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Working Document
on the WORK PROGRAMMES
of the COMMUNITY REFERENCE LABORATORIES
in the field of animal health and live animals
for 2007

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1 INTRODUCTION

1.1 Legal aspects related to the operation of the CRLs

In the context of the EU strategy aimed at improving animal health and establishing the single market for live animals and animal products, a network of Community and National Reference Laboratories (CRLs) dealing with major animal diseases has been gradually set up.

The Council has in a number of Directives designated Community Reference Laboratories (CRL) with scientific and technical expertise within the areas of animal health, public health and zootechnics. The Council Directives contain provisions that specify the functions and duties of each designated Community Reference Laboratory.

Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules¹, which applies from 1 January 2006 lays down the general tasks, duties and requirements for CRLs for food and feed and for animal health. The CRL's are listed in the Annex VIII. That list contains all Community reference laboratories for feed and food that were previously designated in other acts.

These functions and duties consist notably of providing information on analysis methods and organising comparative tests with the national reference laboratories, coordinating the application of the methods and research into new analysis methods, organising training and advanced courses for national reference laboratory staff and providing scientific and technical assistance to the Commission.

Apart from these duties and functions the Commission approves an annual working plan for each CRL specifying their tasks for the next year and grants financial support for the operation of these CRLs.

The designation of Community reference laboratories should contribute to a high quality and uniformity of analytical results.

The said Laboratories may within the framework of Council Decision 90/424/EEC on expenditure in the veterinary field receive Community financial aid for fulfilling duties and functions specified in EU legislation.

CRLs are designated in the animal health sector and in the area of zootechnic as shown below:

- Avian influenza (Dir. 92/40/EEC)
- Newcastle disease (Dir. 92/66/EEC)
- Bluetongue (Dir. 2000/75/EC)

¹ [OJ L 191, 28.5.2004, p. 1.](#)

- African horse sickness (Dir. 92/35/EEC)
- Foot and mouth disease (Dir. 2003/85/EC)
- Swine vesicular disease (Dir. 92/119/EEC)
- African swine fever (Dir. 2002/60/EC)
- Monitoring the effectiveness of rabies vaccination (Dec. 2000/258/EC)
- Bivalve mollusc diseases (Dir. 95/70/EEC)
- Zootechnics (Dec. 96/463/EC)
- Brucellosis (Reg. 2004/882/EC)
- Fish diseases (Dir. 93/53/EEC)
- Classical swine fever (Dir. 2001/89/EC)

1.2 MANAGEMENT AND FINANCIAL ASPECTS RELATED TO THE OPERATION OF THE CRLS

In accordance with the provisions of paragraph 1 of Article 28 of Council Decision 90/424/EEC a CRL may receive Community aid. In paragraph 2 it is stated that the arrangements for granting the aid provided, the conditions to which it may be subject and its amount shall be determined in accordance with the Standing Committee on the Food Chain and Animal Health procedure. Paragraph 3 indicates that appropriations shall be decided upon each year as part of the budgetary procedure.

Commission Regulation (EC) No 1754/2006 of 28 November 2006 lays down detailed rules for the granting of Community financial assistance to Community reference laboratories for feed and food and the animal health sector pursuant to Article 28 of Decision 90/424/EEC. The said Regulation provides that the financial contribution from the Community is to be granted if the approved work programmes are efficiently carried out and that the beneficiaries supply all the necessary information within certain time limits. In accordance with Article 2 of this Regulation, the relationship between the Commission and each Community reference laboratories is laid down in a partnership agreement which is supported by a multi-annual work programme.

In general the Community contributions provided for the operation of a CRL can be used to cover:

- Staff costs
- Capital equipment
- Consumables
- Workshops

2 LIST OF CRLS IN THE FIELD OF ANIMAL HEALTH AND LIVE ANIMALS

DISEASE	CRL
CRL for Avian Influenza	Central Veterinary Laboratory, New Haw, Weybridge, Surrey KT 15 3NB, United Kingdom
CRL for Newcastle Disease	Central Veterinary Laboratory New Haw, Weybridge Surrey KT 15 3NB United Kingdom
CRL for Bluetongue	Institute for Animal Health, Pirbright Laboratory, Pirbright, Woking, Surrey GU24 ONF United Kingdom
CRL for African Horses sickness	Laboratorio de sanidad y producción animal, Ministerio de Agricultura, Pesca y Alimentación, 28110 Algete, Madrid – España
CRL for Foot and Mouth Disease	Institut für Virologie der Tierärztlichen Hochschule Hanover, Bischofscholer Damm 15 D-3000 Hannover 1 Germany
CRL for Swine Vesicular Disease	Institute for Animal Health, Pirbright Laboratory, Pirbright, Woking, Surrey GU24 ONF United Kingdom
CRL for African Swine Fever	Centro de Investigación en Sanidad Animal, Ctra. De Algete a El Casar, Valdeolmos 28130, Madrid, Spain
CRL for Rabies (serology)	AFSSA, Nancy Laboratoire d'études sur la rage et la pathologie des animaux sauvages Domaine de Pixérécourt, BP 9 F-54220 Malzéville
CRL for Bivalve molluscs diseases	The Infremer Laboratory B.P. 133 17390 La tremblade France
CRL for Zootechnics (bovine breeding)	INTERBULL Centre Department of Animal Breeding and Genetics Swedish University of Agricultural Sciences Box: 7023; S-750 07 Uppsala, Sweden

