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COUNCIL DECISION
of 11 December 1991
establishing Community reserves of foot-and-mouth disease vaccines

(91/666/EEC)

(OJ L 368, 31.12.1991, p. 21)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Council Decision 1999/762/EC of 15 November 1999	L 301	6	24.11.1999
►**M2**	Commission Decision 2001/181/EC of 22 February 2001	L 66	39	8.3.2001
►**M3**	Council Regulation (EC) No 807/2003 of 14 April 2003	L 122	36	16.5.2003

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COUNCIL DECISION

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establishing Community reserves of foot-and-mouth disease vaccines

(91/666/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 85/511/EEC of 18 November 1985 introducing Community measures for the control of foot-and-mouth disease ([1]), as amended by Decision 90/423/EEC ([2]), and in particular Article 14 thereof,

Having regard to the proposal from the Commission,

Whereas by 1 January 1992 all Member States must have discontinued routine vaccination against foot-and-mouth disease in their territory;

Whereas, however, in view of the high density of susceptible species in some parts of the Community, it is necessary to provide for the possibility of emergency vaccination in a limited area, in circumstances where slaughter of the entire herd may not be sufficient to eliminate the virus;

Whereas Community reserves of foot-and-mouth disease vaccine should be established, based on stocks of concentrated inactivated antigen capable of being quickly converted into vaccine for emergency use;

Whereas the antigen should be stored at four separate locations; whereas facilities for formulation, bottling and distribution must also be provided;

Whereas the criteria for the supply and storage of antigen and its conversion into vaccine should be established;

Whereas the national institutes responsible for maintaining the reserve of antigen should cooperate with the Community Coordinating Institute for foot-and-mouth disease vaccines designated by Decision 91/665/EEC ([3]) in order to ensure the potency, safety and stability of the antigen, and vaccines produced therefrom, and to ensure that the quantity and sub-types kept are appropriate to the risk, on the basis, in particular, of information supplied by the reference laboratory for the identification of foot-and-mouth disease virus designated by Decision 89/531/EEC ([4]);

Whereas Article 14 of Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field ([5]), as amended by Decision 91/133/EEC ([6]), provides that the establishment of a Community reserve of foot-and-mouth disease vaccines may be eligible for Community aid,

HAS ADOPTED THIS DECISION:

Article 1

The establishment of Community reserves of foot-and-mouth disease vaccine shall consist of:

— the supply of concentrated inactivated antigen by establishments designated by Member States,

([1]) OJ No L 315, 26. 11. 1985, p. 11.
([2]) OJ No L 224, 18. 8. 1990, p. 13.
([3]) See page 19 of this Official Journal.
([4]) OJ No L 279, 28. 9. 1989, p. 32.
([5]) OJ No L 224, 18. 8. 1990, p. 19.
([6]) OJ No L 66, 13. 3. 1991, p. 18.

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— the storage, in reserves, of the antigen referred to in the first indent,

— the guarantee of rapid formulation, bottling and distribution by establishments designated by Member States.

Article 2

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

1. antigen banks: appropriate premises, such as those designated in Article 3 (1), for the storage of Community reserves of concentrated inactivated antigen for the production of foot-and-mouth disease vaccine;

2. Community Coordinating Institute for foot-and-mouth disease vaccine (CCI): the institute designated by Decision 91/665/EEC.

Article 3

1. Antigen banks shall be established at:

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— the Laboratoire de pathologie bovine du centre national d'études vétérinaires et alimentaires, Lyon (France),

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— the Istituto Zooprofilatico Sperimentale di Brescia (Italy),

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— any other establishment designated in accordance with the procedure laid down in Article 10.

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2. The amounts and sub-types of antigen to be held in the antigen banks shall be as laid down in Annex I.

3. The antigen shall be distributed between the antigen banks in such a way as to ensure that, in the event of technical problems which result in deterioration of the antigen in one of the said banks, the availability of antigen for vaccine production is guaranteed by the other antigen banks.

Article 4

The functions and duties of the antigen banks shall be:

(a) to store the Community reserves of concentrated inactivated foot-and-mouth disease virus antigens in such a way as to maintain their usefulness for the production of a safe and potent vaccine for emergency use against foot-and-mouth disease, including the keeping of adequate records of the conditions under which the antigen is stored;

(b) to liaise with the CCI for the purposes of:

  (i) checking incoming batches of antigen for stability, potency and safety;

  (ii) testing batches of stored antigen for stability, potency and safety at intervals to be determined under the procedure laid down in Article 10, following an opinion from the Scientific Veterinary Committee;

  (iii) advising on the need for replacement of an antigen if tests indicate that its potency is inadequate;

(c) to deliver concentrated inactivated antigen to establishments designated for the formulation, bottling and distribution of the vaccine, at the request of the Commission or a Member State under the conditions provided for in the second and third subparagraphs of Article 13 (3) of Directive 85/511/EEC, for use in the Member State or third country in which the vaccine is to be used.

