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)[(2)].

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)[1].

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

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

(**2**) 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, ANNEX is up to date with all changes known to be in force on or before 13 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