CRL for Brucellosis	AFSSA, Nancy Laboratoire d'études sur la rage et la pathologie des animaux sauvages Domaine de Pixérécourt, BP 9 F-54220 Malzéville
CRL for Fish diseases	State Serum Laboratory Hangovej 2, 8200-Aarhus, Denmark
CRL for Classical Swine Fever	Institut für Virologie der Tierärztlichen Hochschule Hanover, Bischofscholer Damm 15 D-3000 Hannover 1 Germany

3 WORK PROGRAMMES OF THE CRLs FOR THE YEAR 2007

3.1 WORK PROGRAMME OF THE COMMUNITY REFERENCE LABORATORY FOR AVIAN INFLUENZA, 2007

I. LEGAL FUNCTIONS AND DUTIES

The functions and duties are specified in Annex VII of Council Directive 2005/94/EC (Official Journal of the European Union of 14.1.2006, No L 10 p.16.)

II. OBJECTIVES FOR THE PERIOD JANUARY – DECEMBER 2007

1. Support by means of information and technical advice National Avian Influenza Laboratories and the European Commission during epidemics.
2. Maintain close awareness of developments in diagnostic methodology and report and advise, as relevant, to the Annual Meeting of National Avian Influenza Laboratories.
3. Prepare the programme and working documents for the Annual Meeting of National Avian Influenza Laboratories.
4. Collect and edit material for a report covering the Annual meeting of National Avian Influenza Laboratories.
5. Ensure genetic data of avian influenza viruses is accessible to all national avian influenza laboratories.
6. Annually review and revise as required the EU AI diagnostic manual.
7. Provide targeted training in the light of developments for new diagnostic methodology.
8. In the light of the occurrence of influenza in birds and other animals keep under review the possible zoonotic impact arising from the risk of reassortment between influenza viruses.
9. Formally liaise with Public Health Laboratories to ensure rapid flow of information and viruses as appropriate.
10. Preparation and publications of articles and reports associated with above work.

3.2 WORK PROGRAMME FOR THE COMMUNITY REFERENCE LABORATORY FOR NEWCASTLE DISEASE, 2007

I. LEGAL FUNCTIONS AND DUTIES

The functions and duties are specified in Annex V of Council Directive 92/66/EEC (Official Journal of the European Communities No L 260 of 5.9.1992).

II. OBJECTIVES FOR THE PERIOD JANUARY – DECEMBER 2007

1. Characterising viruses submitted to the Laboratory by Member States and third countries listed in Commission Decisions 95/233/EC and 94/85/EC. This will, at the request of the European Commission or the submitting National Laboratory or at the discretion of the Reference Laboratory, include:
 - Determining the intracerebral pathogenicity index (ICPI)
 - Determining basic amino acids composition adjacent to the cleavage site of the FO protein in the virus and phylogenetic analysis
 - Antigenic grouping of viruses
 - Limited phylogenetic analysis to assist in epidemiological investigations.
2. Maintain and distribute virus repository and reagents necessary for virus characterisation.
3. Prepare and distribute antisera, antigens and reagents for the inter-laboratory comparison tests.
4. Analyse results submitted by National Laboratories for the inter-laboratory comparison tests.
5. Assist MS on the use of PCR techniques and organise the inter-laboratory comparison tests for PCR.
6. Conduct work to evaluate reported problem areas in diagnosis.
7. Supporting by means of information and technical advice National Newcastle Disease Laboratories and the European Commission during epidemics.
8. Prepare programme and working documents for the Annual Meeting of National Newcastle Disease Laboratories.
9. Collecting and editing of material for a report covering the annual meeting of National Newcastle Disease Laboratories.
10. Provide targeted training in the light of developments for new diagnostic methodology.
11. Preparation and publications of articles and reports associated with above work.

3.3 WORK PROGRAMME FOR THE COMMUNITY REFERENCE LABORATORY FOR SWINE VESICULAR DISEASE, 2007

I. LEGAL FUNCTIONS AND DUTIES

The functions and duties are specified in Council Directive 92/119/EC (OJ L 62, 15.3.1993 p.69).

II. OBJECTIVES FOR THE PERIOD JANUARY-DECEMBER 2007

1. Storing and supplying cell cultures for use in diagnosis

2. Building up and holding a SVD virus collection by means of biological and biochemical characterisation of recent isolates to allow a greater understanding of the epidemiology of SVD.

