COMMISSION

COMMISSION DECISION

of 5 April 2001

amending Decision 2001/246/EC laying down the conditions for the control and eradication of foot-and-mouth disease in the Netherlands in application of Article 13 of Directive 85/511/EEC

(notified under document number C(2001) 1070)

(Text with EEA relevance)

(2001/279/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market [1], as last amended by Directive 92/118/EEC [2], and in particular Article 10 thereof,

Having regard to Council Directive 85/511/EEC of 18 November 1985 introducing Community measures for the control of foot-and-mouth disease [3], as last amended by the Act of Accession of Austria, Finland and Sweden, and in particular Article 13(3) thereof,

Whereas:

(1) Based on a programme to employ suppressive vaccination submitted by the competent authorities of the Netherlands, the Commission adopted Decision 2001/246/EC [4] laying down the conditions for the approval and eradication of foot-and-mouth disease in the Netherlands in application of Article 13 of Directive 85/511/EEC.

(2) Based on a programme to employ protective vaccination submitted by the competent authorities of the United Kingdom, the Commission adopted Decision 2001/257/EC [5] laying down the conditions for the approval and eradication of foot-and-mouth disease in the United Kingdom in application of Article 13 of Directive 85/511/EEC.

(3) The competent authorities of the Netherlands have now presented to the Commission a programme to employ in addition to the measures laid down in Decision 2001/246/EC protective vaccination as an additional instrument to control and eradicate foot-and-mouth disease, taking into account the epidemiological situation and the high density of susceptible animals in certain parts of the territory.

(4) The principles provided for in Article 13 of Directive 85/511/EEC require to balance the decision on resorting to vaccination against basic Community interests which must not be endangered.

(5) Recourse to any kind of vaccination will inevitably jeopardise the foot-and-mouth disease status in terms of international trade not only for the Member State or part of its territory where vaccination is carried out.

(6) The Commission prior to taking a Decision on emergency vaccination must ensure that the measures to be taken include at least those provided for in Article 13(3) first to sixth indent of Directive 85/511/EEC.

(7) It is the purpose of this Decision to define the conditions under which the Netherlands may apply emergency vaccination without prejudice to Commission Decision 2001/223/EC [6] as last amended.

(8) The measures provided for in this Decision are in accordance with the opinion of the Standing Veterinary Committee,

HAS ADOPTED THIS DECISION:

Article 1

Decision 2001/246/EC is amended as follows:

1. A third paragraph is added to Article 1 as follows:

'3. Protective vaccination shall mean emergency vaccination of bovine animals in identified holdings situated in the vaccination zone, which is carried out exclusively in conjunction with pre-emptive killing of certain categories of other animals of susceptible species as defined in paragraph 1 whether or not in conjunction with suppressive vaccination as defined in paragraph 2.

[1] OJ L 224, 18.8.1990, p. 29.
[2] OJ L 62, 15.3.1993, p. 49.
[3] OJ L 315, 26.11.1985, p. 11.
[4] OJ L 88, 28.3.2001, p. 21.
[5] OJ L 91, 31.3.2001, p. 98.
[6] OJ L 82, 22.3.2001, p. 29.

It is aimed at an urgent reduction of the amount of virus circulating and the risk of virus spreading beyond the perimeters of the area, however it is carried out under the condition that animals of susceptible species vaccinated under the conditions of protective vaccination are not subject to pre-emptive killing.'

2. Article 2 is replaced by the following:

'*Article 2*

1. Without prejudice to Council Directive 85/511/EEC, and in particular Articles 4, 5 and 9 thereof, the competent authorities of the Netherlands may decide on resorting to emergency vaccination under the conditions set out in the Annexes.

2. Before commencing suppressive and protective vaccination under the conditions laid down respectively in Annex I and Annex II, the Netherlands shall ensure that the Member States and the Commission are officially informed on the details concerning the geographical and administrative definition of the vaccination zone, the number of holdings and animals by species affected and the time when vaccination will be started and accomplished and the circumstances motivating the decision to implement the measures.

