ANNEX XIII

DIAGNOSTIC TESTS AND STANDARDS FOR FOOT-AND-MOUTH DISEASE AND FOR THE DIFFERENTIAL DIAGNOSIS OF OTHER VESICULAR VIRUS DISEASES

In the context of this Annex, a 'test' refers to a laboratory diagnostic procedure and a 'standard' to a reference reagent that has become an internationally accepted standard following a procedure of comparative testing carried out in several different laboratories.

PART A

Diagnostic tests

1. Recommended procedures

Diagnostic tests described in the OIE Manual, hereinafter the 'OIE Manual', as the 'Prescribed Tests' for international trade, constitute the reference tests for vesicular disease diagnosis within the Community. National Laboratories must adopt standards and tests at least as stringent as those defined in the OIE Manual.

The Commission may, in accordance with the procedure referred to in Article 89(2) decide to adopt more stringent testing procedures than those defined in the OIE Manual.

2. Alternative procedures

The use of tests defined in the OIE Manual as 'Alternative Tests', or other tests not included in the OIE Manual, is permitted provided that the performance of the test has been shown to match or exceed the sensitivity and specificity parameters laid down in the OIE Manual or in the annexes to Community legislation, whichever is the more stringent.

National Laboratories generating results for the purposes of national, intra-Community or international trade must generate and store the necessary records demonstrating compliance of their testing procedures with the relevant OIE or Community requirements.

3. Standards and quality control

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

In the framework of such exercises, the Community Reference Laboratory may take account of the results achieved by a National Laboratory which has within a reasonable timespan participated in a quality assurance exercise organised by one of the international organisations responsible for external quality assurance of vesicular virus disease diagnosis, such as OIE, the Food and Agriculture Organisation (FAO) of the United Nations or the International Atomic Energy Agency.

National Laboratories shall operate internal quality assurance programmes. The specification of such programmes may be laid down in accordance with the procedure referred to in Article 89(2). Pending the adoption of detailed provisions, the specifications in the OIE Guidelines for Laboratory Quality Evaluation shall apply (OIE Standards Commission, September 1995).

As part of quality assurance, National Laboratories shall demonstrate compliance of the tests in routine use with the requirements for sensitivity and specificity defined in the OIE Manual, or in Annexe XIV of this Directive, whichever is more stringent.

4. Procedures for adoption and review of tests and standards for vesicular virus disease diagnosis.

Tests and standards for vesicular virus disease diagnosis shall be adopted in accordance with the procedure referred to in Article 89(2).

The Commission may consider the scientific advice produced by the meetings of the National Laboratories to be organised by the Community Reference Laboratory.

5. Compliance procedure

Data from standardisation and external quality assurance exercises organised by the Community Reference Laboratory shall be assessed at the annual meetings of the National Laboratories and communicated to the Commission for review of the list of National Laboratories as laid down in Part A of Annex XI.

Those laboratories whose tests do not meet the prescribed requirements for sensitivity and specificity shall be required by the Commission to adapt their procedures within an appropriate period of time to ensure that these requirements are met. Failure to demonstrate the required level of proficiency within the time limit required shall result in loss of recognition within the Community of all testing performed after that deadline.

6. Selection and transportation of samples

An aliquot of field material should be sent to one of the laboratories listed in Part A of Annex XI. However, where such samples are not available or not suitable for transport, animal passage material, obtained from the same host species, or low passage cell culture material is acceptable.

The history of animal or cell passage material should be provided.

Samples for vesicular virus diagnosis can be transported at 4 °C if the anticipated transport time to the recipient laboratory is less than 24 hours.

For oesophageal-pharyngeal (probang) samples, transportation above solid carbon dioxide or liquid nitrogen is recommended, especially if delays at airports cannot be excluded.

