Council Directive 2003/85/EC of 29 September 2003 on Community measures for the control of foot-and-mouth disease repealing Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC (Text with EEA relevance)

CHAPTER III

PREVENTATIVE MEASURES

SECTION 10

LABORATORIES AND ESTABLISHMENTS HANDLING FOOT-AND-MOUTH DISEASE VIRUS

Article 65

Laboratories and establishments handling live foot-and-mouth disease virus

Member States shall ensure that:

(a) laboratories and establishments in which live foot-and-mouth disease virus, its genome, antigens or vaccines produced from such antigens are handled for research, diagnosis or manufacture are strictly controlled by the competent authorities;

(b) the handling of live foot-and-mouth disease virus for research and diagnosis is carried out only in approved laboratories listed in Part A of Annex XI;

(c) the handling of live foot-and-mouth disease virus for the manufacturing of either inactivated antigens for the production of vaccines or vaccines and related research is carried out only in the approved establishments and laboratories listed in Part B of Annex XI;

(d) the laboratories and establishments referred to in points (b) and (c) are operated at least according to the bio-security standards set out in Annex XII.

Article 66

Checks of laboratories and establishments handling live foot-and-mouth disease virus

Veterinary experts from the Commission, in collaboration with the competent authorities of the Member States, shall carry out spot-checks to ascertain whether the security systems applied in the establishments and laboratories referred to in Parts A and B of Annex XI comply with the bio-security standards set out in Annex XII.

Article 67

Modification of the list of approved laboratories and establishments handling live foot-and-mouth disease virus

1 The list of establishments and laboratories in Part A and B of Annex XI may be amended in accordance with the procedure referred to in Article 89(3), in the light of the spot-checks provided for in Article 66.

2 The list of establishments and laboratories in Part A and B of Annex XI shall be regularly updated based on written information submitted by the Member States, in accordance with the procedure referred to in Article 89(2).

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) liases 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.

Article 69

Community Reference Laboratory

1 The Community Reference Laboratory shall be designated in agreement with the laboratory concerned and in accordance with the procedure referred to in Article 89(2), for a period to be determined under that procedure.

2 When designating a Community Reference Laboratory, the technical and scientific competence of the laboratory as well as the expertise and excellence of the scientific and technical staff employed shall firstly be taken into account.

3 The Commission shall review the designation of the Community Reference Laboratory by the end of the designated period of operation or earlier in the light of its compliance with the functions and duties of the Community Reference Laboratory specified in Annex XVI.

Article 70

Security standards and guidelines for surveillance, code of conduct for approved laboratories and establishments handling live foot-and-mouth disease virus

1 An Operational Manual for Minimum Standards for Laboratories working with the foot-and-mouth disease virus in vitro and in vivo may be adopted in accordance with the procedure referred to in Article 89(2).

2 Guidelines for the surveillance required to recover the foot-and-mouth disease and infection free status may be adopted in accordance with the procedure referred to in Article 89(2).

3 A uniform code of good conduct for the security systems applied in the establishments and laboratories listed in Parts A and B of Annex XI may be adopted in accordance with the procedure referred to in Article 89(2).