Subsequently the Netherlands shall ensure that the information submitted in accordance with the first subparagraph is completed without undue delay with the details concerning the killing of vaccinated animals, in particular the number of animals killed, the number of holdings and animals affected, the time the killing was completed, and the modifications of the restrictions applied in the areas concerned with regard to suppressive vaccination carried out under the conditions laid down in Annex I and the maintenance of restrictions imposed on movement of live animals and certain of their products from animals which have been subject to protective vaccination carried out under the condition laid own in Annex II.'

3. The Annex is replaced by the Annexes to this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 5 April 2001.

For the Commission

David BYRNE

Member of the Commission

ANNEX I

Conditions for the use of suppressive vaccination in the control and eradication of foot-and-mouth disease in application of Article 13(3) of Directive 85/511/EEC

1.	Extent of the geographical area in which suppressive vaccination is to be carried out	The vaccination zone shall be within the area defined in Annex III(A). The restrictions applicable in the vaccination zone shall be those in Annex I and where applicable in Annex II of this Decision, without prejudice to the provisions in Articles 4, 5 and 9 of Directive 85/511/EEC. The vaccination zone must be situated in the parts of the territory of the Netherlands included in Annex I of Commission Decision 2001/223/EC as last amended.
2.	Species and age of the animals to be vaccinated	All animals of susceptible species independently of their sex, age and gestational or productive status
3.	Duration of the vaccination campaign	The campaign must be completed within 48 hours on holdings situated within a radius of up to 2 km around a holding placed under the restrictions laid down in Articles 4 or 5 of Directive 85/511/EEC.
4.	Specific standstill of vaccinated animals and products of vaccinated animals	The measures laid down in Article 4 of Directive 85/511/EEC shall apply to holdings on which suppressive vaccination is to be carried out until the animals vaccinated under the terms of suppressive vaccination have been killed. Where applicable such holdings will continue to be under the restrictions laid down in Annex II with regard to bovine animals.
5.	Special identification and special registration of the vaccinated animals	The measures laid down in Article 4 of Directive 85/511/EEC shall apply to holdings on which suppressive vaccination is to be carried out. An indelible mark must be applied to vaccinated animals at the time of vaccination.
6.	Other matters appropriate to the suppressive vaccination	
6.1.	Adjustment of zones established in accordance with Article 9 of Directive 85/511/EEC	A surveillance zone of at least 10 km around the vaccination zone referred to in point 1.
6.2.	Period for which the measures applied in the zones established in accordance with Article 9 of Directive 85/511/EEC are maintained	The measures applied in the protection zone referred to in point 6.1 must be maintained for at least 15 days after the elimination of all animals of susceptible species vaccinated under the terms of suppressive vaccination and the completion of the preliminary cleansing and disinfection on the holding where suppressive vaccination was carried out. The measures applied in the surveillance zone must remain in force in the protection zone for at least another 15 days. The measures applied in the surveillance zone must remain in force for at least 30 days after the elimination of all animals of susceptible species vaccinated under the terms of suppressive vaccination and the completion of the preliminary cleansing and disinfection on the holding where suppressive vaccination was carried out and where applicable the surveillance zone shall be maintained in accordance with point 6.2. of Annex II.
6.3.	Execution of the vaccination campaign	Vaccination must be carried out by an official of the competent authorities. Necessary measures must be in place to avoid possible spread of virus. Any residual quantities of vaccine must be returned to the point of vaccine distribution with a written record on number of animals vaccinated and the number of doses used.
6.4.	Vaccine to be used	The inactivated vaccine of at least 6 PD_{50} to be used must be suitably formulated for the species concerned and be effective against the virus type circulating. It shall be used in accordance with the instructions of the manufacturer.

6.5.	Elimination of all animals of susceptible species on holdings where suppressive vaccination was carried out	Without undue delay and at least at the earliest possible moment when the conditions referred to in Article 1(2) third subparagraph, first and second indent do no longer apply. Killing of animals may be carried out in designated premises outside the holding, if at least 14 days have elapsed since the completion of vaccination of susceptible animals on the holding concerned. The authorities must ensure proper cleansing and disinfection of the premises after each days operation.
6.6.	Information on implementation of this programme to the Commission	A detailed report on the execution of the programme shall be provided to the Commission and the Member States in the framework of a Standing Veterinary Committee before the lifting of the restrictions referred to in points 6.1 and 6.2.