Receive new isolates from Member States as part of the diagnostic or confirmatory service of the CRL for SVD.

- Grow up isolates and characterise antigenically using polyclonal and monoclonal antisera.
- Determine the nucleotide sequence ("genetic fingerprint") of the VP1 gene of new
- isolates and compare with sequences in the IAH database to construct dendrograms ("family trees") indicating relationships with established strains.
- Provide sequence data in the form of dendrograms to the CEC and to EU National SVD Reference Laboratories

3. Typing, storing and supplying strains of SVD virus for serological tests and preparation of antisera.

- Examination of new isolates for significant differences to current reference strains.
- Immunisation of animals to produce polyclonal antisera as necessary.
- Quality control of antisera.
- Make reagents available to Member States of the EU individually or in the form of diagnostic kits.
- Production and supply of the reagents for the 5B7 monoclonal SVD antibody competition ELISA (Brescia test) to National Reference Laboratories of Member States

4. Standardisation of the tests and reagents employed in Member States by means of the organisation of comparative tests of diagnostic procedures at Community level

- Prepare necessary documents for standardisation exercise on SVD testing carried out in 2007.
- Infect pigs as necessary to obtain materials for distribution. Standardise and quality control material to be distributed.

- Distribute material to be tested together with standardised reagents and protocols as required by National Laboratories.
- Collate and analyse results.
- Prepare and present report at Annual Meeting of National SVD Laboratories.
- Make recommendations to the Commission regarding the testing carried out in National Laboratories and requirements for standardisation.

- 5. Review laboratory contingency plans for dealing with SVD outbreaks in National Reference Laboratories**
- 6. Keeping abreast of developments in surveillance, epidemiology and prevention of SVD throughout the world.**
- 7. Retaining expertise on SVD virus and other pertinent viruses to enable rapid differential diagnosis.**
- 8. To have trained personnel available for emergency situations, missions and inspections**
- 9. To support by means of information and technical advice projects of epidemiological investigation on recent outbreaks of SVD.**
- 10. To support by means of information and technical advice the Commission and its activities concerning SVD.**
- 11. Prepare programme and working documents for Annual Meeting of SVD National Reference Laboratories, 2007¹.**
- 12. Collecting and editing material for the report covering The Annual Meetings of the SVD National Reference Laboratories, 2006.**

3.4 WORK PROGRAMME FOR THE COMMUNITY REFERENCE LABORATORY FOR CLASSICAL SWINE FEVER, 2007

I. LEGAL FUNCTIONS AND DUTIES

The functions and duties are specified in Council Directive 2001/89/EEC (OJ L 316 of 1.12.2001).

II. OBJECTIVES FOR THE PERIOD JANUARY – DECEMBER 2007

1. Inter-laboratory comparison test: production and standardization of sera, distribution and evaluation.
2. Inter-laboratory comparison test: Improvement and extension of the PCR part.
3. Preparation of programme and working documents for the Annual Meeting of National Swine Fever Laboratories 2007.
4. Collection and editing of material for a report covering the Annual Meeting of National Swine Fever Laboratories 2007.
5. Support National Swine Fever Laboratories by means of information, technical advice and reference material.
6. Provision of training in laboratory diagnosis at the CRL.
7. This may include, upon request of the European Commission, the training of experts from non EU countries.
8. Continuation of work to improve differential diagnosis of other pestiviral infections in pigs.
9. Genetic typing of CSF virus isolates from primary outbreaks of CSF in the EU and Third Countries (upon request) and evaluation of data from Member States on molecular epidemiology of CSF.
10. Maintenance, improvement, and enlargement of the World Wide Web database for CSFV isolates and sequences. Development of new tools to enhance usability.
11. • Update of the Diagnostic Manual with special regard to PCR diagnosis, antigen ELISA, and FAT
12. • Virulence and pathogenesis studies on recent CSFV virus isolates.
13. • Preparation and conduction of a workshop on CSF diagnosis
14. • Preparation and publication of articles and reports associated with above work.
15. • Attendance of international meetings and conferences.
16. • Participation in international research projects and networks.

3.5 WORK PROGRAMME FOR THE COMMUNITY REFERENCE LABORATORY FOR DISEASES OF FISH, 2007

I. LEGAL FUNCTIONS AND DUTIES

The functions and duties of the Reference Laboratory are described in the Council Directive 93/53/EEC (OJ L 175, 19.7.1993, p 23), and are mainly concerned with fish diseases of list I and II in Council Directive 91/67/EEC (OJ L 46, 19.2.1991, p.1)

