

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)

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## ANNEX I

### DEFINITION OF OUTBREAK

An outbreak shall be declared where a holding meets one...  
Foot-and-mouth disease virus has been isolated from an animal,  
any...

## 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...
2. In case of primary outbreaks or cases in premises or...
3. In case of secondary outbreaks, the information referred to in...
4. The Member State concerned shall ensure that the information to...
5. Where the Animal Disease Notification System is for whatever reason...

## ANNEX III

### SURVEY

1. Clinical examination
  - 1.1. Holdings must undergo clinical examinations of all animals of susceptible...
  - 1.2. Special emphasis must be laid on animals which may have...
  - 1.3. The clinical examination must take into account the transmission of...
  - 1.4. Relevant records kept on the holding must be examined in...
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...
      - 2.1.1.2. in support of tracing and the provision of evidence, taking...
    - 2.1.2. Where sampling is carried out in the framework of disease...
    - 2.1.3. Sampling of animals of susceptible species shall be carried out...
  - 2.2. Sampling on holdings
  - 2.3. Sampling in protection zones
  - 2.4. Sampling in surveillance zones
    - 2.4.1. from holdings in all administrative units within the perimeter of...
    - 2.4.2. from as many holdings referred to above as necessary to...
    - 2.4.3. from as many sheep and goats per holding as necessary...
  - 2.5. Sampling for monitoring

- 2.5.1. For monitoring the areas outside the zones established in accordance...
3. The number of samples calculated in accordance with requirements in...

## 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...
  - 1.2. The disinfectants to be used and their concentrations shall be...
  - 1.3. The activity of disinfectants must not be impaired by prolonged...
  - 1.4. The choice of disinfectants and of procedures for disinfection should...
  - 1.5. The conditions under which degreasing agents and disinfectants are used...
  - 1.6. Independently of the disinfectant used, the following general rules shall...
    - 1.6.1. thorough soaking of bedding and litter as well as faecal...
    - 1.6.2. washing and cleaning by careful brushing and scrubbing of all...
    - 1.6.3. then further application of disinfectant for a minimum contact time...
    - 1.6.4. the water used for cleaning operations is to be disposed...
  - 1.7. Where washing is carried out with liquids applied under pressure...
  - 1.8. Washing, disinfecting or destroying of equipment, installations, articles or compartments...
  - 1.9. Cleansing and disinfection operations required in the framework of this...
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...
    - 2.1.2. Carcasses of killed animals must be sprayed with disinfectant and...
    - 2.1.3. As soon as the carcasses of the animals of susceptible...
    - 2.1.4. Any tissue or blood which may have been spilled during...
    - 2.1.5. The used disinfectant shall remain on the surface for at...
  - 2.2. Final cleansing and disinfection
    - 2.2.1. Grease and dirt should be removed from all surfaces by...
    - 2.2.2. After washing with cold water further spraying with disinfectant should...
    - 2.2.3. After seven days the premises should be treated again with...
3. Disinfection of contaminated bedding, manure and slurry
  - 3.1. The solid phase of manure and used bedding should be...
  - 3.2. The liquid phase of manure and slurry should be stored...
4. Special cases
  - 4.1. Where for technical or security reasons the cleansing and disinfection...
  - 4.2. By way of derogation from points 2.1 and 2.2, in...
  - 4.3. By way of derogation from point 3, the competent authority...

## ANNEX V

### RESTOCKING OF HOLDINGS

1. General principles
  - 1.1. Restocking should not commence until 21 days after completion of...

- 1.2. Animals for restocking can only be introduced under the following...
    - 1.2.1. the animals shall not come from areas subject to animal...
    - 1.2.2. the competent authorities must be satisfied that any possible residual...
    - 1.2.3. in order to ensure an adequate immune response referred to...
      - 1.2.3.1. either originate in and come from a holding situated in...
      - 1.2.3.2. the animals have been tested with negative results in an...
  - 1.3. Irrespective of the type of farming practised on the holding,...
    - 1.3.1. animals must be introduced in all units and buildings of...
    - 1.3.2. in the case of a holding consisting of more than...
    - 1.3.3. animals must be subjected to clinical inspection every three days...
    - 1.3.4. during the period from 15 to 28 days after re-introduction,...
    - 1.3.5. not earlier than 28 days after the last re-introduction, all...
  - 1.4. The restocking procedure shall be considered completed when the measures...
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...
      - 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...
  3. Restocking in connection with emergency vaccination
    - 3.1. Restocking in a vaccination zone established in accordance with Article...
    - 3.2. The competent authorities may authorise the restocking of holdings situated...
      - 3.2.1. the proportion of vaccinated animals used for restocking exceeds 75...
      - 3.2.2. The proportion of vaccinated animals does not exceed 75 %...

