ANNEX XII

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[F1ANNEX XII

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

Textual Amendments

- **F1** Substituted by 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).
- 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 2224 April 2013 in Rome (bio-security standards)⁽¹⁾.
- 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.]

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