II. OBJECTIVES FOR THE PERIOD JANUARY – DECEMBER 2007

1. Organise and prepare for the Annual Meeting for the National Reference Laboratories for Fish Diseases in 2007, planned for the 4th-7th June 2007 at the Institute in Copenhagen
2. Produce a report from the Annual Meeting 2007.
3. Collect data on the fish disease situation in EU, including the new listed diseases in the new Fish Directive: ISA, SVC and KHV
4. Identify and characterise selected isolates of listed viruses (serological and genetic characterisation)
5. Production of antisera against selected isolates if necessary
6. Optimization and standardisation of RT-PCR and real-time PCR for the diagnosis and identification of VHS.
7. Update and maintain a library of Infectious salmon anaemia (ISA), Viral Haemorrhagic Septicaemia (VHS) and Infectious Haematopoietic Necrosis (IHN) virus isolates (including the sequences and GIS data of selected isolates) and entering this information into a database.
8. Cooperate with existing projects concerning databases on viral genomes in order to obtain a functional and accessible system for molecular epidemiological tracing.
9. Maintain and update the webpage for the CRL.
10. Supply standard antisera and other reference reagents to the National Reference Laboratories in Member States.

11. Prepare the Annual Inter-laboratory Proficiency Test year 2007 for the National Reference Laboratories.
12. Collate and analyse information gained from the Inter-laboratory Proficiency Test
13. Facilitate and provide training in laboratory diagnosis.
14. Attending international meetings and conferences.

3.6 WORK PROGRAMME FOR THE COMMUNITY REFERENCE LABORATORY FOR DISEASES OF BIVALVE MOLUSCS, 2007

I. LEGAL FUNCTIONS AND DUTIES

The functions and duties of the Community Reference Laboratory for Mollusc Diseases are given in Annex B of the Council Directive 95/70/EC.(OJ L 332, 30.12.1995, p. 33)

II. OBJECTIVES FOR THE PERIOD JANUARY – DECEMBER 2007

1. To organise and prepare the Annual Meeting of the National Reference Laboratories in March or April 2007.
2. To collect material for and produce reports on the Annual Meeting of National Reference Laboratories
3. Maintain and update the library and collections of molluscs pathogens
4. Update the CD_ROM of histology and anatomo pathology for guidance in diagnosis of molluscs diseases
5. Update the internet site of the Community Reference Laboratories in the Member States
6. Identify and characterise mollus pathogen isolates on assistance request of the National Referenca Laboratories
7. Provide National Reference Laboratories with Sandard Operating Procedures (SOPs) to hyelp them to build their Quality Assurance System
8. Organise a technical workshop on diagnostic for the detection of mollusc diseases based on hystology and molecular tools
9. Organise Inter-Laboratory Proficiency testing for diagnosis by histology of mollus pathos-gens included in the Council Directives 91/67/ECC AND 95/67/EE
10. Provide opportunities for education, training and retraining in laboratory diagnosis of mollus
11. Attend and organise international meetings and conferences

3.7 WORK PROGRAMME FOR THE COMMUNITY REFERENCE LABORATORY FOR FOOT-AND-MOUTH DISEASE, 2007

I. FUNCTIONS AND DUTIES

The functions and duties for the CRL for Foot and Mouth Disease are established in Directive 2003/85/EC (OJ L 306, 22.11.2003, p 1).

II. WORK PLAN AND SPECIFIC TASKS FOR 2007

1. Prepare guinea pig and rabbit antisera against FMDV vaccine strains to be used in ELISA-based vaccine matching tests. The specific strains of vaccine to be selected will be those that provide vaccine antigens within the European Union Vaccine bank and for which bovine vaccinal antisera were prepared by the CRL in 2006.
2. Predict the ability of EU Vaccine Bank derived vaccines to provide protection against FMD viruses from Africa that have been recently isolated by the WRL.
3. Review requirements for potency testing of the vaccine antigens held in the European Union FMD vaccine bank and for preparation of reference materials.
4. Make a contingency to undertake two European Pharmacopeia potency tests on vaccine antigens held in the European Union FMD vaccine bank, one test to be conducted by the CRL at Pirbright and the other by the German National Reference Laboratory (NRL) for FMD at Insel Riems.
5. Start work on preparation of a panel of bovine reference sera (for the detection of antibodies against both structural and non-structural proteins of the FMD virus) for those serotypes and subtypes of FMDV where OIE recognised reference materials are not already available.
6. Prepare and distribute virological and serological samples for an interlaboratory comparative testing exercise of EU NRLs for FMD so that their proficiency can be evaluated and documented.
7. Collate information on the diagnostic capability of EU NRLs for FMD for presentation at the 2007 Annual Meeting of the EU NRLs for FMD.
8. In liaison with FAO FMD WRL, organise a training course on FMD virological and serological diagnostic techniques to be held at Pirbright with a proposed date of April/May 2007.
9. Develop a FMD web-site to share information between the CRL and EU NRLs.

