Commission Decision of 9 August 2010 implementing Council Decision 2000/258/EC as regards proficiency tests for the purposes of maintaining authorisations of laboratories to carry out serological tests to monitor the effectiveness of rabies vaccines (notified under document C(2010) 5421) (Text with EEA relevance) (2010/436/EU)

COMMISSION DECISION

of 9 August 2010

implementing Council Decision 2000/258/EC as regards proficiency tests for the purposes of maintaining authorisations of laboratories to carry out serological tests to monitor the effectiveness of rabies vaccines

(notified under document C(2010) 5421)

(Text with EEA relevance)

(2010/436/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Decision 2000/258/EC 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[(1)], and in particular Article 3(3) thereof,

Whereas:

(1) Decision 2000/258/EC designates the laboratory of the Agence française de sécurité sanitaire des aliments de Nancy ('AFSSA, Nancy'), as the specific institute responsible for establishing the criteria necessary for standardising the serological tests to monitor the effectiveness of rabies vaccines. That Decision also lays down the duties of that laboratory.

(2) In particular, AFSSA, Nancy is to appraise the laboratories in Member States and third countries for the purposes of their authorisation to carry out serological tests to monitor the effectiveness of rabies vaccines. In addition, AFSSA, Nancy is to organise inter-laboratory aptitude tests (proficiency tests).

(3) In view of maintaining the authorisation granted to such laboratories, AFSSA, Nancy has, since the year 2000, been organising proficiency tests at least once per year.

(4) Experience has shown that those proficiency tests provide an effective system of monitoring the laboratories which carry out serological tests to monitor the effectiveness of rabies vaccines.

(5) Article 3 of Decision 2000/258/EC does not include any provisions concerning the maintenance of authorisations already granted to laboratories in Member States or in third countries to carry out such serological tests.

Changes to legislation: *There are currently no known outstanding effects for the Commission Decision of 9 August 2010 implementing Council Decision 2000/258/EC as regards proficiency tests for the purposes of maintaining authorisations of laboratories to carry out serological tests to monitor the effectiveness of rabies vaccines (notified under document C(2010) 5421) (Text with EEA relevance) (2010/436/EU). (See end of Document for details)*

(6) In order to ensure the uniform application of that Article, it is appropriate to make the maintenance of those authorisations dependant on appraisal reports established by AFSSA, Nancy following the proficiency tests of the laboratories concerned.

(7) It is therefore appropriate to lay down rules for the regular carrying out of the proficiency tests by AFSSA, Nancy, as well as for the drawing up of the appraisal reports.

(8) The carrying out of the proficiency tests by AFSSA, Nancy is currently included in the yearly approved work programme for that laboratory. That work programme benefits from financial aid from the Union, granted pursuant to Council Decision 2009/470/EC of 25 May 2009 on expenditure in the veterinary field[(2)].

(9) From 1 January 2011, the costs incurred by AFSSA, Nancy for carrying out proficiency tests should no longer be covered by such financial aid from the Union. However, in order to ensure that it has adequate resources to carry out proficiency tests, AFSSA, Nancy should charge certain fees to the laboratories which take part in those tests.

(10) Those fees should be fixed by AFSSA, Nancy taking into account the criteria laid down in Annex VI to Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules[(3)].

(11) The laboratories in the Member States authorised to perform analysis to check the effectiveness of vaccination against rabies in certain domestic carnivores have been listed in Annex I to Commission Decision 2004/233/EC[(4)].

(12) However, Decision 2000/258/EC, as amended by Council Directive 2008/73/EC[(5)], provides that the competent authorities of the Member States may, from 1 January 2010, authorise laboratories to carry out serological tests to monitor the effectiveness of rabies vaccines. That Decision also provides that Member States are to draw up and keep up to date a list of those laboratories that they have authorised and make it available to the other Member States and to the public.

(13) Decision 2004/233/EC has therefore become obsolete and should be repealed for the sake of clarity of Union legislation.

(14) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

Annual proficiency test

1 Each laboratory in a Member State or a third country which is authorised for carrying out serological tests to monitor the effectiveness of rabies vaccines in accordance with Article 3(1) and (2) of Decision 2000/258/EC shall undergo a proficiency test each year.

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2 That proficiency test shall be carried out by the laboratory of the Agence française de sécurité sanitaire des aliments de Nancy ('AFSSA, Nancy').

3 Following each proficiency test as referred to in paragraph 1, AFSSA, Nancy shall submit, at the latest by 31 October of the same year, the respective appraisal report to:

a the corresponding laboratory which underwent the proficiency test;

b the competent authority of the Member State; where the laboratory referred to in point (a) is located, in the case of a laboratory authorised in accordance with Article 3(1) of Decision 2000/258/EC;

c the Commission, in the case of a laboratory referred to in point (a) authorised in accordance with Article 3(2) of Decision 2000/258/EC.

4 By way of derogation from the deadline referred to in paragraph 3, an unfavourable report shall be submitted within 30 days after the appraisal.

Article 2

Maintaining the authorisations granted to laboratories in the Member States

The authorisation granted to a laboratory in a Member State in accordance with Article 3(1) of Decision 2000/258/EC shall be maintained provided that the appraisal report established by AFSSA, Nancy following the proficiency test provided for in Article 1 is favourable.

Article 3

Maintaining the authorisations granted to laboratories in third countries

The authorisation granted to a laboratory in a third country in accordance with Article 3(2) of Decision 2000/258/EC shall be maintained provided that the appraisal report established by AFSSA, Nancy following the proficiency test provided for in Article 1 is favourable.

Article 4

Fees for the annual proficiency testing

1 From 1 January 2011, AFSSA, Nancy shall charge each laboratory a fee for taking part in the proficiency tests provided for in Article 1.

2 That fee shall be fixed by AFSSA, Nancy taking into account the criteria for the calculation of fees or charges set out in Annex VI to Regulation (EC) No 882/2004.

Article 5

Repeal

Decision 2004/233/EC is repealed.

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Article 6

Addressees

This Decision is addressed to the Member States.

Done at Brussels, 9 August 2010.

For the Commission

John DALLI

Member of the Commission

***Changes to legislation:** There are currently no known outstanding effects for the Commission Decision of 9 August 2010 implementing Council Decision 2000/258/EC as regards proficiency tests for the purposes of maintaining authorisations of laboratories to carry out serological tests to monitor the effectiveness of rabies vaccines (notified under document C(2010) 5421) (Text with EEA relevance) (2010/436/EU). (See end of Document for details)*

(**1**) OJ L 79, 30.3.2000, p. 40.

(**2**) OJ L 155, 18.6.2009, p. 30.

(**3**) OJ L 165, 30.4.2004, p. 1.

(**4**) OJ L 71, 10.3.2004, p. 30.

(**5**) OJ L 219, 14.8.2008, p. 40.

Changes to legislation:
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