ANNEX II

Conditions for the use of protective vaccination in the control and eradication of foot-and-mouth disease in application of Article 13(3) of Directive 85/511/EEC

1.	Extent of the geographical area in which protective vaccination is to be carried out	The vaccination zone shall be within an area defined in Annex III(B). The restrictions applicable in the vaccination zone shall be those in Annex IV of this Decision, without prejudice to the provisions in Article 9 of Directive 85/511/EEC.
2.	Species and age of the animals to be vaccinated	All animals over 1 week of age independently of their sex and gestational or productive status.
3.	Duration of the vaccination campaign	The vaccination shall be completed within 7 days.
4.	Specific standstill of vaccinated animals and products of vaccinated animals	Measures laid down in Annex IV and the treatments of products derived from vaccinated bovine animals as laid down in Annexes V, VI, VII-A and VII-B.
5.	Special identification and special registration of the vaccinated animals	— Identification of all bovine animals in accordance with Regulation (EC) No 1760/2000 (OJ L 204, 11.8.2000, p. 1), — on the spot ear-tagging of calves less than 20 days of age and application of an indelible mark with subsequent issuing of passport, — marking of vaccination status in the passport, — entering vaccination details in the database established in accordance with Regulation (EC) No 1760/2000.
6.	Other matters appropriate to the protective vaccination	
6.1.	Adjustment of zones established in accordance with Article 9 of Directive 85/511/EEC	A surveillance zone of at least 10 km around the vaccination zone referred to in point 1.
6.2.	Period for which the measures applied in the zones established in accordance with Article 9 of Directive 85/511/EEC are maintained	Without prejudice to the provisions in Article 9 of Directive 85/511/EEC and of Commission Decision 2001/223/EC the measures applied in the vaccination zone must remain in force until the measures are lifted in accordance with point 6.6.
6.3.	Execution of the vaccination campaign	Vaccination must be carried out by an official of the competent authorities. Necessary measures must be in place to avoid possible spread of virus. Any residual quantities of vaccine must be returned to the point of vaccine distribution with a written record on number of animals vaccinated and the number of doses used.
6.4.	Vaccine to be used	The inactivated vaccine of at least 6 PD_{50} to be used must be suitably formulated for the species concerned and be effective against the virus type circulating. It shall be used in accordance with the instructions of the manufacturer.
6.5.	Information on implementation of this programme to the Commission	A detailed report on the execution of the programme shall be provided to the Commission and the Member States in the framework of a Standing Veterinary Committee before the lifting of the restrictions referred to in points 6.1 and 6.2.
6.6.	Lifting of restrictions	In accordance with Article 16 and without prejudice to Article 9 of Directive 85/511/EEC and not earlier than — 12 months after the completion of the measures in point 3 or 12 months after the last outbreak in the vaccination zone, whichever is the latest, or — 3 months after the slaughter of the last vaccinated animal.

ANNEX III

(A) Suppressive vaccination zone:

Areas in the provinces of Gelderland, Overijssel, Noord-Brabant and Flevoland in the Netherlands as notified and described in accordance with Article 2(2).

(B) Protective vaccination zone:

An area of about 25 km around Oene as notified and described in accordance with Article 2(2).

ANNEX IV

MEASURES APPLICABLE IN THE VACCINATION ZONE WITH REGARD TO BOVINE ANIMALS VACCINATED UNDER THE TERMS OF PROTECTIVE VACCINATION

1. The Netherlands shall ensure that the following measures are applied in the vaccination zone during the period from the beginning of the vaccination until at least 30 days have elapsed following the completion of the vaccination:

   (a) Movement of live vaccinated bovine animals is prohibited within and out of the vaccination zone.

   Derogating from the prohibition above and after clinical inspection of the animals in question and of the herds of origin or dispatch, the competent authorities may authorise the direct transport of live bovine animals for immediate slaughter in a slaughterhouse designated by the competent authority and situated within the vaccination zone or in exceptional circumstances to be authorised on a case by case basis by the competent authorities preferably close to that zone.

