eufmd/Lab_guidelines/FMD_Minimumstandards_2013_Final_version.pdf).]

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#### **Textual Amendments**

- F2** Substituted by [Commission Implementing Decision \(EU\) 2015/1358 of 4 August 2015 amending Annexes XI, XII and XV to Council Directive 2003/85/EC as regards the list of laboratories authorised to handle live foot-and-mouth disease virus and minimum bio-security standards applicable to them \(notified under document C\(2015\) 5341\) \(Text with EEA relevance\).](#)