COUNCIL DIRECTIVE

of 26 June 1990

amending Directive 85/511/EEC introducing Community measures for the control of foot-and-mouth disease, 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

(90/423/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 thereof,

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas Directive 85/511/EEC (4) introduced Community measures for the control of foot-and-mouth disease;

Whereas, in view of the completion of the internal market for 1 January 1993, it is necessary to amend the measures already taken at Community level to control foot-and-mouth disease in the entire Community; whereas it is essential that a uniform policy should be implemented throughout the Community;

Whereas a Commission study on control of foot-and-mouth disease has shown that the adoption of a non-vaccination policy for the Community as a whole would be preferable to a vaccination policy; whereas it has been concluded that a risk exists in the manipulation of virus in laboratories due to the possibility of escape to local susceptible animals and in the use of vaccine if inactivation procedures do not ensure its safety;

Whereas the Commission's study as regards a vaccination policy for the future has clearly shown that an official withdrawal of vaccination against the disease should be implemented from a given date and that such withdrawal should be accompanied by a policy of total slaughter and destruction (stamping out) of infected animals;

Whereas Commission Decision 88/379/EEC of 12 July 1988 coordinating rules laid down by Member States in application of Article 6 of Council Directive 85/511/EEC (5) has already provided for a minimum set of rules to be applied in all Member States when granting exceptions from total slaughter on an infected holding;

Whereas, in extreme situations where an epizootic disease threatens to become extensive, it may be necessary to have recourse to emergency vaccination; whereas it is necessary to lay down conditions under which this vaccination may be carried out;

Whereas the adoption of a uniform Community policy in the campaign against foot-and-mouth disease involves an adjustment of the rules governing intra-Community trade in live animals and the import, from third countries, of live animals and certain animal products;

Whereas financial support to Member States concerning slaughter, destruction and other emergency actions should be laid down in separate measures;

Whereas the functioning of the new measures must be kept under the review of the Commission, which shall report to the Council annually on their implementation,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 85/511/EEC is hereby amended as follows:

1. Article 1 is replaced by the following:

   'Article 1

   This Directive defines the Community control measures to be applied in the event of outbreaks of foot-and-mouth disease, whatever the type of virus concerned.'

2. In Article 5:

   (a) in point 2, '(a) in Member States or regions where vaccination is prohibited' and the whole of point (b) are deleted;

   (b) in point 3 'shall not apply' is replaced by 'need not apply'.

(1) OJ No C 327, 30. 12. 1989, p. 84.
(2) OJ No C 113, 7. 5. 1990, p. 179.
(3) OJ No C 62, 12. 3. 1990, p. 44.
(4) OJ No L 315, 26. 11. 1985, p. 11.
(5) OJ No L 189, 20. 7. 1988, p. 25.

3. In Article 6:

(a) in the first subparagraph of paragraph 1, 'Article 5 (2) (a), first and second indents and (2) (b) (i)' is replaced by 'Article 5 (2), first and second indents';

(b) in the second subparagraph of paragraph 1, '(a)' is deleted;

(c) paragraph 2 is replaced by the following:

'2. When recourse is had to paragraph 1, Member States shall apply the measures specified in Commission Decision 88/397/EEC (*).

(*) OJ No L 189, 20. 7. 1988, p. 25.'

4. In Article 9:

(a) the last sentence of paragraph 1 is replaced by the following:

'The definition of zones shall take account of natural boundaries, supervision facilities and technological progress which make it possible to foresee the possible dispersion of the virus by air or any other means and will have to be reviewed, if necessary, in the light of such elements.'

(b) in paragraph 2 (a), the first indent is replaced by the two following indents:

'— a census of all the holdings with animals of susceptible species must be carried out,

— holdings which are the subject of such a census must periodically undergo a veterinary inspection,'.

5. In Article 11 (1), first and second indents, 'Annex' and 'Annex I' are replaced each time by 'Annex B'.

6. Article 13 is replaced by the following:

'Article 13

1. Member States shall ensure that:

— the use of foot-and-mouth vaccines is prohibited,

— the manipulation of foot-and-mouth virus for research, diagnosis and/or manufacture of vaccines shall be carried out only in approved establishments and laboratories listed in Annex A and B,

— the storage, supply, distribution and sale of foot-and-mouth vaccines on the territory of the Community are carried out under official control,

— the establishments and laboratories referred to in the second indent shall be approved only if they fulfil the minimum standards recommended by the FAO for laboratories working on foot-and-mouth viruses *in vitro* and *in vivo*.

2. 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 Annexes A and B comply with the FAO's minimum standards.

The Commission shall carry out these checks at least once a year, the first of these checks being due before 1 January 1992, and shall submit, also before that date, an initial report to the Standing Veterinary Committee. The list of establishments and laboratories in Annexes A and B may be reviewed in the light of these checks by the Commission, in accordance with the procedure referred to in Article 17, by 31 December 1991. The list will be regularly updated in accordance with the same procedure.

In accordance with the same procedure, a decision may be taken to adopt a uniform code of good conduct for the security systems applied in the establishments and laboratories listed in Annexes A and B.

