ANNEX XIII

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

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.