Commission Implementing Decision (EU) 2018/1099 of 1 August 2018 amending Annex XI to Council Directive 2003/85/EC as regards the list of laboratories authorised to handle live foot-and-mouth disease virus and amending Commission Implementing Decision (EU) 2018/136 as regards the denomination of the designated European Union reference laboratory for foot-and-mouth disease (notified under document C(2018) 4987) (Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) 2018/1099

of 1 August 2018

amending Annex XI to Council Directive 2003/85/EC as regards the list of laboratories authorised to handle live foot-and-mouth disease virus and amending Commission Implementing Decision (EU) 2018/136 as regards the denomination of the designated European Union reference laboratory for foot-and-mouth disease

(notified under document C(2018) 4987)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 2003/85/EC of 29 September 2003 on Community measures for the control of foot-and-mouth disease repealing Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC[1], and in particular Articles 67(2) and 69(1) thereof,

Whereas:

(1) Directive 2003/85/EC sets out the minimum control measures to be applied in the event of an outbreak of foot-and-mouth disease and certain preventive measures aimed at increasing the awareness and preparedness of the competent authorities and the farming community concerning that disease.

(2) The preventive measures set out in Directive 2003/85/EC include the requirement that the handling of live foot-and-mouth disease virus for research, diagnosis or vaccine manufacturing is carried out only in approved laboratories listed in Annex XI to that Directive.

(3) Part A of Annex XI to Directive 2003/85/EC lists the national laboratories authorised to handle live foot-and-mouth disease virus for research and diagnostic purposes. Part B of that Annex lists the laboratories authorised to handle live foot-and mouth disease virus for vaccine production and related research.
The Netherlands has submitted a request to the Commission to change the name of its national laboratory for foot-and-mouth disease listed in Part A of Annex XI to Directive 2003/85/EC to ‘Wageningen Bioveterinary Research (WBVR), Lelystad’, due to organisational changes.

Belgium has also submitted a request to the Commission to change the name of its national laboratory for foot-and-mouth disease listed in Part A of Annex XI to Directive 2003/85/EC. The Belgian national laboratory for foot-and-mouth disease, the Veterinary and Agrochemical Research Centre (CODA-CERVA), has now become part of the new Belgian federal research centre, Sciensano, following a merge of the CODA-CERVA and the Scientific Institute of Public Health (WIV-ISP), which took effect on 1 April 2018. Sciensano has taken over all the rights and duties of its predecessors, including those of the CODA-CERVA.
Greece has submitted a request to the Commission to complete the name of its national laboratory for foot-and-mouth disease listed in Part A of Annex XI to Directive 2003/85/EC, which is also responsible for the diagnosis of rickettsial infections.

(4) The Pirbright Institute, which is located in the United Kingdom, provides the services of a national reference laboratory for foot-and-mouth disease to Bulgaria, Croatia, Estonia, Finland, Ireland, Latvia, Lithuania, Malta, Portugal, Slovenia, Sweden and the United Kingdom, and it is duly listed as such in Part A of Annex XI to Directive 2003/85/EC. As a consequence of the United Kingdom's notification in accordance with Article 50 of the Treaty on European Union, the United Kingdom will no longer be a Member State of the European Union as of 30 March 2019. In accordance with Article 68(2), the Pirbright Institute may no longer provide the services of a national reference laboratory for foot-and-mouth disease to Bulgaria, Croatia, Estonia, Finland, Ireland, Latvia, Lithuania, Malta, Portugal, Slovenia and Sweden after the date of 29 March 2019.

(5) For the reasons of legal certainty, it is important to keep the list of national laboratories for foot-and-mouth disease set out in Part A of Annex XI to Directive 2003/85/EC updated. Therefore, it is necessary to amend the name of the respective national laboratories in Belgium, in the Netherlands and in Greece and to indicate the date of withdrawal of the United Kingdom from the European Union as the date until which the Pirbright Institute may provide the services of a national reference laboratory for foot-and-mouth disease to other Member States and until which other Member State may use the services of the Pirbright institute as a national reference laboratory for foot-and-mouth disease.

(6) Following organisational changes affecting the laboratory authorised to handle live foot-and-mouth disease virus for vaccine production listed in Part B of Annex XI to Directive 2003/85/EC, the Netherlands has submitted a request to the Commission to change the name of that laboratory situated on its territory to ‘Boehringer Ingelheim Animal Health Netherlands BV’.

(7) Annex XI to Directive 2003/85/EC should therefore be replaced accordingly.