   (b) Fresh meat produced from vaccinated animals slaughtered during the period referred to in this paragraph shall bear the stamp provided for in Article 5a of Directive 72/461/EEC, shall be stored and transported separately from meat not bearing the said stamp, and shall subsequently be transported in sealed containers to an establishment designated by the competent authorities for treatment in accordance with Annex V.

   (c) Milk and milk products produced from vaccinated animals during the period referred to in this paragraph may be placed on the market within or out of the vaccination zone, provided that at least one of the treatments referred to in Annexes VII-A and VII-B has been applied in an establishment located in the vaccination zone or, in exceptional circumstances to be authorised on a case by case basis by the competent authorities outside that zone. This treatment shall be certified by the competent veterinary authorities.

   (d) The collection of semen for artificial insemination from male bovine animals kept in centres situated within the vaccination zone shall be suspended.

   Derogating from the prohibition above, the competent authorities may authorise the collection at semen collection centres within the vaccination zone of semen from male bovine animals for the production of frozen semen to be used within the vaccination zone, if it is ensured that the semen collected during that period is stored separately for at least 30 days and is dispatched only after the following measures have been taken:

   1. the donor males have been vaccinated following a negative test for antibodies against foot-and-mouth disease virus, and

   2. a negative result has been achieved in all susceptible animals present at the time on the semen collection centre, in a virus isolation test or in an approved test for antibody against non-structural proteins carried out at end of the quarantine period for the semen.

   (e) Collection of ova and embryos from donor female bovines shall be prohibited.

2. The Netherlands shall ensure that the following measures are applied in the vaccination zone after the completion of the measures laid down in paragraph 1 and until the restrictions on the vaccination zone are lifted:

   (a) Intra-Community trade in bovine animals vaccinated against foot-and-mouth disease is prohibited.

   (b) Intra-Community trade in semen, ova and embryos of bovine animals vaccinated against foot-and-mouth disease is prohibited.

   (c) Collection of ova shall be prohibited.

   (d) Movement of bovine animals may only take place under the following conditions:

   1. Movement out of the vaccination zone of non-vaccinated bovine animals other than those referred to in point (3) below may be authorised not earlier than 3 months after completion of all vaccination and in accordance with Directive 85/511/EEC.

   Derogating from the provisions in the first subparagraph above, the Netherlands may authorise the transport of non-vaccinated bovine animals to a slaughterhouse outside the vaccination zone for immediate slaughter, provided that the meat shall be subjected to the treatment in Annex VI.

   2. Movement out of the vaccination zone of vaccinated bovine animals shall be prohibited, unless 12 months have elapsed after the completion of the measures referred to in paragraph 1 or 12 months after the last outbreak in the zone, whichever is the latest.

   Derogating from the provisions in the first subparagraph, the Netherlands may authorise the transport of vaccinated bovine animals to a designated slaughterhouse outside the vaccination zone for direct slaughter, provided that the meat shall be subjected to the treatment in Annex VI.

3. Non-vaccinated offspring of vaccinated dams, shall be prohibited from leaving the holding of origin unless being transported to:
   (i) either a slaughterhouse for immediate slaughter, the meat being subject to the treatment in Annex VI, or
   (ii) to another holding within the vaccination zone, or
   (iii) any holding after obtaining a negative result in a serological test for the detection of antibody against the foot-and-mouth disease virus.

(e) The restrictions applied to fresh meat produced from vaccinated bovine animals as laid down in Annex VI, and to meat products as laid down in Annex V, shall continue to apply until the restrictions on movements of vaccinated bovine animals have been lifted in accordance with Article 16 of Directive 85/511/EEC, and in any case not earlier than 12 months after the completion of vaccination or 12 months after the last outbreak in the vaccination zone whichever is the latest, or until 3 months have elapsed after the slaughter of the last vaccinated bovine animal.

(f) The restrictions applied to fresh milk produced from vaccinated bovine animals and to milk products produced from such milk as laid down in Annexes VII-A and VII-B shall continue to apply until the restrictions on movements of vaccinated bovine animals have been lifted in accordance with Article 16 of Directive 85/511/EEC, and in any case not earlier than 12 months after the completion of vaccination and 12 months after the last outbreak in the vaccination zone whichever is the latest, or until 3 months have elapsed after the slaughter of the last vaccinated bovine animal.