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Article 5

1. The establishments which are to supply the quantities and subtypes of antigens mentioned in Annex I and, without prejudice to Article 13 of Directive 85/511/EEC, those which are to ensure the formulation, production, bottling and distribution of the foot-and-mouth disease vaccine produced from the antigen shall be designated in accordance with the procedure laid down in Article 10 of this Decision.

2. For the purposes of paragraph 1, the Commission shall issue a call for tenders, taking into account the following criteria in particular:

(a) the technical requirements concerning the supply of antigens, in accordance with Annex II;

(b) the supply and delivery of the specified quantity to the antigen bank in a form suitable for long-term storage in liquid nitrogen, or other storage methods recognized, under the procedure laid down in Article 10 after obtaining the opinion of the Scientific Veterinary Committee, as giving at least equivalent stability, including the provision of separate replicates suitable for routine testing;

(c) a guarantee that any antigen supplied will meet the safety and stability requirements defined for vaccine by the European Pharmacopoeia, as well as the required potency (6 PD 50/dose) when tested as specified for vaccine;

(d) the reagents and materials to be used in the formulation of the vaccine;

(e) a guarantee that the vaccine supplied complies fully with the European Pharmacopoeia;

(f) supply of the vaccine, within a given time and at a guaranteed rate of delivery, in bottles of suitable size, labelled in the language or languages of the country in which the vaccine is to be used;

(g) compliance by the establishment which supplies an antigen with the 'minimum standards for laboratories working with foot-and-mouth disease virus *in vitro* and *in vivo*' — European Commission for the control of foot-and-mouth disease — 26th session, Rome, April 1985, on the basis, where necessary, of a report by experts acting under the procedure laid down in Article 10;

(h) quoted costs for the supply of the antigen or the provision of the service, as appropriate.

Article 6

The antigen banks, the establishments supplying the antigen and the establishments carrying out formulation and bottling shall operate under strict conditions of hygiene and safety, in accordance with the generally accepted standards for good manufacturing practice in Europe, which shall be monitored by the CCI.

Article 7

Detailed arrangements for the implementation of this Decision shall be adopted under the procedure laid down in Article 10, in particular as regards:

— the distribution of antigen reserves between antigen banks,

— general procedures for replacing antigen reserves,

— the rules to be followed, should Decision 90/424/EEC be invoked, in making available to third countries vaccines produced from antigens to be replaced in accordance with the second indent,

— any derogations, after obtaining the opinion of the Standing Veterinary Committee, from the figure of 6 PD 50/dose laid down in Article 5 (2) (c) for new vaccines.

Article 8

Commission veterinary experts may, in collaboration with the competent authorities of the Member States, carry out on-the-spot

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inspections to verify whether or not the establishments and antigen banks are operating in accordance with this Decision.

The Commission shall inform the Member States of the outcome of such inspections.

The Member State in whose territory the inspections are carried out shall provide the experts with all the assistance required for the accomplishment of their task.

General rules for the application of this Article shall be adopted in accordance with the procedure laid down in Article 10.

Article 9

Annexes I and II may be supplemented or amended in accordance with the procedure laid down in Article 10.

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Article 10

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health set up by Article 58 of Regulation (EC) No 178/2002 ([1]).

2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC ([2]) shall apply.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at fifteen days.

3. The commitee shall adopt its rules of procedure.

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Article 11

The Council, acting by a qualified majority on a proposal from the Commission, shall review this Decision before 1 January 1995.

Article 12

This Decision is addressed to the Member States.

([1]) OJ L 31, 1.2.2002, p. 1.
([2]) OJ L 184, 17.7.1999, p. 23.

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ANNEX I

Quantities and sub-types of antigen to be held in the antigen banks

Potent well-tested vaccine strains corresponding to:

1.	O	European strain	O1-BFS
		Middle East strain	O1-Manisa
2.	A	South American strain	A24-Cruzeiro
		Middle East strain	A22-Iraq
		Middle East strain	A-Iran 96
		Middle East strain	A-Iran 99
		Asian strain	A-Malaysia 97
3.	C	European strain	C1-Noville
4.	ASIA1		ASIA1-Shamir
5.	SAT	SAT 1	
		SAT 2	— East African strain — Southern African strain
		SAT 3	

The above strains shall be kept in quantities sufficient to carry out an emergency vaccination taking into account the estimated risks the different subtypes present to the Community livestock and in any case not less than two million doses of each subtype.