## ANNEX VI

### RESTRICTIONS ON THE MOVEMENT OF EQUIDAE

1. Minimum measures
2. Recommended additional measures
  - 2.1. Measures during the stand-still
    - 2.1.1. the emergency must be documented by the veterinary surgeon on...
    - 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...
    - 2.1.4. equidae must be accompanied during the transport by an identification...
    - 2.1.5. the on-call official veterinarian must be informed about the route...
    - 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...
  - 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...
    - 2.2.2. Movement of equidae within the protection and surveillance zones established...
      - 2.2.2.1. the use of equidae kept on holdings in the protection...
      - 2.2.2.2. equidae may be transported without restrictions in dedicated equine transport...



- 2.2.2.3. the competent authorities may in exceptional cases authorise the transport...
- 2.2.2.4. movement of equidae may be allowed on public roads, on...
- 2.2.3. The collection of equine semen, ova and embryos from donor...
- 2.2.4. Visits from owners of equidae, the veterinary surgeon, the inseminator...
  - 2.2.4.1. equidae are kept separated from animals of susceptible species and...
  - 2.2.4.2. all visitors must be registered;
  - 2.2.4.3. cleansing and disinfecting of means of transportation and of the...

## 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...
2. Hides and skins complying with the requirements in Article 20...
3. Sheep wool, ruminant hair and pig bristles complying with the...
4. Products derived from animals of susceptible species which have undergone:...
5. Blood and blood products of animals of susceptible species used...
6. Lard and rendered fats which have undergone the heat treatment...
7. Petfood and dogchews which comply with the requirements of points...
8. Game trophies of ungulates which comply with the requirements of...
9. Animal casings which in accordance with Chapter 2 of Annex...

#### PART B

##### Products not of animal origin

1. Straw and forage which

## ANNEX VIII

#### PART A

##### Treatment of fresh meat

1. De-boned fresh meat:

2. Trimmed offal:
3. Maturation:
4. Effective measures must be applied to avoid cross-contamination.

#### PART B

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

1. Fresh meat, excluding heads, viscera and offals, intended for placing...
2. Trimmed offal shall be marked with the health mark provided...
3. Other products shall be subjected to the treatment provided for...

#### ANNEX IX

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

##### PART A

Milk and milk products intended for human consumption

1. Milk intended for human consumption must be subject to at...
  - 1.1. sterilisation at a level of at least F03;
  - 1.2. UHT treatment;
  - 1.3. HTST treatment applied twice to milk with a pH equal...
  - 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...
    - 1.5.2. additional heating to 72 °C or more, combined with desiccation....
2. Milk products must either undergo one of the above treatments...
3. Any other treatment shall be decided in accordance with the...

##### PART B

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

1. Milk not intended for human consumption and milk intended for...
  - 1.1. sterilisation at a level of at least F03;
  - 1.2. UHT combined with another physical treatment referred to in either...
  - 1.3. HTST applied twice;
  - 1.4. HTST combined with another physical treatment by:
    - 1.4.1. either lowering the pH below 6 for at least one...
    - 1.4.2. additional heating to 72 °C or more, combined with desiccation....
2. Milk products must either undergo one of the above treatments...

3. They to be fed to animals of susceptible species and...

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##### CRITERIA FOR THE DECISION TO APPLY PROTECTIVE VACCINATION AND GUIDELINES FOR THE EMERGENCY VACCINATION PROGRAMMES

1. Criteria for the decision to apply protective vaccination
2. Additional criteria for the decision to introduce emergency vaccination
3. Definition of Densely Populated Livestock Areas (DPLAs)
  - 3.1. When deciding about the measures to be taken in application...
  - 3.2. Animals of susceptible species

#### ANNEX XI

##### PART A

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

##### PART B

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

#### ANNEX XII

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

1. The laboratories and establishments handling live foot-and-mouth disease virus must...
2. The laboratories and establishments handling live foot-and-mouth disease virus shall...
3. The inspection team shall have at its disposition expertise from...
4. Inspection teams deployed by the European Commission shall submit a...