ANNEX V

TREATMENT OF MEAT TO ENSURE DESTRUCTION OF FOOT-AND-MOUTH DISEASE VIRUS

Treatment	Foot-and-mouth disease
(a) Heat treatment in a hermetically sealed container with an F_0 value of 3,00 or more	+
(b) Heat treatment at a minimum temperature of 70 °C, which must be reached throughout the meat	+
(c) Heat treatment in a hermetically sealed container to at least 60 °C for a minimum of 4 hours, during which time the core temperature must be at least 70 °C for 30 minutes	+
(d) Natural fermentation and maturation of not less than 9 months for boneless meat, resulting in the following characteristics: aw value of not more than 0,93 and a pH value of not more than 6,0	+
(e) As (d) above but meat may contain bone. All the necessary measures must be taken to avoid cross contamination	+
(f) Heat treatment ensuring a core temperature of at least 65 °C is reached for the time necessary to achieve a pasteurisation value (pv) equal to or more than 40	+
'+': Effectiveness recognised	

ANNEX VI

TREATMENT OF FRESH MEAT

1. De-boned fresh meat:

   Meat as described in Article 2(a) of Council 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)(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.

ANNEX VII-A

TREATMENT OF MILK TO ENSURE DESTRUCTION OF FOOT-AND-MOUTH VIRUS IN MILK FOR HUMAN CONSUMPTION

Treatment of milk must be carried out in accordance with paragraph 1 below and in any case 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 for human consumption must be subject to at least one of the following treatments:

1.1. sterilisation at a level of at least $F_0 3$,

1.2. single UHT [1] treatment,

1.3. double HTST [2] treatment of milk with a pH above 7,0,

1.4. single HTST treatment of milk with a pH less than 7,0,

1.5. single HTST combined with another physical treatment by:

1.5.1. either a second heat treatment resulting in a negative reaction to the peroxidase test,

1.5.2. or lowering the pH < 6 for at least one hour,

1.5.3. or additional heating to 72 °C or more, combined with desiccation.

2. Milk based products must be produced from milk after the treatment referred to in paragraph 1.

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[1] UHT = Ultra High Temperature treatment at 130 °C for 2–3 sec.
[2] HTST = High Temperature Short Time pasteurisation at 72 °C for 15–17 sec or equivalent pasteurisation effect achieving a negative reaction to a phosphatase test.

ANNEX VII-B

TREATMENT OF MILK TO ENSURE DESTRUCTION OF FOOT-AND-MOUTH VIRUS IN MILK NOT INTENDED FOR HUMAN CONSUMPTION AND IN MILK FOR ANIMAL CONSUMPTION

Treatment of milk and milk-based products must be carried out in accordance with paragraphs 1 to 3 below depending on the intended use of the milk or milk-based products, and in any case necessary precautions must be taken to avoid contact of the milk or milk based products with any potential source of foot-and-mouth virus after processing.

1. Milk not intended for human consumption and milk intended for animal consumption must be subject to at least one of the following treatments:

1.1. sterilisation at a level of at least $F_0 3$,

1.2. single UHT [1] combined with another physical treatment referred to in either paragraph 1.4.1. or 1.4.2.

1.3. double HTST [2],

1.4. single HTST combined with another physical treatment by:

1.4.1. either lowering the pH < 6 for at least one hour,

1.4.2. or additional heating to 72 °C or more, combined with desiccation.

2. Milk-based products not intended for human consumption must be produced from milk after the treatments referred to in paragraph 1.

3. Milk-based products intended for animal consumption must be produced from milk after one of the treatments referred to in paragraph 1.1., 1.2. and 1.4.

4. Whey to be fed to pigs 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.

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[1] UHT = Ultra High Temperature treatment at 130 °C for 2–3 sec.
[2] HTST = High Temperature Short Time pasteurisation at 72 °C for 15–17 sec or equivalent pasteurisation effect achieving a negative reaction to a phosphatase test.