ANNEX XV

FUNCTIONS AND DUTIES OF NATIONAL LABORATORIES

The functions and duties of National Laboratories referred to in Article 68 for foot-and-mouth and other vesicular diseases shall be as follows:

1. **[**[F1]All national laboratories handling live foot-and-mouth disease virus must operate at least according to the bio-security standards referred to in point 1 of Annex XII.**]**

2. National Laboratories must provide an uninterrupted service for diagnosing vesicular viral diseases and must be equipped and skilled for providing a rapid initial diagnosis.

3. **[**[F2]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.**]**

4. National Laboratories must be equipped and skilled for large-scale serological surveillance.

5. In all suspected primary outbreaks appropriate samples must be collected and quickly transported, according to a set protocol, to a National Laboratory. In anticipation of a suspicion of foot-and-mouth disease, the National Authority shall ensure that the necessary equipment and materials for sample collection and transportation to a National Laboratory are stored in readiness at local sites.

6. Antigenic typing and genomic characterisation must be carried out on all viruses responsible for new incursions into the Community. This can be performed by the National Laboratory, if facilities exist. Otherwise, at the earliest possible occasion, the National Laboratory must send a sample of virus from the primary case to the Community Reference Laboratory for confirmation and further characterisation, including advice on the antigenic relationship of the field strain to vaccine strains in the Community antigen and vaccine banks. The same procedure should be followed for viruses received by National Laboratories from third countries in situations where characterisation of the virus is likely to be of benefit to the Community.

7. National Laboratories should provide disease data to their State Veterinary Service, which shall provide these data to the Community Reference Laboratory.

8. National Laboratories should collaborate with the Community Reference Laboratory in ensuring that members of the field section of State Veterinary Services have the opportunity of seeing clinical cases of foot-and-mouth disease in National Laboratories as part of their training.

9. National Laboratories shall collaborate with the Community Reference Laboratory and other National Laboratories to develop improved diagnostic methods and exchange relevant materials and information.

10. National Laboratories shall participate in external quality assurance and standardisation exercises organised by the Community Reference Laboratory.

11. National Laboratories shall use tests and standards that meet or exceed the criteria laid down in Annex XIII. National Laboratories shall provide the Commission on request with data proving that the tests in use meet or exceed the requirements.

12. National Laboratories should have the competence to identify all vesicular disease viruses and encephalomyocarditis virus in order to avoid delays in diagnosis and consequently in implementing control measures by the competent authorities.

13. **[**[F2]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 2224 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.**]**

Textual Amendments

F1 Substituted by Commission Decision of 27 November 2009 amending Annexes XI, XII, XV and XVI to Council Directive 2003/85/EC as regards the list of and minimum security standards applicable to laboratories authorised to handle live foot-and-mouth disease virus (notified under document C(2009) 9094) (Text with EEA relevance) (2009/869/EC).

F2 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) **[**[F2]http://www.fao.org/fileadmin/user_upload/eufmd/Lab_guidelines/FMD_Minimumstandards_2013_Final_version.pdf.**]**

Textual Amendments

F2 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).