COMMISSION

COMMISSION DECISION
of 18 January 2001
for safety and potency testing of foot-and-mouth disease vaccines and bluetongue vaccines

(notified under document number C(2001) 118)

(2001/75/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field [1], as last amended by Regulation (EC) No 1258/1999 [2], and in particular Articles 6 and 14 thereof,

Having regard to Council Decision 91/666/EEC of 11 December 1991 establishing Community reserves of foot-and-mouth disease vaccines [3], as last amended by Decision 1999/762/EC [4], and in particular Article 5 thereof,

Whereas:

(1) In conformity with Decision 91/666/EEC, the purchase of antigens is a part of the Community action to establish Community reserves of foot-and-mouth disease vaccines.

(2) By Commission Decision 93/590/EC of 5 November 1993 for the purchase by the Community of foot-and-mouth disease antigens within the framework of the Community action concerning reserves of foot-and-mouth disease vaccines [5], as last amended by Decision 95/471/EC [6], arrangements were made for purchase of A5, A22 and O1 foot-and-mouth disease antigen.

(3) Foot-and-mouth disease virus antigens kept in the emergency stock since 1993 must be tested with regard to safety and potency to ensure that the antigen reserves kept for emergency use are of high quality.

(4) By Commission Decision 98/64/EC of 9 December 1997 on a Community financial contribution for improving the foot-and-mouth disease control programme in Turkey [7], it was agreed as a part of a work plan that the European Commission would make arrangements for testing of foot-and-mouth disease vaccine produced in Turkey.

(5) By Commission Decision 2000/292/EC of 6 April 2000 for purchase by the Community of bluetongue vaccine for emergency stock [8], arrangements were made for purchase of bluetongue vaccine for emergency.

(6) No bluetongue vaccine is produced by the pharmaceutical industry based in the Member States of the European Union (EU).

(7) Bluetongue vaccine purchased abroad for emergency use should be tested with the objective of obtaining information of importance for the use of the vaccine under different epidemiological conditions.

(8) Safety and potency testing of foot-and-mouth disease vaccine and bluetongue vaccine can only be carried out at laboratories being operated under approved biosecurity levels.

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

HAS ADOPTED THIS DECISION:

Article 1

1. The Community shall make arrangements for appropriate safety and potency testing of:

— foot-and-mouth disease virus antigens purchased in 1993 and since then kept as a part of the EU emergency stock,

[1] OJ L 224, 18.8.1990, p. 19.
[2] OJ L 160, 26.6.1999, p. 103.
[3] OJ L 368, 31.12.1991, p. 21.
[4] OJ L 301, 24.11.1999, p. 6.
[5] OJ L 280, 13.11.1993, p. 33.
[6] OJ L 269, 11.11.1995, p. 29.
[7] OJ L 16, 21.1.1998, p. 45.
[8] OJ L 95, 15.4.2000, p. 39.

— foot-and-mouth disease vaccine produced in Turkey and used in a prophylactic vaccination programme which includes vaccination of susceptible animals kept in the area of Turkish Thrace,

— bluetongue vaccines produced outside the European Community and purchased for an emergency stock.

2. The maximum cost of the measures referred to in paragraph 1 shall be up to EUR 430 000.

Article 2

The measures mentioned in Article 1 shall be carried out by the Commission in cooperation with the supplier designated by call for tender.

Article 3

1. To meet the objectives of Articles 1 and 2 the Commission shall conclude contracts without delay.

2. The Director-General of the Directorate-General for Health and Consumer Protection shall be authorised to sign the contracts on behalf of the European Commission.

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 18 January 2001.

For the Commission

David BYRNE

Member of the Commission