ITEM 3 PROPOSED MINIMUM REQUIREMENTS FOR ADOPTION AT THE 38TH EUFMD GENERAL SESSION (2009) AS A MINIMUM FOR MEMBER STATES

MINIMUM REQUIREMENTS IN EUFMD MEMBER STATES FOR THE LABORATORY CONFIRMATION OF FOOT-AND-MOUTH DISEASE (FMD)

1. Member States shall ensure that:

(a) The veterinary services of the Member State have permanent access to the services of at least one Reference Laboratory (RL), either within their territory (National Reference Laboratory -NRL) or in the territory of another state, that is capable of undertaking
   i) Laboratory tests for the confirmation of FMD virus, and
   ii) Of undertaking tests for confirming presence of specific antibodies, to a level that is compliant with the Council Directive 2003/85/EC. Different RL maybe utilised to undertake tests for virus and antibody.

(b) The RL / NRL for confirmation of FMDV must be capable of achieving a rapid initial diagnosis, and must be suitably staffed and equipped to initiate laboratory procedures within 12 hours of receipt of samples.

(c) Provision is made for emergency situations where the FMD diagnostic services of the Reference Laboratory are unavailable through fire, flood or other contingency.

(d) The access to services of a Reference Laboratory on their territory is guaranteed by contracts that adequately equip and staff the reference laboratory with the appropriate numbers of trained personnel to carry out the laboratory investigations required, or through contracts established with laboratories in another state to provide the RL services.

2. The functions and duties of Reference Laboratories shall be as follows:

1. All Reference Laboratories handling live Foot-and-Mouth Disease Virus must operate under high security conditions laid down by the most recent decision of the Sessions of the European Commission for the Control of Foot-and-Mouth Disease (EUFMD)\(^2\). Reference Laboratories undertaking test procedures that do not involve live virus need not comply all requirements of the minimum bio-security standards for laboratories handling live virus, but must operate procedures which ensure that the risks associated with the possible entry of foot-and-mouth disease virus in samples are recognised and effectively contained.

2. Reference Laboratories shall participate AT LEAST ONCE IN EVERY TWO YEARS in the external quality assurance and standardisation exercises organised by the FAO World Reference Laboratory or the European Community Reference Laboratory (if different).


4. Reference Laboratories shall provide the EUFMD Commission on request with data proving that the tests in use meet or exceed the requirements.

REFERENCE TEXTS


Article 68

National Laboratories

1. Member States shall ensure that:
   (a) Laboratory testing for foot-and-mouth disease is carried out in laboratories authorised for such testing by the competent authorities;
   (b) Laboratory testing to confirm the presence of Foot-and Mouth Disease virus or other vesicular disease viruses is carried out in accordance with Article 71 by one of the laboratories listed in Part A of Annex XI;
   (c) One of the laboratories listed in Part A of Annex XI shall be designated as the national reference laboratory for the Member State on whose territory it is situated, and it shall be responsible for coordinating standards and methods of diagnosis in that Member State;
   (d) The national reference laboratory carries out at least the functions and duties set out in Annex XV;
   (e) The national reference laboratory referred to in point (c) liaises with the Community Reference Laboratory provided for in Article 69 and in particular ensures the sending of appropriate samples to the Community Reference Laboratory.

2. The national reference laboratory referred to in paragraph 1(c) of one Member State may provide the services of a national reference laboratory to one or more other Member States. Member States which have no national reference laboratory situated on their territory may use the services of the national reference laboratory in one or more other Member States. That cooperation shall be formalised in a mutual agreement between the competent authorities of the Member States concerned, which shall be notified to the Commission. Such cooperation shall be listed in the special column in the table in Part A of Annex XI.

3. Member States shall ensure that laboratory investigations provided for in this Directive are first of all carried out to confirm or rule out foot-and-mouth disease and to exclude other vesicular diseases. Where an outbreak of foot-and-mouth disease has been confirmed and the serotype of the virus was identified, that virus shall be antigenically characterised in relation to the reference vaccine strains, where necessary with the assistance of the Community Reference Laboratory. Samples from domestic livestock showing signs of vesicular disease which are negative for foot-and-mouth disease virus and, where relevant, Swine Vesicular Disease virus shall be sent to the Community Reference Laboratory for further investigation.

4. Member States shall ensure that the national reference laboratory on their territory is adequately equipped and staffed with the appropriate numbers of trained personnel to carry out the laboratory investigations required in accordance with this Directive.

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:


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. National Laboratories 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. National Laboratories shall cooperate with other laboratories designated by the competent authorities 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 detection in samples taken from suspect cases of vesicular diseases. Such laboratories need not comply with the biosecurity standards referred to in Annex XII, point 1, but must have established procedures which ensure that the possible spread of foot-and-mouth disease virus is effectively prevented. Samples giving inconclusive results in tests must be transmitted to the National Reference Laboratory for carrying out confirmatory tests.