DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2018/193

of 7 February 2018

authorising laboratories in Brazil and the Russian Federation to carry out serological tests to monitor the effectiveness of rabies vaccines in dogs, cats and ferrets

(notified under document C(2018) 593)

(Text with EEA relevance)

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(2) thereof,

Whereas:

(1) Council Directive 92/65/EEC ([2]) provides for an alternative system to quarantine for rabies for the entry of certain domestic carnivores into Member States. In accordance with the second paragraph of Article 16 of that Directive, that system requires in case of imports from certain third countries of dogs, cats and ferrets checks on the effectiveness of the vaccination of those animals by titration of antibodies.

(2) Such checks are also required in accordance with Article 10(1)(c) of Regulation (EU) No 576/2013 of the European Parliament and of the Council ([3]) in respect of the non-commercial movement of dogs, cats and ferrets from certain third countries.

(3) Decision 2000/258/EC designates the *Agence française de sécurité sanitaire des aliments* (AFSSA) in Nancy, France, as the specific institute responsible for establishing the criteria necessary for standardising the serological tests to monitor the effectiveness of rabies vaccines. The AFSSA has now been integrated into the *Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail* (ANSES) in France.

(4) Decision 2000/258/EC provides *inter alia* that the ANSES is to appraise laboratories in third countries that have applied for approval to carry out serological tests to monitor the effectiveness of rabies vaccines.

(5) The competent authority of Brazil has submitted an application for the approval of the laboratory 'TECSA LABORATÓRIOS LTDA' in Belo Horizonte, for which the ANSES has established and submitted to the Commission a favourable appraisal report, dated 23 October 2017.

(6) The authorisation granted on 31 January 2006 in accordance with Decision 2000/258/EC to 'Instituto Pasteur' in São Paulo, Brazil, has been withdrawn in accordance with Commission Decision 2010/436/EU ([4]) following the unfavourable appraisal report dated 30 September 2011 established by the ANSES for this laboratory and submitted to the Commission.

(7) The competent authority of Brazil has submitted an application for re-approval of 'Instituto Pasteur' in São Paulo, for which the ANSES has established and submitted to the Commission a favourable appraisal report, dated 23 October 2017.

([1]) OJ L 79, 30.3.2000, p. 40.
([2]) 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(I) to Directive 90/425/EEC (OJ L 268, 14.9.1992, p. 54).
([3]) Regulation (EU) No 576/2013 of the European Parliament and of the Council of 12 June 2013 on the non-commercial movement of pet animals and repealing Regulation (EC) No 998/2003 (OJ L 178, 28.6.2013, p. 1).
([4]) Commission Decision 2010/436/EU 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 (OJ L 209, 10.8.2010, p. 19).

(8) The competent authority of the Russian Federation has submitted an application for the approval of the laboratories 'NoviStem LLC' in Moscow and the 'Institute of Veterinary Medicine Biotechnology LLC (IBVM)' in Volginski, for which the ANSES has established and submitted to the Commission a favourable appraisal report, dated 23 October 2017.

(9) The laboratories 'TECSA LABORATÓRIOS LTDA' in Belo Horizonte, 'Instituto Pasteur' in São Paulo, 'NoviStem LLC' in Moscow and the 'Institute of Veterinary Medicine Biotechnology LLC (IBVM)' in Volginski, should therefore be authorised to carry out serological tests to monitor the effectiveness of rabies vaccines in dogs, cats and ferrets.

(10) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

Article 1

In accordance with Article 3(2) of Decision 2000/258/EC, the following laboratories are hereby authorised to perform serological tests to monitor the effectiveness of rabies vaccines in dogs, cats and ferrets:

(a) TECSA LABORATÓRIOS LTDA
Avenida do Contorno, 6226º
Funcionários — CEP: 30110-042
Belo Horizonte/MG
Brazil

(b) Instituto Pasteur
Avenida Paulista
393 Cerqueira César
São Paulo
Brazil

(c) Institute of Veterinary Medicine Biotechnology LLC (IBVM)
27 Starovskogo ulitsa
Volginski urban locality
Petushinski region
Vladimir oblast
Russian Federation

(d) NoviStem LLC
2-oy Roshchinski Proyezd
Block 8, Building 5, Office 2
Moscow
Russian Federation

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 7 February 2018.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission