ANNEX VI

Functions and duties of laboratories

PART I

Community reference laboratories

1. In order to be designated as a Community reference laboratory in accordance with Article 55, laboratories shall fulfil the following requirements. They must:

   (a) have suitably qualified staff with adequate training in diagnostic and analytical techniques applied in their area of competence, including trained personnel available for emergency situations occurring within the Community;

   (b) possess the equipment and products needed to carry out the tasks assigned to them;

   (c) have an appropriate administrative infrastructure;

   (d) ensure that their staff respect the confidential nature of certain subjects, results or communications;

   (e) have sufficient knowledge of international standards and practices;

   (f) have available, as appropriate, an updated list of available reference substances and reagents and an updated list of manufacturers and suppliers of such substances and reagents;

   (g) take account of research activities at national and Community level.

2. However, the Commission may designate only laboratories that operate and are assessed and accredited in accordance with the following European Standards, account being taken of the criteria for different testing methods laid down in this Directive:

   (a) EN ISO/IEC 17025 on ‘General requirements for the competence of testing and calibration laboratories’;

   (b) EN 45002 on ‘General criteria for the assessment of testing laboratories’;

   (c) EN 45003 on ‘Calibration and testing laboratory accreditation system — General requirements for operation and recognition’.

3. The accreditation and assessment of testing laboratories referred to in paragraph 2 may relate to individual tests or groups of tests.

4. For one or more of the diseases under their responsibility, the Community reference laboratories may take advantage of the skills and capacity of laboratories in other Member States or EFTA Member States, provided that the laboratories concerned comply with the requirements laid down in points 1, 2 and 3 of this Annex. Any intention to take advantage of such cooperation shall be part of the information provided as a basis for the designation in accordance with Article 55(1). However, the Community reference laboratory shall remain the contact point for the National reference laboratories in the Member States, and for the Commission.

5. The Community reference laboratories shall:

(a) coordinate, in consultation with the Commission, the methods employed in the Member States for diagnosing the disease concerned, specifically by:

(i) typing, storing and, where appropriate, supplying strains of the pathogen of the relevant disease to facilitate the diagnostic service in the Community,

(ii) supplying standard sera and other reference reagents to the national reference laboratories in order to standardise the tests and reagents used in each Member State, where serological tests are required,

(iii) organising periodic comparative tests (ring tests) of diagnostic procedures at Community level with the national reference laboratories designated by the Member States, in order to provide information on the methods of diagnosis used and the results of tests carried out in the Community;

(iv) retaining expertise on the relevant disease pathogen and other pertinent pathogens to enable rapid differential diagnosis;

(b) assist actively in the diagnosis of outbreaks of the relevant disease in Member States by receiving pathogen isolates for confirmatory diagnosis, characterisation and epizootic studies;

(c) facilitate the training or retraining of experts in laboratory diagnosis with a view to harmonising diagnostic techniques throughout the Community;

(d) collaborate, as regards methods of diagnosing animal diseases falling within their areas of competence, with the competent laboratories in third countries where those diseases are prevalent;

(e) collaborate with the relevant OIE reference laboratories with regard to exotic diseases listed in Part II of Annex IV under their responsibility;

(f) collate and forward information on exotic and endemic diseases, that are potentially emerging in Community aquaculture.

PART II

National reference laboratories

1. The national reference laboratories designated pursuant to Article 56 shall be responsible for coordinating the diagnostic standards and methods within their field of responsibility in the Member State concerned. These national reference laboratories shall:

(a) undertake to notify, without delay, the competent authority whenever the laboratory is aware of a suspicion of any of the diseases referred to in Annex IV;

(b) coordinate, in consultation with the relevant Community reference laboratory, the methods employed in Member States for diagnosing the diseases concerned under their responsibility;

(c) assist actively in the diagnosis of outbreaks of the relevant disease by receiving pathogen isolates for confirmatory diagnosis, characterisation and epizootic studies;

(d) facilitate the training or retraining of experts in laboratory diagnosis with a view to harmonising diagnostic techniques throughout the Member State;

(e) ensure confirmation of positive results of all outbreaks of exotic diseases listed in Part II of Annex IV, and of primary outbreaks of non-exotic diseases listed in that Annex;

(f) organise periodic comparative tests (ring tests) of diagnostic procedures at national level with the laboratories designated by the Member States in accordance with Article 57, in order to provide information on the methods of diagnosis used and the results of tests carried out in the Member State;

(g) cooperate with the Community reference laboratory referred to in Article 55 and participate in the comparative tests organised by the Community reference laboratories;

(h) ensure a regular and open dialogue with their national competent authorities;

(i) operate and be assessed and accredited in accordance with the following European Standards account being taken of the criteria for different testing methods laid down in this Directive:

(i) EN ISO/IEC 17025 on ‘General requirements for the competence of testing and calibration laboratories’;

(ii) EN 45002 on ‘General criteria for the assessment of testing laboratories’;

(iii) EN 45003 on ‘Calibration and testing laboratory accreditation system — General requirements for operation and recognition’.

2. The accreditation and assessment of testing laboratories referred to in point 1(i) may relate to individual tests or groups of tests.

3. The Member States may designate national reference laboratories which do not comply with the requirements referred to in point 1(i)(i) of this Part, where operation under EN ISO/IEC 17025 is practically difficult, provided the laboratory operates under quality assurance in line with the guidelines in ISO 9001.

4. Member States may authorise a national reference laboratory situated on their territory to take advantage of the skills and capacity of other laboratories designated pursuant to Article 57, for one or more of the diseases under their responsibility, provided that these laboratories comply with the relevant requirements of this Part. However, the national reference laboratory shall remain the contact point for the central competent authority of the Member State, and for the Community reference laboratory.

PART III

Designated laboratories in Member States

1. The competent authority of a Member State shall designate only laboratories for diagnostic services pursuant to Article 57 that fulfil the following requirements. They must:

   (a) undertake to notify, without delay, the competent authority whenever a laboratory is aware of a suspicion of any of the diseases referred to in Annex IV;

   (b) undertake to participate in comparative tests (ring-tests) of diagnostic procedures arranged by the national reference laboratory;

   (c) operate and be assessed and accredited in accordance with the following European Standards account being taken of the criteria for different testing methods laid down in this Directive:

      (i) EN ISO/IEC 17025 on ‘General requirements for the competence of testing and calibration laboratories’;

      (ii) EN 45002 on ‘General criteria for the assessment of testing laboratories’;

      (iii) EN 45003 on ‘Calibration and testing laboratory accreditation system — General requirements for operation and recognition’.

2. The accreditation and assessment of testing laboratories referred to in paragraph 1(c) may relate to individual tests or groups of tests.

3. The Member States may designate laboratories which do not comply with the requirements referred to in point 1(c)(i) of this Part, where operation under EN ISO/IEC 17025 is practically difficult, provided that the laboratory operates under quality assurance in line with the guidelines in ISO 9001.

4. The competent authority shall cancel the designation where the conditions referred to in this Annex are no longer fulfilled.