# 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)

## 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).

*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) liases 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.

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).

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).

*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 liasing with diagnostic laboratories;

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

h liasing with the media;

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

*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).

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.

## 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;

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, guaranties 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 guaranties 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 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.