3. Notwithstanding the provisions of paragraph 1 concerning the use of foot-and-mouth disease vaccine, it may be decided, when foot-and-mouth disease has been confirmed and threatens to become extensive, that emergency vaccination using technical procedures guaranteeing the animals' total immunity may be introduced. In this case, the measures to be taken shall include:

— the extent of the geographical area in which emergency vaccination is to be carried out,

— the species and the age of the animals to be vaccinated,

— the duration of the vaccination campaign,

— a specific standstill of vaccinated animals and their products,

— the special identification and special registration of the vaccinated animals,

— other matters appropriate to the emergency situation.

The decision to introduce emergency vaccination shall be taken by the Commission in collaboration with the Member State concerned, acting in accordance with the procedure laid down in Article 16. This decision shall have particular regard to the degree of concentration of animals in certain regions and the need to protect special breeds.

However, by way of derogation from the first subparagraph, the decision to introduce emergency vaccination around the outbreak may be taken by the Member State concerned following notification to the Commission, provided that basic Community interests are not endangered. This decision shall be immediately reviewed in the Standing Veterinary Committee in accordance with the procedure laid down in Article 16.'

7. Article 14 is replaced by the following:

'Article 14

1. Pending the setting up of Community reserves of foot-and-mouth disease vaccine, Member States shall

be authorized to retain reserves of antigens in one of the establishments referred to in the Annexes.

For the purposes of the first subparagraph, contracts between the Commission and those responsible in the establishments designated by the Member States shall be concluded; the contracts will in particular specify the quantities of antigen doses necessary, taking account of the requirements estimated in the context of the plans referred to in Article 5 (1) of Directive 90/423/EEC (*), for a maximum of 10 serotypes.

After this transitional period, Member States shall be authorized under Community supervision to retain establishments for the packaging and storage of ready-to-use vaccines for emergency vaccination.

2. Before 1 April 1991, the Council, acting by a qualfied majority on a proposal from the Commission, shall designate a specialized institute for vaccine and cross-immunity checks and shall determine its powers.

3. Before 1 April 1991, the Commission shall submit to the Council a report accompanied, where appropriate, by proposals on the rules relating to the packaging, production, distribution and state of the stocks of anti-foot-and-mouth disease vaccines in the Community, together with proposals on the setting up of at least two Community reserves of anti-foot-and-mouth disease vaccines.'

(*) OJ No L 224, 18. 8. 1990, p. 13.

8. Article 15 is deleted.

9. Article 18 is replaced by the following:

'Article 18

On the basis of a report from the Commission on the experience gained in the application of this Directive, accompanied by proposals where appropriate, the Council shall review the situation within two years of the adoption of Directive 90/423/EEC (*).

(*) OJ No L 224, 18. 8. 1990, p. 13.'

10. An Annex, which shall be known as 'Annex A' and which appears in the Annex to this Directive, shall be added. The present Annex, entitled 'National Laboratories dealing with Foot-and-Mouth Disease', becomes Annex B.

Article 2

Article 4a of Directive 64/432/EEC (1), as last amended by Directive 89/662/EEC (2), is hereby amended as follows:

1. In the first subparagraph, in point 1:

(i) line 3 reads: '. . . which have not practised vaccination for at least 12 months and . . .';

(ii) B is replaced by the following:

'B. where the animal comes from a Member State which has, during the previous 12 months, practised prophylactic vaccination or has had recourse, in exceptional cases, to emergency vaccination on its territory';

(iii) the following subparagraph is added at the end of B and at the end of the first subparagraph of point 2:

'In this case, the aforementioned guarantees may be required for a period of 12 months after completion of the emergency vaccination operations.'

2. In the first subparagraph, in point 2, the introductory words are replaced by the following:

'2. Member States having recourse, in exceptional cases, to emergency vaccination on the whole of their territory and allowing vaccinated animals on to their territory shall make the introduction into their territory of live cattle subject to the following conditions:'

3. The following subparagraph is inserted before the last subparagraph:

'Where a Member State is authorized, in accordance with Article 13 (3) of Directive 85/511/EEC (*), as last amended by Directive 90/423/EEC (**), to have recourse to emergency vaccination on a limited part of its territory, the status of the remainder of the territory shall not be affected, providing that the immobilization measures for the vaccinated animals are effective during a period of 12 months following the end of the vaccination operations.

(*) OJ No L 315, 26. 11. 1985, p. 11.
(**) OJ No L 224, 18. 8. 1990, p. 13.'

Article 3

Directive 72/462/EEC (3), as last amended by Directive 89/662/EEC (4), is hereby amended as follows:

1. Article 6 is replaced by the following:

'Article 6

1. Without prejudice to Article 3 (1), Member States shall not authorize importation of animals covered by this Directive unless they come from third countries:

(a) which have been free of those diseases to which the animals are susceptible:

— for the previous 12 months, in respect of cattle plague, contagious pleuro-pneumonia, blue-tongue, African swine fever and contagious porcine paralysis (Teschen disease),

— for the previous six months, in respect of contagious vesicular stomatitis;

(b) in which, during the preceding 12 months, vaccination against the diseases referred to in the first indent of (a) to which these animals are susceptible has not been carried out.

(1) OJ No 121, 29. 7. 1964, p. 1977/64.
(2) OJ No L 395, 30. 12. 1989, p. 13.
(3) OJ No L 302, 31. 12. 1972, p. 28.
(4) OJ No L 395, 30. 12. 1989, p. 13.