Special precautions are required for the safe packaging of material from suspect cases of foot-and-mouth disease both within and between countries. These regulations are mainly designed to prevent breakage or leakage of containers and the risk of contamination, but are also important to ensure that specimens arrive in a satisfactory state. Ice-packs are preferred to wet ice to prevent the possibility of escape of water from the package.

Prior notice of arrival, and agreement for receipt, must be arranged with the receiving laboratory before despatch of samples.

Compliance with the import and export regulations of the Member States involved must be ensured.

PART B

Standards

The protocols specified in the OIE Manual provide reference procedures for virus isolation, antigen detection and antibody detection for vesicular diseases.

1. Foot-and-mouth disease

1.1. Antigen detection

The standards for detecting foot-and-mouth disease virus antigen shall be established in accordance with the procedure referred to in Article 89(2) after consultation of the Community Reference Laboratory.

Standardised, inactivated antigens of all seven serotypes are available from the OIE/FAO World Reference Laboratory for foot-and-mouth disease (WRL).

National Laboratories should ensure that their antigen detection system complies with these minimum standards. They shall where necessary receive advice from the Community Reference Laboratory on the dilutions of these antigens to be used as strong and weak positive controls.

1.2. Virus isolation

The standards for foot-and-mouth disease virus detection shall be established in accordance with the procedure referred to in Article 89(2) after consultation of the Community Reference Laboratory.

Isolates of foot-and-mouth disease virus are available from the WRL.

National Laboratories shall ensure that the tissue culture systems in use for foot-and-mouth virus isolation are sensitive to the full range of serotypes and strains for which the laboratory maintains a diagnostic capacity.

1.3. Nucleic acid detection methods

The standards for the detection of foot-and-mouth disease viral RNA shall be established in accordance with the procedure referred to in Article 89(2) after consultation of the Community Reference Laboratory.

The Commission may arrange that for future standardisation, comparative testing of the sensitivity of RNA detection methods is carried out between National Laboratories.

The Commission may arrange that, taking into account the practical difficulties of storing nucleic acids for prolonged periods of time, standardised quality assurance reagents for the detection of foot-and-mouth viral RNA will become available from the Community Reference Laboratory.

1.4. Antibody detection (structural proteins)

The standards for the detection of antibody to foot-and-mouth disease virus shall be established in accordance with the procedure referred to in Article 89(2) after consultation of the Community Reference Laboratory.

Standardised antisera for foot-and-mouth disease virus types O1-Manisa, A22-Iraq and C-Noville have been defined by the ‘FAO Phase XV Standardisation Exercise in foot-and-mouth disease antibody detection’ in 1998.

The Commission may arrange that standardised reference sera for all the main antigenic variants of foot-and-mouth disease virus are adopted as a result of standardisation exercises between the Community Reference Laboratory and the National Laboratories. These reference sera will be adopted as the standards for use by National Laboratories within the Community.

1.5. Antibody detection (non-structural proteins)

The standards for the detection of antibody to foot-and-mouth disease virus shall be established in accordance with the procedure referred to in Article 89(2) after consultation of the Community Reference Laboratory.

The Commission may arrange that standardised reference sera are adopted as a result of standardisation exercises between the Community Reference Laboratory and the National Laboratories. These reference sera will be adopted as the standards for use by National Laboratories within the Community.

2. Swine vesicular disease (SVD)

Diagnosis of SVD must be carried out in accordance with Decision 2000/428/EC.

3. Other vesicular diseases

Where necessary, the Commission may arrange that standards for the laboratory diagnosis of vesicular stomatitis or vesicular exanthema of swine are established in accordance with the procedure referred to in Article 89(2).

Member States may maintain the laboratory capacity to diagnose the vesicular virus diseases other than foot-and-mouth disease and SVD, i.e. vesicular stomatitis and vesicular exanthema of swine.

National Laboratories wishing to maintain a diagnostic capacity for these viruses can obtain reference reagents from the WRL, Pirbright or from the relevant OIE Reference Laboratory.