Commission Implementing Decision (EU) 2015/1358 of 4 August 2015 amending Annexes XI, XII and XV to Council Directive 2003/85/EC as regards the list of laboratories authorised to handle live foot-and-mouth disease virus and minimum bio-security standards applicable to them (notified under document C(2015) 5341) (Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) 2015/1358

of 4 August 2015

amending Annexes XI, XII and XV to Council Directive 2003/85/EC as regards the list of laboratories authorised to handle live foot-and-mouth disease virus and minimum bio-security standards applicable to them

(notified under document C(2015) 5341)

(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 87(3) thereof,

Whereas:

(1) Directive 2003/85/EC sets out 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 provision that Member States are to ensure 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 national laboratories authorised to handle live foot-and-mouth disease virus for research and diagnostic purposes. Part B of that Annex lists laboratories handling virus antigen during the manufacturing of vaccines.

(4) Croatia and Lithuania have officially informed the Commission that their respective national reference laboratories are no longer considered to meet the bio-security standards provided for in Article 65(d) of Directive 2003/85/EC. The entries for those countries should therefore be deleted from the list in Part A of Annex XI to that Directive. Greece and Hungary have requested a change of the name of its national laboratory provided for in that list due to organisational changes. The Czech Republic

has requested a correction of a spelling mistake in the name of its national laboratory provided for in that list.

(5) For legal certainty, it is important to keep the list of national laboratories set out in Part A of Annex XI to Directive 2003/85/EC updated. Therefore, it is necessary to remove the entries for Croatia and Lithuania from that list of laboratories, to amend the names of the national laboratories in the Czech Republic, Greece and Hungary, as well as to specify in that list of laboratories that the Pirbright Institute provides the services of a National Reference Laboratory for Bulgaria, Croatia, Lithuania and Portugal.

(6) Germany has requested a change of the name of the laboratory listed in Part B of Annex XI to Directive 2003/85/EC due to organisational changes. At the same time, Part B of that Annex should be amended to correct the ISO-country code used for the United Kingdom.

(7) Parts A and B of Annex XI to Directive 2003/85/EC should therefore be amended accordingly.

(8) Point 1 of Annex XII to Directive 2003/85/EC sets out bio-security standards for laboratories handling live foot-and-mouth disease virus. It provides that such laboratories are to meet at least the minimum requirements laid down in the 'Minimum standards for laboratories working with foot-and-mouth virus in vitro and in vivo' adopted by the European Commission for the control of foot-and-mouth disease (EuFMD) at its 38th General Session on 29 April 2009 in Rome (bio-security standards). A revised edition of those bio-security standards was adopted at the 40th General Session of EuFMD on 22-24 April 2013 in Rome[(2)].

(9) The revised edition of the bio-security standards consists of Section I, concerning laboratories working with foot-and-mouth disease virus in vitro and in vivo, and Section II concerning laboratories undertaking diagnostic investigations for foot-and-mouth disease in the framework of a national contingency plan.

(10) Therefore the referrence to the bio-security standards in Point 1 of Annex XII to Directive 2003/85/EC should be amended in order to refer to the relevant section of their most current revised edition.

(11) From June 2009 to June 2012, the Commission carried out 19 audits in 15 Member States hosting 16 national laboratories and three vaccine production laboratories authorised to handle live foot-and-mouth disease virus and listed in Annex XI to Directive 2003/85/EC. Those audits aimed to assess the official controls and to evaluate the bio-security systems applied by those laboratories. The outcome of the audits was presented during a workshop on bio-security for laboratories handling live foot-and-mouth disease virus which took place on 27 and 28 January 2015 in Grange, Ireland. The audit report was published immediately thereafter[(3)].

(12) Points 2 and 3 of Annex XII to Directive 2003/85/EC provide for the obligation for the inspections of the laboratories and establishments handling live foot-and-mouth disease virus, their frequency, as well as inspection team composition. Following the recommendations from the series of audits carried out by the Commission and taking into account the obligations for official controls in accordance with Article 45

of Regulation (EC) No 882/2004 of the European Parliament and of the Council[4], it is possible to provide for regular and risk-based inspections of the laboratories handling live foot-and-mouth disease virus without establishing fixed intervals and team compositions.

(13) Annex XII to Directive 2003/85/EC should therefore be amended accordingly.

(14) Annex XV to Directive 2003/85/EC sets out the functions and duties of national laboratories. For the sake of clarity it is necessary to specify that the obligations detailed in point 3 of that Annex apply only to those national laboratories which are designated as national reference laboratories in accordance with Article 68(1)(c) of that Directive.

(15) In addition, one of the outcomes of the audits in Member States and of the discussion at the workshop on 27 and 28 January 2015 was that Member States should list in advance the other designated laboratories referred to in point 13 of Annex XV to Directive 2003/85/EC in their contingency plans and ensure that the measures taken to prevent the possible escape of foot-and-mouth disease virus are based on the recommendations provided for in Section II of the bio-security standards concerning laboratories undertaking diagnostic investigations for foot-and-mouth disease in the framework of a national contingency plan.