Each dose of vaccine reconstituted from the above antigen should have an observed potency of 6 PD50 in cattle, when tested according to the European Pharmacopoeia.

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ANNEX II

Technical requirements for supply of concentrated inactivated monovalent foot-and-mouth disease virus antigen and its formulation into vaccine

1. Availability of concentrated inactivated antigen suitable for storage in liquid nitrogen, or by a method giving at least equivalent stability.

2. Availability of antigen corresponding to each of the sub-types specified in Annex I. The antigen must also be suitable for the preparation of oil emulsion vaccines for pigs, in which case ⅙ of a dose volume must protect at least 5 out of 10 pigs if challenged by intrapodal injection of 1 000 ID50.

3. Full information should be provided on the tests conducted by the producer on seed virus, cells and other materials used in the production.

   Samples of each master seed virus must be submitted to the CCI for confirmatory tests of identity and purity.

   Samples of the cells used to produce the virus should be submitted to the CCI.

4. The manufacture and quality of antigen must be consistent with the generally accepted standards for good manufacturing practice in Europe.

   The vaccines to be produced on the basis of the antigen must comply with the requirements of the European Pharmacopoeia. In addition:

   (a) the antigen shall have been inactivated before concentration using a first order inactivant. For each batch of antigen the kinetics of inactivation must be followed and documented by the producer. The range of inactivation must be such that the batch as a whole is free from infective virus, and the safety margin should be in the range of about 3 log10 (based on extrapolation); and

   (b) the mixture of virus preparation/inactivant must have been transferred to a second sterile container when half of the inactivation time has elapsed in such a manner as to prevent contamination; an equivalent method could, however, be acceptable; and

   (c) subsequent processing of the antigen should be carried out in a non-contaminated environment (FMD virus free). Polyethyleneglycol (PEG) precipitation, polyethyleneoxide (PEO) precipitation, ultrafiltration or a combination of these are permitted methods for the concentration of inactivated antigen; and

   (d) before and during the performance of innocuity tests, the inactivated antigen should be stored in a sealed container, in a quarantine area, outside the restricted (high-security) area; and

   (e) the concentrated product containing the inactivated antigen should be in a volume at least 100 times less than that used for formulation of conventional vaccines. The producer must indicate the number of vaccine doses per volume unit of concentrated material; and

   (f) the main bulk of the inactivated antigen should be supplied in containers suitable for storage over liquid nitrogen and divided into volumes to be agreed between the producer and the CCI.

   In consultation with, and under the supervision of, the CCI, the producer must also provide 20 representative samples containing at least 1 mg each of concentrated 146S antigen for periodic *in vitro* and *in vivo* tests; and

   (g) the producer must provide relevant information about the antigen and its formulation into vaccine for consideration by the CCI.

5. (a) On receipt, each batch of concentrated inactivated antigen will be checked by the CCI for possible residual infective virus *in vitro* and in cattle using the method prescribed for vaccine in the European Pharmacopoeia; and

   (b) potency of the vaccines prepared from the concentrated antigen will be tested by the CCI. Vaccines will be formulated according to the prescription of the producer. Vaccines for pigs will be formulated as oil emulsions. For cattle, aluminium-hydroxide-, saponin- or oil-adjuvanted vaccines may be used. Any batches found to be unsatisfactory when tested immediately upon reconstitution following deposit in the antigen bank will be rejected and be replaced at the producer's expense. The cost of testing the replacement batch will be met by the producer;

   (c) components of the concentrated antigen must not interfere with the preparation and stability of the oil-emulsion vaccines.

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6. The antigen as provided by the producer should have an expected stability of at least five years.

7. (a) The concentration and quality of the vaccine adjuvants will be agreed with the CCI.

   (b) The producer should also specify the expected shelf-life of the product after formulation into vaccine. This shelf-life should be at least four months.

8. Vaccines which have exceeded their expiry date must not be used; this date can be checked and if necessary reviewed by the CCI.

9. Formulated vaccines must be kept under cool temperature conditions as specified in the European Pharmacopoeia. Care should be taken to maintain the correct temperature during distribution, until administered.