3.8 WORK PROGRAMME FOR THE COMMUNITY REFERENCE LABORATORY FOR BLUETONGUE, 2007

I. LEGAL FUNCTIONS AND DUTIES

The functions and duties are specified in Council Directive 2000/75/EC (OJ L 327, 22.12.2000, p. 74–83)

II. OBJECTIVES FOR THE PERIOD JANUARY – DECEMBER 2007

1. Receive, examine and report on samples submitted by EU Member States

2. Storing and supplying cell cultures for use in diagnosis

- Introduce and maintain cell lines for BT virus isolation, maintenance of cell stocks and media for testing purposes

3. Maintaining, characterising, and holding a BT virus collection by means of biological and biochemical characterisation of historical and recent isolates to enable a greater understanding of the epidemiology of BT

- Seek and receive virus isolates and related information from Member States and from any other country, as part of the diagnostic or confirmatory service of the CRL for BT.
- Grow and antigenically characterise isolates using serogroup specific polyclonal and monoclonal antisera, as required.
- Clone and sequence isolates to add to the IAH database for topo-typing virus isolates and determination of their phylogenetic and functional relationships, for the purposes of identifying the geographical and biological origins of BT virus isolates.
- Provide sequence data, phylogenetic relationships and information on origins of BT virus isolates, and viral relationships to the EC and National BT Reference Laboratories.

4. Typing, storing and supplying strains of BT virus for serological tests and preparation of antisera.

- Examination of new isolates, field and vaccine derived, for significant differences to current reference strains, by serological, PCR and sequencing techniques.
- Immunisation of animals to produce polyclonal antisera and possibly monoclonal antisera to all 24 serotypes.
- Characterise and define all serotypes
- Quality control of antisera.
- Supply reagents to Member States of the EU

5. Standardisation of the tests and reagents employed in Member States by means of the organisation of comparative tests of diagnostic procedures at Community level

- Undertake a standardization or ring trial of BT PCR and ELISA testing with EU National BT Laboratories, States bordering the EU and, as appropriate, those countries trading with the EU and/or of epidemiological importance to the EU.
- Prepare necessary documents for the standardisation exercise and circulate to EU National Laboratories.

- Infect sheep or other animals as necessary to obtain materials for distribution. Standardise and quantify control material to be distributed.
 - Distribute material to be tested, together with standardised reagents and protocols, as required, by National Laboratories.
 - Collate and analyse results.
 - Prepare and present the report on the standardization exercise.
 - Make recommendations to the Commission regarding the testing carried out in National Laboratories and requirements for standardisation.
- 6. Review laboratory contingency plans for dealing with BT outbreaks in National Reference Laboratories.**
- Laboratory contingency Plans for the UK, including ramping up exercises, will be finalized and reviewed as necessary during 2007. This is also part of the UK National reference laboratory requirements.
- 7. Keeping abreast of developments in surveillance, epidemiology and prevention of BT throughout the world.**
- Attend and participate in meetings, workshops and conferences in epidemiology, virology and entomology associated with BT. Peruse all relevant literature.
- 8. Retaining and develop expertise on BT virus (and other arboviruses) which are pertinent to rapid differential diagnosis.**
- Undertaken training, reading, research and participation in conferences and workshops in epidemiology, virology and entomology on BT, AHS, EHD and EEV.
 - Develop further capacity and keep abreast with molecular testing e.g. nested PCR and real time PCR to improve capacity for rapid diagnosis and surveillance
- 9. To have trained personnel available for emergency situations, missions and inspections**
- Provide training in BT diagnosis in clinical assessment, serological and molecular testing techniques and vector surveillance to UK national and other staff as required.
- 10. To support, by means of information and technical advice, projects of epidemiological investigation on recent outbreaks of BT.**
- On-going projects on several areas of BT research (funded by EU, DEFRA and BBSRC based at IAH and elsewhere) already benefit from CRL advice and information. These interactions will continue and be extended in 2007.
 - Lead, participate in and support the EFSA BT Working Group, the EC CA project (MedReo Net) and other such operations as required.
- 11. To support by means of information and technical advice, the Commission and its activities concerning BT.**
- Respond to requests from and proactively offer advice to the Commission
- 12. Prepare programme and working documents for a Meeting of BT National Reference Laboratories, 2007¹.**

13. Collecting and editing material for the report covering the Annual Meetings of the BT National Reference Laboratories in 2007 and the CRL Annual Report for the year 2007.

