Council Decision of 20 March 2000 designating a specific institute responsible for establishing the criteria necessary for standardising the serological tests to monitor the effectiveness of rabies vaccines (2000/258/EC)

COUNCIL DECISION

of 20 March 2000

designating a specific institute responsible for establishing the criteria necessary for standardising the serological tests to monitor the effectiveness of rabies vaccines

(2000/258/EC)

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)], and in particular Article 10(6) thereof,

Having regard to the proposal from the Commission,

Whereas:

(1) Directive 92/65/EEC provides for an alternative system to quarantine for the entry of certain 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 guarantee an effective system of monitoring the laboratories which will carry out these analyses, it is appropriate to establish a system of Community approval of such laboratories.

(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[(2)].

(6) The measures necessary for the implementation of this Decision should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[(3)],

HAS ADOPTED THIS DECISION:

Article 1

The laboratory of the Agence française de sécurité sanitaire des aliments de Nancy (AFSSA, Nancy), the details of which are set out in Annex I, is hereby designated as the specific institute responsible for establishing the criteria necessary for standardising 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.

[F1 Article 3

1 On the basis of a favourable result of the appraisal of an applicant laboratory in a Member State, documented by AFSSA, Nancy, the competent authority of the Member State may authorise the applicant laboratory to carry out the serological tests to monitor the effectiveness of rabies vaccines.

Member States shall draw up and keep up to date a list of those laboratories that they have authorised and shall make it available to the other Member States and to the public.

2 On the basis of a favourable result of the appraisal of an applicant laboratory in a third country documented by AFSSA, Nancy, and following an application for approval from the competent authority of the third country of origin of the applicant laboratory, such laboratory shall be authorised in accordance with the procedure referred to in Article 5(2) to carry out serological tests to monitor the effectiveness of rabies vaccines.

3 Detailed rules for the uniform application of this Article may be adopted in accordance with the procedure referred to in Article 5(2).**]**

Textual Amendments

F1 Substituted by Council Directive 2008/73/EC of 15 July 2008 simplifying procedures of listing and publishing information in the veterinary and zootechnical fields and amending Directives 64/432/EEC, 77/504/EEC, 88/407/EEC, 88/661/EEC, 89/361/EEC, 89/556/EEC, 90/426/EEC, 90/427/EEC, 90/428/EEC, 90/429/EEC, 90/539/EEC, 91/68/EEC, 91/496/EEC, 92/35/EEC, 92/65/EEC, 92/66/EEC, 92/119/EEC, 94/28/EC, 2000/75/EC, Decision 2000/258/EC and Directives 2001/89/EC, 2002/60/EC and 2005/94/EC (Text with EEA relevance).

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, hereinafter referred to as the 'Committee', set up by Article 1 of Decision 68/361/EEC[(4)].

2 Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply.

The period provided for in Article 5(6) of Decision 1999/468/EC shall be three months.

3 The Committee shall adopt its rules of procedure.

[F2]Article 5a

. . . . . .

Textual Amendments

F2 Deleted by Council Decision of 5 May 2009 correcting Directive 2008/73/EC simplifying procedures of listing and publishing information in the veterinary and zootechnical fields (2009/436/EC).

Article 6

This Decision is addressed to the Member States.

[[F1]ANNEX I

AFSSA, Nancy

Laboratoire d'études sur la rage et la pathologie des animaux sauvages

Technopôle agricole et vétérinaire

BP 40 009

54220 Malzéville Cedex

France

ANNEX II

The specific institute responsible for establishing the criteria necessary for standardising the serological test to monitor the action of rabies vaccines shall:

— coordinate the establishment, improvement and standardisation of methods of serological titration on carnivores vaccinated against rabies,

— appraise those laboratories in Member States which have submitted an application to perform the serological titrations referred to in the first indent; the result of this appraisal must be sent to the applicant laboratory and to the competent authorities of the Member State where the result is favourable for the purposes of approval,

— appraise those laboratories in third countries which have submitted an application to perform the serological titrations referred to in the first indent; the result of this appraisal must be sent to the applicant laboratory and to the Commission where the result is favourable for the purpose of approval,

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

— organise inter-laboratory aptitude tests (proficiency tests),

— provide scientific and technical assistance to the Commission and the competent authorities concerned on the matters referred to in this Annex, in particular in cases of disagreement on results of serological titrations.**]**

(**1**) OJ L 268, 14.9.1992, p. 54. Directive as last amended by Commission Decision 95/176/EC (OJ L 117, 24.5.1995, p. 23).

(**2**) OJ L 224, 18.8.1990, p. 19. Decision at last amended by Regulation (EC) No 1258/1999 (OJ L 160, 26.6.1999, p. 103).

(**3**) OJ L 184, 17.7.1999, p. 23.

(**4**) OJ L 255, 18.10.1968, p. 23.

Changes to legislation:
There are outstanding changes not yet made to Council Decision of 20 March 2000 designating a specific institute responsible for establishing the criteria necessary for standardising the serological tests to monitor the effectiveness of rabies vaccines (2000/258/EC). Any changes that have already been made to the legislation appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to :

- Decision repeal by EUR 2016/429 Regulation (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Annex 1 omitted by S.I. 2018/1410 reg. 5(5)
- Annex 2 words inserted by S.I. 2018/1410 reg. 5(6)(b)
- Annex 2 words inserted by S.I. 2018/1410 reg. 5(6)(d)
- Annex 2 words omitted by S.I. 2018/1410 reg. 5(6)(c)
- Annex 2 words substituted by S.I. 2018/1410 reg. 5(6)(a)
- Annex 2 words substituted by S.I. 2018/1410 reg. 5(6)(e)
- Art. 1 substituted by S.I. 2018/1410 reg. 5(2)
- Art. 3(1) words substituted by S.I. 2018/1410 reg. 5(3)(a)
- Art. 3(1) words substituted by S.I. 2018/1410 reg. 5(3)(b)
- Art. 3(1) words substituted in earlier amending provision S.I. 2018/1410, reg. 5(3)(a) by S.I. 2020/1388 reg. 25(2)(a)
- Art. 3(1) words substituted in earlier amending provision S.I. 2018/1410, reg. 5(3)(b) by S.I. 2020/1388 reg. 25(2)(b)
- Art. 3(2) words omitted by S.I. 2018/1410 reg. 5(3)(c)(i)
- Art. 3(2) words omitted by S.I. 2018/1410 reg. 5(3)(c)(ii)
- Art. 3(3) omitted by S.I. 2018/1410 reg. 5(3)(e)
- Art. 4 omitted by S.I. 2018/1410 reg. 5(4)
- Art. 5 omitted by S.I. 2018/1410 reg. 5(4)
- Art. 6 omitted by S.I. 2018/1410 reg. 5(4)

Changes and effects yet to be applied to the whole legislation item and associated provisions

- Art. 3(2A) inserted by S.I. 2018/1410 reg. 5(3)(d)
- Art. 3(2A)(ii)(iii) Art. 3(2A)(iii)(iv) renumbered as Art. 3(2A)(ii)(iii) in earlier amending provision S.I. 2018/1410, reg. 5(3)(d) by S.I. 2020/1388 reg. 25(2)(c)
- Art. 3(2A)(ii) omitted in earlier amending provision S.I. 2018/1410, reg. 5(3)(d) by S.I. 2020/1388 reg. 25(2)(c)