

## ANNEX XVI

### FUNCTIONS AND DUTIES OF A COMMUNITY REFERENCE LABORATORY FOR FOOT-AND-MOUTH DISEASE

The functions and duties of the Community Reference Laboratory referred to in Article 69 for foot-and-mouth disease shall be as follows:

1. To ensure liaison between the national laboratories of the Member States and to provide optimal methods for the diagnosis of foot-and-mouth disease in livestock, and differential diagnosis of other vesicular viral diseases, where necessary, for each Member State specifically by:
  - 1.1. regularly receiving field samples from Member States and countries geographically or commercially linked to the European Union in terms of trade in animals of susceptible species or products derived from such animals with a view to monitoring the disease situation globally and regionally, to estimating and where possible predicting the risk evolving from emerging virus strains and particular epidemiological situations and determining the identity of the virus, where necessary in close collaboration with OIE designated regional reference laboratory and the WRL;
  - 1.2. typing and full antigenic and genomic characterisation of vesicular viruses from the samples referred to in point 1.1 and communicating the results of such investigations without delay to the Commission, the Member State, and the National Laboratory concerned;
  - 1.3. building up and maintaining an up-to-date collection of vesicular virus strains;
  - 1.4. building up and maintaining an up-to-date collection of specific sera against vesicular virus strains;
  - 1.5. advising the Commission on all aspects related to foot-and-mouth disease vaccine strain selection and use.
2. To support the functions of National Laboratories, in particular by:
  - 2.1. storing and supplying National Laboratories with reagents and materials for use in diagnosis of foot-and-mouth disease such as virus and/or inactivated antigens, standardised sera, cell lines and other reference reagents;
  - 2.2. retaining expertise on foot-and-mouth disease virus and other pertinent viruses to enable rapid differential diagnosis;
  - 2.3. promoting harmonisation of diagnosis and ensuring proficiency of testing within the Community by organising and operating periodic comparative trials and external quality assurance exercises on foot-and-mouth disease diagnosis at Community level and the periodic transmission of the results of such trials to the Commission, the Member States, and National Laboratories;
  - 2.4. carrying out research studies with the objective of developing improved methods of disease control in collaboration with National Laboratories and as agreed in the annual work plan of the Community Reference Laboratory.
3. To provide information and carry out further training, in particular by:

---

*Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.*

---

- 3.1. gathering data and information on the methods of diagnosis and differential diagnosis used in National Laboratories and the distribution of such information to the Commission and the Member States;
- 3.2. making and implementing the necessary arrangements for the further training of experts in laboratory diagnosis with a view to harmonising diagnostic techniques;
- 3.3. keeping abreast of developments in foot-and-mouth disease epidemiology;
- 3.4. organising an annual meeting where representatives of the National Laboratories may review diagnostic techniques and the progress of coordination.
4. To perform experiments and field trials in consultation with the Commission directed towards an improved control of foot-and-mouth disease.
5. To review at the annual meeting of National Reference Laboratories the contents of Annex XIII defining the tests and standards for foot-and-mouth disease diagnosis within the European Union.
6. To cooperate with the national reference laboratories of candidate countries in accordance with this Annex.
- [<sup>F17</sup>. The Community Reference Laboratory must operate at least according to the bio-security standards referred to in point 1 of Annex XII.]

---

**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\) \(Text with EEA relevance\) \(2009/869/EC\)](#).

8. The Community Reference Laboratory shall provide assistance to the Commission as required on the disease security measures to be taken by the National Laboratories in matters of foot-and-mouth disease diagnosis.