3.9 WORK PROGRAMME FOR THE COMMUNITY REFERENCE LABORATORY FOR AFRICAN SWINE FEVER, 2007

I. LEGAL FUNCTIONS AND DUTIES

The functions and duties are specified in Council Directive in 2002/60/EC (OJ L 192, 20.7.2002, p. 27)

II. OBJECTIVES FOR THE PERIOD JANUARY – DECEMBER 2007

- 1.- Prepare programme and working documents for Annual Meeting of National Reference Laboratories for African swine fever.
- 2.- Evaluation of the results obtained from the different laboratories during the IV inter-laboratory comparison test and elaboration of a document including these results and a brief discussion.
- 3.- Updating and maintenance of a web site of EU Reference Laboratory for ASFV.
4. Updating and maintainance of the sequence data Bank.
- 5.- Assist ASF National Reference laboratories of adjoining member countries to improve their technical standard, including a training at CISA if necessary.
- 6.- To have trained personnel available for emergency situations, missions and inspections.
- 7.- Prepare and distribute reference standards (antisera, antigens) and other biological reagents for ASF serological and virological diagnosis.
- 8.- Clinical, and pathological characterization of viral isolates collected in the recent ASF outbreaks occurred in Eastern Africa.
- 9.- Continuing the collaboration between the CRL and ASF affected countries in the EU (Italy) and Africa for the characterization of ASFV isolates.
- 10.-To examine genetic variation of ASFV virus from ticks that have fed on warthogs, the major mammalian reservoir of ASFV in East African countries.

11.- Continuing with the assessment of new serological tests using ASFV recombinant proteins.: collaboration with Italy and African countries for field evaluation of the new tests.

12.- Standardization of Real Time PCR assays for African swine fever diagnosis.

3.10 WORK PROGRAMME FOR THE COMMUNITY REFERENCE LABORATORY FOR RABIES, 2007

I. LEGAL FUNCTIONS AND DUTIES

Legal functions and duties of CRL for establishing the criteria necessary for standardising the serological tests to monitor the effectiveness of rabies vaccines are laid down in Council Decision 2000/258/EC (OJ L 79, 30.3.2000, p. 40)

II. OBJECTIVES FOR THE PERIOD JANUARY – DECEMBER 2007

1. Receiving and responding to application for appraisal of laboratories to be approved to perform serological tests to monitor the effectiveness of rabies vaccines.
2. Production of reagents and maintaining a stock of reagents required for serological titration of carnivores vaccinated against rabies.
3. Arranging for dispatch of reagents and sera to laboratories which have applied for being approved to monitor the effectiveness of vaccinations against rabies.
4. Analyses of laboratory results provided by laboratories referred to under 3.
5. Preparing technical reports on the capability of laboratories referred to under 3 as regards the approval of the laboratories for being included in a list to be published by the European commission on community laboratories authorised to carry out serological tests to monitor the effectiveness of rabies vaccines. Submit the reports to the Commission.
6. Prepare programme and working documents for the annual meeting of laboratories authorised to carry out serological tests to monitor the effectiveness of rabies vaccination and selected laboratories seeking to obtain an authorisation.
7. Preparation and publication of articles and reports associated with the above work.
8. Bring a technical and scientific assistance to the laboratories for rabies serology.

3.11 WORK PROGRAMME FOR THE COMMUNITY REFERENCE LABORATORY FOR BRUCELLOSIS, 2007

I. LEGAL FUNCTIONS AND DUTIES

Functions and duties are specified in Commission Regulation (EC) No 776/2006 of 23 May 2006 amending Annex VII to Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards Community reference laboratories, as the Community Reference Laboratory (CRL) for Brucellosis (OJ L 136, 24.5.2006, p. 3–8)

II. OBJECTIVES FOR THE PERIOD JANUARY – DECEMBER 2007

1. Set up of the network of the NRLs – 1st Annual Workshop of NRLs (annual)

The CRL will organise the first workshop of the NRLs in March 2007 in order to launch the network. At the workshop, the CRL and all the NRLs would present themselves. Based on the needs, particularly those identified through the questionnaire sent in 2006, the activities of the CRL and of the NRL network would be planned with the aim of improving the standardisation of diagnosis methods in the EU (serological tests, *Brucella* isolation and/or identification and biotyping methods including the recently developed molecular methods). Any question arising from DG SANCO or from the NRLs could be dealt. During this meeting it is already planned to discuss the way NRLs could report annually to the CRL on their respective activities (bacteriology and immunology particularly). This workshop could also discuss of the opportunity of developing specific European Norms for the diagnosis of animal brucellosis in the frame of the CEN (European Committee for standardization).

It is planned that the meeting be held in AFSSA, Maisons-Alfort, France, in order to make its organisation easier for the first time. Further meetings could be held either in the Commission HQ in Brussels or in other MSs, if the Commission agrees in this proposal.

2. Standardization of Serological testing in the EU (multi-annual)

In 2007, it is planned to organise a proficiency ring-trial aiming at evaluating the reliability of routine testing performed in all the EU MS's NRLs (including Bulgaria and Romania). This proficiency RT would be limited to the already EU approved blood tests, *i.e.* RBT, CFT in sheep, goats and cattle and iELISA and SAT in cattle. This proficiency RT is planned to be launched before the summer 2007. The first semester would be dedicated to the harvest of field positive and negative sera in sufficient volumes for being used in the RT. Positive sera would be asked to colleagues from Southern Europe where brucellosis is present.

Specific assistance would be given during fall 2007 to all the NRLs with results showing discrepancies with expected results and new sets of sera would be sent to these labs if needed in order to ensure that mistakes have been corrected.

