WORK PROGRAMME FOR THE COMMUNITY REFERENCE LABORATORY FOR FISH DISEASE, 2008

I. LEGAL FUNCTIONS AND DUTIES

The functions and duties of the Community Reference Laboratory are described in the Council Directive 2006/88/EF Annex VI part I

II. OBJECTIVES FOR THE PERIOD JANUARY - DECEMBER 2008

- 1. Organise and prepare for the 12th Annual Meeting for the National Reference Laboratories for Fish Diseases in 2008.
- 2. Produce a report from the Annual Meeting 2008.
- 3. Collect data on the fish disease situation in EU, including the new listed non-exotic diseases in Council Directive 2006/88/EF: ISA, SVC and KHV
- 4. Identify and characterise selected isolates of listed viruses (serological and genetic characterisation)
- 5. Production of antisera against selected isolates when necessary.
- 6. Assess the options for screening of other fish diseases in samples collected as part of a VHS/IHN surveillance programme
- 7. Optimization and standardisation of real-time PCR for the diagnosis and identification of VHS.
- 8. Update and maintain a library of Infectious salmon anaemia (ISA), Viral Haemorrhagic Septicaemia (VHS) and Infectious Haematopoietic Necrosis (IHN), Spring Viraemia of Carp (SVC) and Koi Herpes virus (CyHV3) virus isolates (including the sequences and the geographical coordinates of selected isolates) and entering this information into a database
- 9. In collaboration with OIE reference laboratories to establish and recommend standard operating procedures for the diagnosis of the two exotic fish disease EHN and EUS.
- 10. Organise a practical workshop in the diagnosis of the listed exotic fish diseases EHN and EUS (to be organised back to back with the 12th Annual Meeting).

- 11. Establish and update a new webpage for the CRL.
- 12. Supply standard antisera and other reference reagents to the National Reference Laboratories in Member States.
- 13. Prepare the Annual Inter-laboratory Proficiency Test year 2008 for the National Reference Laboratories.
- 14. Collate and analyse information gained from the Inter-laboratory Proficiency Test
- 15. Facilitate and provide training in laboratory diagnosis.
- 16. Attending international meetings and conferences.

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 laboratoriums 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.

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, L 328/48 EN Official Journal of the European Union 24.11.2006
- (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.