#### 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...

##### PART A

Diagnostic tests

1. Recommended procedures

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3. Standards and quality control
4. Procedures for adoption and review of tests and standards for...
5. Compliance procedure
6. Selection and transportation of samples

#### PART B

#### Standards

1. Foot-and-mouth disease
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  - 1.2. Virus isolation
  - 1.3. Nucleic acid detection methods
  - 1.4. Antibody detection (structural proteins)
  - 1.5. Antibody detection (non-structural proteins)
2. Swine vesicular disease (SVD)
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#### COMMUNITY ANTIGEN AND VACCINE BANK

1. Conditions for the supply and storage of the concentrated inactivated...
2. Conditions for the formulation, finishing, bottling, labelling and delivery of...

#### ANNEX XV

#### FUNCTIONS AND DUTIES OF NATIONAL LABORATORIES

The functions and duties of National Laboratories referred to in...  
All national laboratories handling live foot-and-mouth disease virus must operate...

#### 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...

1. To ensure liaison between the national laboratories of the Member...
  - 1.1. regularly receiving field samples from Member States and countries geographically...

- 1.2. typing and full antigenic and genomic characterisation of vesicular viruses...
  - 1.3. building up and maintaining an up-to-date collection of vesicular virus...
  - 1.4. building up and maintaining an up-to-date collection of specific sera...
  - 1.5. advising the Commission on all aspects related to foot-and-mouth disease...
2. To support the functions of National Laboratories, in particular by:...
  - 2.1. storing and supplying National Laboratories with reagents and materials for...
  - 2.2. retaining expertise on foot-and-mouth disease virus and other pertinent viruses...
  - 2.3. promoting harmonisation of diagnosis and ensuring proficiency of testing within...
  - 2.4. carrying out research studies with the objective of developing improved...
3. To provide information and carry out further training, in particular...
  - 3.1. gathering data and information on the methods of diagnosis and...
  - 3.2. making and implementing the necessary arrangements for the further training...
  - 3.3. keeping abreast of developments in foot-and-mouth disease epidemiology;
  - 3.4. organising an annual meeting where representatives of the National Laboratories...
4. To perform experiments and field trials in consultation with the...
  5. To review at the annual meeting of National Reference Laboratories...
  6. To cooperate with the national reference laboratories of candidate countries...
  7. The Community Reference Laboratory must operate at least according to...
  8. The Community Reference Laboratory shall provide assistance to the Commission...

## ANNEX XVII

### CRITERIA AND REQUIREMENTS FOR CONTINGENCY PLANS

Member States shall ensure that contingency plans meet at least...

1. Provision shall be made to ensure the legal powers necessary...
2. Provision must be made to ensure access to emergency funds,...
3. A chain of command shall be established guaranteeing a rapid...
4. Each Member State must be prepared to immediately establish a...
5. Detailed plans shall be available to enable a Member State...
6. Member States shall ensure the cooperation between the national disease...
7. A permanently operational expert group shall be created, where necessary...
8. Provision must be made for adequate resources to ensure a...

9. An up-to-date operations manual shall be available. It shall describe...
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...
  - 11.2. real-time alert exercises, conducted as follows:
    - 11.2.1. two times within a five years period, the first of...
    - 11.2.2. during the five years period after an outbreak of a...
    - 11.2.3. one of the two exercises referred to in paragraph 11.2.1...
    - 11.2.4. by way of derogation from paragraph 11.2.1 and subject to...
  - 11.3. Training in communication skills to provide ongoing disease awareness campaigns...
12. Contingency Plans shall be prepared taking into account the resources...
13. Without prejudice to veterinary requirements, contingency plans shall be prepared...
14. Such plans shall include the identification of appropriate sites and...
15. Member State shall ensure that farmers, the rural populace and...

## 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...
2. If a case of foot-and-mouth disease has occurred in wild...
3. By way of derogation to the provisions in point 1...

### 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,...
2. The Commission shall examine the plan in order to determine...
3. After the measures provided for in the plan mentioned in...
4. The plan mentioned in paragraph 1 shall contain information on:...
5. A report concerning the epidemiological situation in the defined area...
6. More detailed rules relating to the establishment of plans for...

## ANNEX XIX

### DEADLINES FOR TRANSPOSITION INTO NATIONAL LAW

## ANNEX XX

### CORRELATION TABLE

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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](#).