In 2006, it is expected to produce brucellosis sheep and goats' sera, candidates for establishing European sheep & goats brucellosis standard sera. These candidates would be validated as reference sera through another ring-trial (RT) that would be organised during the last 6 months of 2007. Only the NRLs having succeeded in the previous proficiency RT (at least for RBT and CFT) would be invited to participate to this second "validation" ring-trial. This second RT should allow the determination of standardisation conditions of RBT and CFT in small ruminants against these two candidates. Once other tests (*e.g.* FPA or iELISA) have been validated by EFSA or the CRL, the two reference sera would be tested in a further RT to

determine the conditions of standardisation of these new tests in sheep and goats (*foreseen in 2008*).

3. Standardization of *Brucella* identification and biotyping in the EU (multi-annual) - Preparation of Brucellaphages and monospecific sera (annual).

The CRL has planned to produce the 4 phages conventionally used for *Brucella* biotyping (*ie* the Wb, Tb, Iz₁ and R/C phages) and to provide adequate amounts on NRLs' demand. This would be a first step in improving the standardisation of *Brucella* identification in the EU. It is planned in 2007 to prepare such sufficient amounts of monospecific anti-A, -M and anti-R sera to make the more critical tools available and standardised for adequate conventional biotyping. Once all these materials are available in all NRLs, a specific ring-trial would be organised (probably early 2008) to complete the harmonisation of *Brucella* biotyping in the EU. Until the complete harmonisation of the *Brucella* isolation, identification and typing methods within the EU, the CRL will provide full assistance to the NRLs in this area.

4. Development and validation of a real-time PCR (multi-annual)

These past years, the CRL has developed a sensitive and very specific PCR method for direct diagnosing of *Brucella* infection in animal biological samples. The aim is to apply the strategy to a real-time PCR system (already designed), easier to perform in routine labs. It is proposed to compare the analytical sensitivity and specificity of both PCR on standard concentrations of *Brucella* of various species and biovars. Once this method has been validated (probably the end of 2007) then the diagnostic sensitivity and specificity could be evaluated on field and/or experimental samples. Finally the method could be validated through a ring-trial organised in 2008 together with field validation by voluntary NRLs.

5. First evaluation of the available tests (conventional, ELISAs and FPA) for the serological diagnosis of *Brucella* infections in domestic pigs (multi-annual)

The present regulation regarding intra-community trade of pigs and pig semen of embryos precludes a serological testing, particularly as brucellosis is concerned. The unique official test is the Rose Bengal test. Nevertheless this test is poorly specific and member states regularly face problems for qualifying pigs of high genetic value and certainly safe (pig brucellosis is almost absent in the whole European pig industry) but presenting false positive RBT reactions. This labs has started a few years ago a study aiming at assessing all the available tests in pig brucellosis in order to validate better strategies for (*i*) certifying the free animals and, (*ii*) identifying *Brucella* infection in pig farms where it sporadically occurs, especially in free ranging farming systems. It is now planned to complete this study (as regards specificity) by the end of June 2007. First conclusions could be presented at the 2008 workshop for discussion. It is already planned to produce in 2008 the standard pig serum that is needed for defining the standardisation requirements as regards the tests that could be candidates for approval.

6. Permanent activities (basic continuous activities)

The CRL will provide full assistance to the NRLs regarding the following tasks:

1. studies on sera giving unexpected or doubtful results ;
2. collection of a representative sample of *Brucella* strains isolated in the Community and maintenance of the collection ;
3. identification and biotyping of *Brucella* strains (when the NRL is unable to fully identify/biotype the strain or in case of atypical strain) ;
4. supplying field or reference *Brucella* strains and standardised reagents as soon as available ;

5. control of vaccines and diagnostic antigens or kits (EU official tests only) according to the EU or OIE standards.

All these activities would be presented to the NRLs during the first NRLs' 2007 workshop. The way of optimising these activities for the benefit of the NRLs (especially the way of collecting and shipping strains) would be discussed during this workshop as well.

The CRL will also go on providing full assistance to the services of DG SANCO in charge of animal and public health as regards Brucellosis in man and animals.

3.12 WORKING PROGRAMME FOR THE COMMUNITY REFERENCE LABORATORY FOR ZOOTECNIQUES, 2007

I. LEGAL FUNCTIONS AND DUTIES

The functions and duties of the CRL for zootechniques are established in Decision 96/463/EC (OJ L 192, 2.8.1996, p. 19–20)

II. OBJECTIVES FOR THE PERIOD JANUARY – DECEMBER 2007

The following workplan refers to items 1-15 of the original Programme Objectives, and the additional items 16 and 17, for the period January to December 2007. Most activities are of a continuous operational nature and follow previous workplans and activity reports. Only comments related to changes and developments under each item are therefore given. An estimated percentage of the total resources needed are given for each activity provided the laboratory is fully financed.