(16) Annex XV to Directive 2003/85/EC should therefore be amended accordingly.

(17) Directive 2003/85/EC should therefore be amended accordingly.

(18) 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

Annexes XI, XII and XV to Directive 2003/85/EC are amended in accordance with the Annex to this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 4 August 2015.

For the Commission

Vytenis ANDRIUKAITIS

Member of the Commission

ANNEX

Annexes XI, XII and XV to Directive 2003/85/EC are amended as follows:

(1) In Annex XI, Parts A and B are replaced by the following:

PART A

National laboratories authorised to handle live foot-and-mouth disease virus

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	Veterinary and Agrochemical Research Centre CODA-CERVA-VAR, 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	Greece

		Κέντρου Αθηνών, Τμήμα Μοριακής Διαγνωστικής, Αφθώδους Πυρετού, Ιολογικών 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

NL	Netherlands	Centraal Veterinair Instituut, Lelystad (CVI- 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 Croatia Estonia Finland Ireland Latvia Lithuania Malta Portugal Slovenia Sweden

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	Merial S.A.S., Lelystad Laboratory, Lelystad
UK	United Kingdom	Merial, S.A.S., Pirbright Laboratory, Pirbright

(2) Annex XII is replaced by the following:

‘ANNEX XII

BIO-SECURITY STANDARDS FOR LABORATORIES AND ESTABLISHMENTS HANDLING LIVE FOOT-AND-MOUTH DISEASE VIRUS

1. The laboratories and establishments handling live foot-and-mouth disease virus must operate at least in accordance with Section I of the “Minimum biorisk management standards for laboratories working with foot-and-mouth disease virus in vitro and in vivo” in Appendix 7 to the Report adopted by the 40th General Session of the European Commission for the control of foot-and-mouth disease (EuFMD) on 22-24 April 2013 in Rome (bio-security standards)[(6)].

2. The laboratories and establishments handling live foot-and-mouth disease virus shall be subject to regular and risk-based inspections, including those carried out by and on behalf of the European Commission.

3. The inspection team shall have at its disposition expertise from the Commission or a Member State in foot-and-mouth disease and bio-security in laboratories working with microbiological hazards.

4. Inspection teams deployed by the European Commission shall submit a report to the Commission and the Member States in accordance with Decision 98/139/EC.

(3) Annex XV is amended as follows:

(a) Point 3 is replaced by the following:

3. National Laboratories, designated as the National Reference Laboratories in accordance with Article 68(1)(c), must keep inactivated reference strains of all serotypes of foot-and-mouth disease virus, and immune sera against the viruses, as well as all other reagents necessary for a rapid diagnosis. Appropriate cell cultures should be in constant readiness for confirming a negative diagnosis.

(b) Point 13 is replaced by the following:

13. National Laboratories shall cooperate with other laboratories designated by the competent authorities, and listed in the contingency plans for foot-and-mouth disease as referred to in Article 72, for performing tests, for example serological tests, that do not involve handling of live foot-and-mouth disease virus. These laboratories shall not carry out virus isolation (by infection of cells or animals) from samples taken from suspect cases of vesicular diseases. Such laboratories must have established procedures which ensure that the possible spread of foot-and-mouth disease virus is effectively prevented, taking into account the recommendations in Section II of the “Minimum biorisk management standards for laboratories working with foot-and-mouth disease virus in vitro and in vivo” in Appendix 7 to the report adopted by the 40th General Session of the European

Commission for the control of foot-and-mouth disease (EuFMD) on 22-24 April 2013 in Rome (bio-security standards)[(5)].

Samples giving inconclusive results in tests must be transmitted to the National Reference Laboratory for carrying out confirmatory tests..

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

(**2**) http://www.fao.org/fileadmin/user_upload/eufmd/Lab_guidelines/FMD_Minimumstandards_2013_Final_version.pdf

(**3**) Report DG(SANCO) 2012-6916. Available at: http://ec.europa.eu/food/fvo/overview_reports/details.cfm?rep_id=71

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

(**5**) http://www.fao.org/fileadmin/user_upload/eufmd/Lab_guidelines/FMD_Minimumstandards_2013_Final_version.pdf'.

(**6**) http://www.fao.org/fileadmin/user_upload/eufmd/Lab_guidelines/FMD_Minimumstandards_2013_Final_version.pdf'.

Changes to legislation:
Commission Implementing Decision (EU) 2015/1358 is up to date with all changes known to be in force on or before 22 October 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to :

- Decision implicit repeal by EUR 2016/429 Regulation
- Decision implicit repeal by EUR 2020/687 Regulation