(8) Commission Implementing Decision (EU) 2018/136[(2)] designated the consortium ANSES & CODA-CERVA set up by the Laboratory for Animal Health of the Agency for Food, Environmental and Occupational Health and Safety (ANSES), Maisons-Alfort, France, and the Veterinary and Agrochemical Research Centre (CODA-CERVA), Uccle, Belgium, as the European Union reference laboratory for foot-and-mouth disease. It is necessary to amend that Implementing Decision, so that it refers to

Sciensano, instead of CODA-CERVA. Implementing Decision (EU) 2018/136 should therefore be amended accordingly.

(9) 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

Annex XI to Directive 2003/85/EC is replaced in accordance with the Annex to this Decision.

Article 2

Article 1 of Implementing Decision (EU) 2018/136 is replaced by the following:

Article 1

The consortium ANSES & SCIENSANO set up by the Laboratory for Animal Health of the Agency for Food, Environmental and Occupational Health and Safety (ANSES), Maisons-Alfort, France, and the Laboratory for Exotic Viruses and Particular Diseases of the federal research centre Sciensano, Uccle, Belgium, is hereby designated as the European Union reference laboratory for foot-and-mouth disease for an undetermined period.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 1 August 2018.

For the Commission

Vytenis ANDRIUKAITIS

Member of the Commission

ANNEX

Annex XI to Directive 2003/85/EC is replaced by the following:

ANNEX PART ANational laboratories authorised to handle live foot-and-mouth disease virus
XI

Member State where laboratory is located		**Laboratory**	**Member States using the services of laboratory**
ISO code	**Name**		
AT	Austria	Österreichische Agentur für Gesundheit und Ernährungssicherheit Veterinärmedizinische Untersuchungen Mödling	Austria
BE	Belgium	Laboratory for Exotic Viruses and Particular Diseases of the federal research centre Sciensano, Uccle	Belgium Luxembourg
CZ	Czech Republic	Státní veterinární ústav Praha, Praha	Czech Republic
DE	Germany	Friedrich-Loeffler-Institut Bundesforschungsinstitut für Tiergesundheit, Greifswald — Insel Riems	Germany Slovakia
DK	Denmark	Danmarks Tekniske Universitet, Veterinærinstituttet, Afdeling for Virologi, Lindholm Danish Technical University, Veterinary Institute, Department of Virology, Lindholm	Denmark Finland Sweden
EL	Greece	Διεύθυνση Κτηνιατρικού Κέντρου Αθηνών, Τμήμα Μοριακής	Greece

a Use of services in accordance with Article 68(2) until 29 March 2019.

		Διαγνωστικής, Αφθώδους Πυρετού, Ιολογικών, Ρικετσιακών και Εξωτικών Νοσημάτων, Αγία Παρασκευή Αττικής	
ES	Spain	— Laboratorio Central de Sanidad Animal, Algete, Madrid — Centro de Investigación en Sanidad Animal (CISA), Valdeolmos, Madrid	Spain
FR	France	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES), Laboratoire de santé animale de Maisons-Alfort	France
HU	Hungary	Nemzeti Élelmiszerlánc-biztonsági Hivatal, Állategészségügyi Diagnosztikai Igazgatóság (NÉBIH-ÁDI), Budapest	Hungary
IT	Italy	Istituto zooprofilattico sperimentale della Lombardia e dell'Emilia-Romagna, Brescia	Italy Cyprus

a Use of services in accordance with Article 68(2) until 29 March 2019.

NL	Netherlands	Wageningen Bioveterinary Research (WBVR), Lelystad	Netherlands
PL	Poland	Zakład Pryszczycy Państwowego Instytutu Weterynaryjnego — Państwowego Instytutu Badawczego, Zduńska Wola	Poland
RO	Romania	Institutul de Diagnostic și Sănătate Animală, București	Romania
UK	United Kingdom	The Pirbright Institute	United Kingdom Bulgaria[a] Croatia[a] Estonia[a] Finland[a] Ireland[a] Latvia[a] Lithuania[a] Malta[a] Portugal[a] Slovenia[a] Sweden[a]

a Use of services in accordance with Article 68(2) until 29 March 2019.

PART B

Laboratories authorised to handle live foot-and-mouth disease virus for vaccine production

Member State where laboratory is located		**Laboratory**
ISO code	**Name**	
DE	Germany	Intervet International GmbH/ MSD Animal Health, Köln
NL	Netherlands	Boehringer-Ingelheim Animal Health Netherlands BV, Lelystad
UK	United Kingdom	Merial, S.A.S., Pirbright Laboratory, Pirbright[a]

a Applicable until 29 March 2019

(**1**) OJ L 306, 22.11.2003, p. 1.

(**2**) Commission Implementing Decision (EU) 2018/136 of 25 January 2018 designating the European Union reference laboratory for foot-and-mouth disease and amending Annex II to Council Directive 92/119/EEC as regards the European Union reference laboratory for swine vesicular disease (OJ L 24, 27.1.2018, p. 3).