COMMISSION IMPLEMENTING DECISION (EU) 2021/545

of 26 March 2021

authorising laboratories in Brazil, Cambodia, China, Mexico, South Africa, Tunisia, Ukraine and the United Kingdom to carry out serological tests to monitor the effectiveness of rabies vaccines in dogs, cats and ferrets

(notified under document C(2021) 1953)

(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) Decision 2000/258/EC designates the *Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail* ('ANSES') 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.

(2) Decision 2000/258/EC provides, among other things, 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.

(3) The competent authority of Brazil has submitted an application for the approval of the laboratory 'Instituto de Tecnologia do Paraná'. The ANSES has established and submitted to the Commission a favourable appraisal report dated 5 January 2021 for this laboratory.

(4) The competent authority of Brazil has submitted an application for re-approval of two laboratories: the 'TECSA laboratórios LTDA' and the 'Instituto Pasteur '. The ANSES has established and submitted to the Commission a favourable appraisal report dated 5 January 2021 for these laboratories.

(5) The competent authority of Cambodia has submitted an application for the approval of the laboratory 'Pasteur Institute of Cambodia'. The ANSES has established and submitted to the Commission a favourable appraisal report dated 5 January 2021 for this laboratory.

(6) The competent authority of China has submitted an application for the approval of the laboratory 'Technical Centre for animal, plant and food inspection and quarantine of Shanghai customs'. The ANSES has established and submitted to the Commission a favourable appraisal report dated 5 January 2021 for this laboratory.

(7) The competent authority of Mexico has submitted an application for re-approval of the laboratory ' SADER/SENASICA'. The ANSES has established and submitted to the Commission a favourable appraisal report dated 5 January 2021 for this laboratory.

([1]) OJ L 79, 30.3.2000, p. 40.

(8) The competent authority of South Africa has submitted an application for re-approval of the laboratory 'Onderstepoort Veterinary Institute'. The ANSES has established and submitted to the Commission a favourable appraisal report dated 5 January 2021 for this laboratory.

(9) The competent authority of Tunisia has submitted an application for the approval of the laboratory 'Pasteur Institute of Tunis'. The ANSES has established and submitted to the Commission a favourable appraisal report dated 5 January 2021 for this laboratory.

(10) The competent authority of Ukraine has submitted an application for the approval of the laboratory 'State Scientific Control Institute of Biotechnology and Strains of Microorganisms'. The ANSES has established and submitted to the Commission a favourable appraisal report dated 5 January 2021 for this laboratory.

(11) The competent authority of the United Kingdom has submitted an application for the approval of the laboratories 'APHA Weybridge' and 'BioBest Laboratories Ltd'. The ANSES has established and submitted to the Commission a favourable appraisal report dated 5 January 2021 for these laboratories.

(12) These laboratories should therefore be authorised to carry out serological tests to monitor the effectiveness of rabies vaccines in dogs, cats and ferrets.

(13) In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, the authorisation of the application submitted by the competent authority of the United Kingdom does not prevent a national reference laboratory located in a Member State from fulfilling the functions of a national reference laboratory in respect of the United Kingdom (Northern Ireland).

(14) 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) Instituto de Tecnologia do Paraná
Rua Professor Algacyr Munhoz Mader, 3775
Curitiba 81350-010
Brazil

(b) TECSA laboratórios LTDA
Avenida do Contorno, 6226 - Funcionários
Belo Horizonte 30110-042
Brazil

(c) Instituto Pasteur
Avenida Paulista, 393
São Paulo 01311000
Brazil

(d) Pasteur Institute of Cambodia
Laboratory of virology
5 Monivong Boulevard
BP 983
12200 Phnom Penh
Cambodia

(e) Technical Centre for animal, plant and food inspection and quarantine of Shanghai customs
Laboratory of animal quarantine
1208 Minsheng Road
Pudong district
Shanghai 200135
China

(f) SADER/SENASICA
Av. Centenario de la Educación s/n, (km 3,5 Carretera Federal Mexico-Pachuca)
Tecamac de Felipe Villanueva
55740 Estado de México
México

(g) Onderstepoort Veterinary Institute
100 Old Soutpan Road
0110 Pretoria
South Africa

(h) Pasteur Institute of Tunis
Rabies laboratory
13 place Pasteur
BO 74
1002 Tunis Belvedere
Tunisia

(i) State Scientific Control Institute of Biotechnology and Strains of Microorganisms
Department of Biotechnology and Quality Control of Viral Preparations
30, Donetska str.
03151 Kyiv
Ukraine

(j) APHA Weybridge
Virology Vl 1, Woodham Lane
New Haw, Addelestone
Surrey KT15 3NB
United Kingdom

(k) BioBest Laboratories Ltd
6 Charles Darwin House
The Edinburgh technopole, Nr Milton Bridge
Penicuik
United Kingdom

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 26 March 2021.

For the Commission
Stella KYRIAKIDES
Member of the Commission