The number of routine evaluations (item 2) will be reduced to three per year, a decision made after surveying Member States and third countries. The routine international evaluations are being expanded to include female fertility (item 2) and with this expansion the most important health and reproduction traits are covered. The need for further improvement of international evaluations for female fertility and the development will continue (item 13). Funds have been collected for a period of three years to develop a system for international evaluations of beef breeds and traits (item 14). Once ready, this system will be operating at the Interbull Centre.

1. Receiving, storing and validating results. Continuous activity.
2. Routine international evaluations. Regularly performed activity that takes place three times per year for production, conformation, udder health, longevity, calving and female fertility traits.
3. Distribution of results. Regular activity that follows the evaluations of February, May and August.
4. Publishing statistics. Regular activity, as for item 3. Results are also published on the Interbull web site.
5. Test evaluations. Test evaluations are routinely run in March and September as an integral part of the service in preparation for following routine evaluations.
6. International seminar. Prepare programme and working documents for the annual meeting in August. The meeting will take place in Dublin, Ireland. Collect and edit material for a report covering the meeting. At least 150 participants are expected to participate

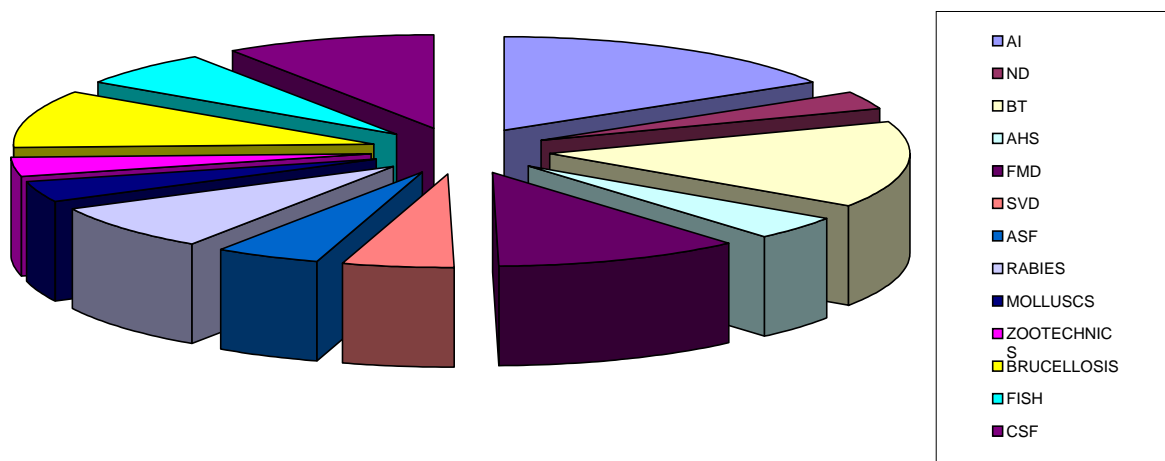
7. International workshop. One workshop is planned for March 2007. Prepare programme and working documents for the meeting. Collect and edit material for a report covering the meeting.
8. Development of information system. Development of the Interbull web site is a continuous activity.
9. Development of methodologies and harmonisation. Continuous activity, but special attention is given to evaluation models that utilize more pedigree information and models based on individual performance data.
10. Development of control protocols. Development of validation procedures and programming of auditing tools.
11. Investigation of problems in harmonisation of methods. Continuous activity. At least one more Member State is expected to join the international evaluations.
12. Assist Member States. General advisory services given, but amount of work pending financing.
13. Harmonisation of evaluations for health, reproduction and other functional traits. Continuous development work, but special emphasis will be given to female fertility, milking ability and temperament.
14. Genetic evaluation of beef cattle. Development of a system for international evaluations of beef traits and breeds, in cooperation with French scientists. The system utilizes individual performance data and yields evaluations of bulls and cows.
15. Assist countries which have become members of EU. Increased support activity pending on finances.
16. Publishing results from development work. Interbull Bulletins are printed and distributed, but also made available on the Interbull web site.
17. Attend international meetings and conferences.

4. COMMUNITY FINANCIAL ASSISTANCE PROVIDED TO CRL IN ANIMAL HEALTH AND ZOOTECHNICS 2007

CRL	2007
Avian Influenza	406000
Newcastle Disease	77000
Classical Swine Fever	232000
Swine Vesicular Disease	126000
African Swine Fever	120000
African Horse Sickness	98000
Fish Diseases	150000
Diseases of bivalve molluscs	90000
Rabies serology	200000
Brucellosis	250000
Foot and Mouth Disease	274000
Bluetongue	373000
Bovine breeding	80000
EURO TOTAL	2476000

BUDGET ALLOCATION FOR THE OPERATION OF THE CRLs IN 2007

EU financial aid to CRLs 2007



CRLs expenditure 2007

