EN

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 10.12.1999
COM(1999) 615 final

Proposal for a

COUNCIL DECISION

designating a specific institute to establish the criteria necessary to standardise the serological tests to monitor the effectiveness of rabies vaccines

(presented by the Commission)

EXPLANATORY MEMORANDUM

Vaccinating domestic carnivores against rabies, followed by a check on the effectiveness of this vaccination by titration of antibodies, provides safety guarantees equivalent to putting the animal into quarantine for six months on entry into countries free of rabies.

In the Community, Sweden has already been using this alternative system for a number of years and the Swedish authorities have approved the laboratories authorised to carry out the required post-vaccination antibody titration.

The United Kingdom has embarked on the same course and aims to set up a pilot system by next April, moving to general application in spring 2001. Following the example of the Swedish authorities, the UK has designated laboratories authorised to carry out the analyses required for such movements of animals. National approval has been necessary in the absence of an international or Community reference laboratory for such analyses.

The procedures for approving laboratories should be coordinated at the Community level by designating a Community reference laboratory for these matters.

Article 10(6) of Directive 92/65/EEC provides for the designation of such an establishment by the Council.

The A.F.S.S.A. Nancy (French Food Safety Agency) laboratory has been chosen as it is recognised throughout Europe as a leading expert on the specific issue of titration of post-vaccine antibodies and is in fact already viewed as a reference laboratory in this field.

At the international level, the Nancy laboratory is the International Office of Epizootics (OIE) reference laboratory for rabies.

The purpose of this draft Council Decision is therefore to designate the A.F.S.S.A. Nancy laboratory as the Community reference laboratory for carrying out serological tests to monitor rabies vaccines.

Proposal for a

COUNCIL DECISION

designating a specific institute to establish the criteria necessary to standardise the serological tests to monitor the effectiveness of rabies vaccines

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (1) to Directive 90/425/EEC[1], as last amended by Commission Decision 95/176/EC[2], and in particular Article 10(6) thereof,

Having regard to the proposal from the Commission[3],

Whereas:

(1) Directive 92/65/EEC provides for an alternative system to quarantine for the entry of specific domestic carnivores into the territory of certain Member States free from rabies. That system requires checks on the effectiveness of the vaccination of those animals by titration of antibodies.

(2) In order to ensure an effective system of monitoring the laboratories which will carry out these analyses, a system of Community approval of those laboratories should be established.

(3) The approval of those laboratories should be coordinated by a Community reference laboratory for those matters.

(4) The Agence Française de Sécurité Sanitaire des Aliments de Nancy (French Food Safety Agency, Nancy) laboratory meets the conditions required for designation as Community reference laboratory for those matters.

(5) That reference laboratory may receive Community aid as provided for in Article 28 of Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field[4], as last amended by Regulation (EC) No 1258/1999[5],

---

1 OJ L 268, 14.9.1992, p. 54.
2 OJ L 117, 24.5.1995, p. 23.
3 OJ C
4 OJ L 224, 18.8.1990, p. 19.
5 OJ L 160, 26.6.1999, p. 103.

HAS ADOPTED THIS DECISION:

Article 1

The laboratory of the Agence Française de Sécurité Sanitaire des Aliments de Nancy (AFSSA, Nancy), whose details are set out in Annex I, is designated as the institute specifically responsible for establishing the criteria necessary to standardise the serological tests to monitor the effectiveness of rabies vaccines.

Article 2

The duties of the laboratory referred to in Article 1 are set out in Annex II.

Article 3

The laboratory referred to in Article 1 shall send the Member States and the Commission the list of approved Community laboratories authorised to carry out serological tests to monitor the effectiveness of rabies vaccines.

Article 4

The Annexes to this Decision shall be amended in accordance with the procedure laid down in Article 5(2).

Article 5

1. The Commission shall be assisted by the Standing Veterinary Committee set up by Article 1 of Council Decision 68/361/EEC[6].

2. Where reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Council Decision 1999/468/EC[7] shall apply, in compliance with Article 7(3) thereof.

3. The period provided for in Article 5(6) of Decision 1999/468/EC shall be 15 days.

[6] OJ L 255, 18.10.1968, p. 23.
[7] OJ L 184, 17.7.1999, p. 23.

Article 6

This Decision is addressed to the Member States.

Done at Brussels,

For the Council
The President

ANNEX I

A.F.S.S.A. Nancy
Laboratoire d'études sur la rage et la pathologie des animaux sauvages
Domaine de Pixérécourt
BP 9
54220 Malzéville
France
Tel: (00 33) 3 83 29 89 50
Fax: (00 33) 3 83 29 89 59
E-mail: maubert@fitech.fr

ANNEX II

The reference institute responsible for establishing the criteria necessary to standardise the serological tests to monitor the action of rabies vaccines shall:

– coordinate research to develop and improve methods designed to prevent the entry of rabid animals into Community territory, such as serological titration on carnivores vaccinated against rabies,

– implement the procedure for approving those laboratories for which the Member States have submitted an application for approval to perform the analyses referred to in the first indent,

– draw up a list of approved Community laboratories authorised to carry out these analyses,

– provide any useful information on analysis methods and comparative trials to these laboratories and organise training sessions and further training courses for their staff,

– organise interlaboratory aptitude tests,

– collaborate with the laboratories responsible for carrying out these analyses in third countries and propose a procedure for approving those laboratories to the Commission,

– provide scientific and technical assistance to the Commission and to Member States on these matters, in particular in cases of disagreement between Member States on analysis results.